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OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 531, 532, 534, and 930

RIN 3206–AO39

Advancing Pay Equity in Governmentwide Pay Systems

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management is issuing final regulations governing the criteria for making salary determinations based on salary history to advance pay equity in the General Schedule, prevailing rate, Administrative Appeals Judge, Administrative Law Judge, Senior Executive Service, and senior-level and scientific or professional pay systems. For individuals receiving their first appointment as a civilian employee of the Federal Government (or a reappointment after a break in service) in one of these pay systems, agencies will not be able to set pay based on a job candidate's non-Federal salary or pay history, which could vary between equally qualified candidates, or based on a competing job offer. Agencies will also be required to have policies regarding setting pay based on a previous Federal salary for employees who have previous civilian service in the Federal Government.

DATES: This final rule is effective April 1, 2024. Agencies must be in full compliance with this final rule not later than October 1, 2024.

FOR FURTHER INFORMATION CONTACT: Carey Jones by telephone at (202) 606–2858 or by email at *paypolicy@opm.gov*.

SUPPLEMENTARY INFORMATION:

Overview

The Federal Government strives to be a model employer that values diversity, equity, inclusion, and accessibility (DEIA). After consideration of public comments on the proposed rule, OPM is issuing a final rule that amends the criteria for making salary determinations for the General Schedule (GS), prevailing rate, Administrative Appeals Judge (AAJ), Administrative Law Judge (ALJ), Senior Executive Service (SES), and senior-level and scientific or professional (SL/ST) pay systems to advance pay equity in pay setting for Federal employees. OPM is issuing this rule pursuant to its authority to issue regulations governing these pay systems in 5 U.S.C. 5333, 5338, 5343, 5372, 5372b, 5376, and 5382.

Generally, when an individual applies for a job and is being considered for employment, the employer may inquire about the individual's salary or pay history [1] and consider it as part of the pay-setting process, if not otherwise prohibited from doing so. The employer may ask the candidate [2] direct questions about salary history or the candidate may offer the information without prompting. The information can be solicited or shared at various points before an offer is accepted or rejected. These and other considerations of a job candidate's salary history are permissible under current statutes and regulations governing the GS, prevailing rate, AAJ, ALJ, SES, and SL/ST pay systems. Consideration of salary history is explicitly allowed under the Federal Government's GS pay system and is not prohibited by the prevailing rate, AAJ, ALJ, SES, and SL/ST pay systems.

As described in the proposed rule and in this final rule, however, salary history is not necessarily a good indicator of worker value, experience, and expertise, and it also may contain or exacerbate biases. Pay setting based on salary history may be inequitable, can perpetuate biases from job to job, and may contribute to a pay gap between the earnings of men and women. Nationally, on average women earn less than men, and this pay gap is even greater for most women of color.[3] Gender and race/ethnicity pay gaps also exist in the Federal Government's civil service. Although such gaps are typically smaller than those in the private sector, they may represent an inequity as acknowledged by the President in Executive Orders (E.O.) 14035 (86 FR 34593) and 14069 (87 FR 15315). As discussed further below, by eliminating a factor that may contain or exacerbate biases inconsistent with merit system principles, this final rule seeks to promote pay equity consistent with the President's Executive Orders.

For individuals receiving their first appointment as a civilian employee of the Federal Government (or a reappointment after a break in Federal service), agencies will no longer be able to set pay based on non-Federal salary history, which could vary between equally qualified candidates. Agencies also will not be permitted to consider a candidate's competing job offer when setting pay. Finally, agencies will be required to have policies regarding setting pay based on a previous Federal salary for employees who have previous civilian service in the Federal Government.

Background

On June 25, 2021, President Biden signed E.O. 14035, titled ''Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce.'' [4] To address any pay inequities and advance equal pay, section 12 of E.O. 14035 requires the Director of OPM to review Governmentwide regulations and, as appropriate and consistent with applicable law, consider prohibiting the use of an applicant's salary history when setting pay for a Federal employee.

On March 15, 2022, the President issued E.O. 14069, titled ''Advancing Economy, Efficiency, and Effectiveness in Federal Contracting by Promoting Pay Equity and Transparency.'' [5] Section 1 of that E.O., describing the policy objectives of the E.O., notes that OPM ''anticipates issuing a proposed rule that would address the use of salary history in the hiring and pay-setting processes

[1] For this rulemaking, ''salary history'' or ''pay history'' refer to the salary or pay a job candidate is currently receiving (*i.e.,* their existing salary or pay) or the salary or pay the candidate has been paid in a previous job (*i.e.,* prior salary or pay). The terms are used interchangeably.

[2] In this final rule, the terms ''applicant'' and ''candidate'' are used interchangeably to refer to an individual under consideration for appointment to a Federal civil service position.

[3] Data on the national pay gap is available on the Department of Labor Women's Bureau website at *https://www.dol.gov/agencies/wb/data/earnings.*

[4] *See* 86 FR 34593 (June 25, 2021).

[5] *See* 87 FR 15315 (Mar. 15, 2022).

for Federal employees,'' consistent with E.O. 14035.

OPM reviewed the pay-setting regulations governing the GS, prevailing rate, AAJ, and ALJ, SES, and SL/ST pay systems. On May 11, 2023, OPM issued a proposed rule at 88 FR 30251 in response to E.O. 14035 and pursuant to its regulatory authorities in 5 U.S.C. 5333, 5338, 5343(c), 5372(c), and 5372b(b).[6] As explained in the proposed rule, the Federal Government's civilian personnel management systems are required to adhere to merit system principles established in law at 5 U.S.C. 2301, including:

- All employees and applicants for employment should receive fair and equitable treatment in all aspects of personnel management without regard to political affiliation, race, color, religion, national origin, sex, marital status, age, or handicapping condition, and with proper regard for their privacy and constitutional rights. 5 U.S.C. 2301(b)(2).
- Equal pay should be provided for work of equal value, with appropriate consideration of both national and local rates paid by employers in the private sector, and appropriate incentives and recognition should be provided for excellence in performance. 5 U.S.C. 2301(b)(3).

For the GS, prevailing rate, AAJ, and ALJ structured pay systems, generally, an agency must set pay at the minimum rate for a new entrant to the civil service. The GS system is designed with standardized classification criteria for determining the grade levels of positions, and each GS grade has a range of pay consisting of ten step rates. The prevailing rate system under 5 U.S.C. chapter 53, subchapter IV, is a uniform pay-setting system that covers Federal Wage System (FWS) appropriated fund and nonappropriated fund employees. Generally, a new appointment to a GS or a prevailing rate position must be made at the minimum (step 1) rate of the grade of the employee's position. The AAJ pay system has six rates of basic pay—AA–1, 2, 3, 4, 5 and 6. Upon initial appointment, an agency generally must set the rate of basic pay of an AAJ who is new to the Federal Government at the minimum rate AA–1 of the AAJ pay system. The ALJ pay system has three levels of basic pay: AL–1, AL–2, and AL–3. Pay level AL–3 has six rates of basic pay. Upon appointment to a position at level AL–3, an ALJ is generally paid at the minimum rate.

Under each of these systems, the default is to set pay at the minimum rate, but agencies have the authority to set pay above the minimum rate for newly appointed employees if specific factors are shown. Under the GS pay system, the largest of the pay systems at issue in this final rule, an agency has the authority to set pay above the minimum rate if it determines that the candidate has superior qualifications or that the agency has a special need for the candidate's services under the criteria in 5 CFR 531.212(b). The current regulations at 5 CFR 531.212(c) state that an agency may consider one or more of nine specified factors or other relevant factors in making this step rate determination. One factor an agency can consider is the candidate's existing pay, recent salary history, or a salary documented in a competing job offer. 5 CFR 531.212(c)(2). Similarly, the AAJ, and ALJ pay systems allow consideration of current pay when setting pay for an applicant with superior qualifications who is not a current Federal employee. Under those circumstances, an agency sets the AAJ or ALJ pay at the rate that is next above the applicant's existing pay or earnings. 5 CFR 534.604 (for AAJ pay system), 930.205 (for ALJ pay system). The prevailing rate pay systems also allow setting pay above the minimum rate based on special qualifications. The prevailing rate pay systems do not specifically list salary or pay history as an allowable factor in setting pay. *See* 5 CFR 532.403.

There are also standard rules when setting pay for current and former employees upon various personnel actions such as reemployment, reassignment, promotion, transfer, or demotion, and the flexibility to set pay above the rate to which the employee would otherwise be entitled based on the employee's Federal salary history. For the GS pay system, an agency may use the ''maximum payable rate'' rule, which bases pay on the employee's highest previous rate of pay in a Federal civilian position. 5 CFR 531.221. The prevailing rate pay system also allows an agency to set an employee's pay at any rate (of the relevant grade) that does not exceed the employee's highest previous rate. 5 CFR 532.405. For the AAJ and ALJ pay systems, an agency can set pay above the minimum rate for an appointee with prior Federal service either based on superior qualifications as used for new entrants or based on the highest previous Federal rate of basic pay. 5 CFR 534.604 (for AAJ pay system), 930.205 (for ALJ pay system).

The SES and SL/ST pay systems do not require an agency to set pay at the minimum rate and, instead, require an agency to consider specific factors when setting pay. *See* 5 CFR 534.404(a), (g); 534.506. The SES and SL/ST pay systems are discussed in more detail in the SES & SL/ST Pay Systems section of this final rule.

This final rule prohibits agencies from considering a candidate's salary history as a factor in setting pay for new Federal civilian employees. If an agency seeks to set pay above the minimum rate of the applicable rate range under the GS, prevailing rate, AAJ, or ALJ pay systems, that adjustment must be based on factors other than a candidate's non-Federal pay history, such as how pay has been set for employees who had similar qualifications (based on the level, type, or quality of the candidate's skills or competencies or other qualities and experiences) and have been newly appointed to positions that are similar to the candidate's position (based on the position's occupational series, grade level, organization, geographic location, or other job-relevant factors), if applicable. Similarly, when setting pay under the SES or SL/ST pay systems, the agency must base the pay on enumerated factors and cannot consider a candidate's non-Federal pay history. When setting pay based on prior Federal salary for reappointed or current employees, agencies must have a policy that supports consistency in setting pay for employees.

In addition to the data summarized in the proposed rule, OPM considered comments received in response to the proposal. OPM received 63 submissions representing 512 commenters during the 30-day public comment period from a variety of individuals (including Federal employees), organizations (including labor organizations), and Federal agencies regarding the substance of the proposed rule.[7] [8] Comments ranged from strong support of the proposed rule to categorical rejection. OPM reviewed and carefully considered all comments. They are summarized below, together with a discussion of the suggestions for revisions and OPM's rationale for either adopting or declining those suggestions.

In the first section below, we discuss comments that address topics related to

[6] *See* 88 FR 30251 (May 11, 2023).

[7] OPM determined one comment was beyond the scope of the proposed changes; that comment is not addressed below.

[8] One commenter recommended that OPM extend the rulemaking process and do more outreach to Federal employees about the proposal. Comment 23, available at *https://www.regulations.gov/comment/OPM-2023-0005-0023.* In addition to publishing the proposed rule in the **Federal Register**, at the beginning of the comment period, OPM shared the proposed rule with numerous stakeholders, including Federal employee unions, and publicized the proposed rule in a press release. Multiple media sources such as Forbes, CNN, Axios, Gov Exec, Federal News Network, and Federal Times, covered the publication of the proposed regulatory changes.

the background and context of this rule, including responses to questions posed by OPM in the proposed rule. In the sections that follow, we address comments related to specific aspects of this final rule.

Comments Regarding Background and Context

Federal Government Pay Gaps and Occupational Segregation

OPM has been periodically updating its pay gap data analysis since issuing its 2014 Governmentwide strategy.[9] Based on September 2021 EHRI[10] data covering nonseasonal, full-time, permanent Executive branch employees, on average for all race/ethnicity groups combined, women are paid 94 cents for every dollar paid to a man—a gender pay gap of six percent. This raw, unadjusted gender pay gap is before considering any factors that might explain the gap, such as occupation.

As discussed in the proposed rule, OPM also conducted an analysis regarding pay gaps for groups of employees identified by both gender and race/ethnicity. This analysis revealed that pay gaps varied significantly depending on the specific population. OPM found that many factors may contribute to the overall gender and race/ethnicity pay gaps in the Federal Government. In conducting its data analysis, OPM observed evidence of the impact of other factors, including occupational segregation. A November 2020 study[11] focused on national pay gaps found that the gender pay gap varied significantly by occupation. OPM's findings regarding Federal pay gaps are consistent with research on pay gaps in the national workforce. Comments on OPM's pay gap analysis are discussed in more detail in the Regulatory Alternatives section.

In instances where pay disparities are found, one organization recommended that OPM ''require agencies to immediately scale up to raise lower gender and racial/ethnic median wage to match the higher median pay at the beginning of the fiscal year.'' Comment 64.[12] Two organizations, several commenters, and an agency also suggested that OPM encourage agencies to conduct pay audits and raise the wages of individuals subject to inequitable pay disparities. *See* Comments 24, 27, 29, 46, 62, 64.

Putting aside the questions of whether, as a policy and legal matter, it would be appropriate and workable to have automatic pay adjustments to achieve a zero pay gap in median pay, OPM has no general statutory authority to require agencies to increase pay of current employees when gender and racial/ethnic pay gaps are found. We note, however, that there are several authorities (*e.g.,* the Equal Pay Act, Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act, the Age Discrimination in Employment Act) under which an agency is authorized to increase the salary of a Federal employee found to be subject to an inequitable pay disparity. We also note that there may be legitimate, non-discriminatory factors that could contribute to pay disparities for selected categories of employees, such as employee seniority, performance, or other factors not controlled for in the analysis. In 2015, OPM encouraged agencies to conduct pay gap analyses by gender, race/ethnicity, or other characteristics for their own workforces to identify where potential pay disparities exist within an agency in order to develop targeted strategies to reduce disparities and has issued guidance to help agencies complete this exercise.[13]

OPM invited comments on what factors OPM should consider for positions of high occupational segregation (wherein women and men often tend to work in different occupations, and the occupations that are predominantly held by women pay less, compared to those predominantly held by men at the same level of skill or education). Four organizations responded to this request for comment. One recommended that OPM consider race and ethnicity alongside gender when looking into the issue of positions of high occupational segregation. Comment 33. Another stated that ''[g]iven that the goal is equal pay for equal work, the focus of these initial steps to fight pay discrimination needs to be on ensuring fairness in pay setting for like positions. Ultimately, changes in pay between different positions will require modification of the classification standards used to adjust the scoring results, as those classification standards are the main measure OPM has in place for instilling uniformity in pay-setting across different agencies.'' Comment 49. The two other organizations recommended that OPM consider job evaluations. Comments 60, 61. One of these organizations stated that conducting job evaluations is a strategy ''to identify and remedy pay inequities so that women and people of color receive equitable compensation for their labor. Job evaluation schemes assess jobs across occupations on a range of factors to establish fair and equitable pay and promotion. These schemes make it more likely that pay and promotion are based on performance rather than bias.'' Comment 61.

Occupational segregation in both the public and private sectors is a systemic and persistent issue identified in pay equity studies. Addressing occupational segregation, however, is outside the scope of the Federal pay and classification system. OPM will assist agencies, in exercising their delegated classification authority, in collecting metrics and other relevant agency data to examine classification practices based on a variety of factors, including gender analysis by occupation. OPM will also assist agencies to expand the use of skills-based hiring practices to address occupational segregation.

Pay Equity in Structured Pay Systems

OPM invited comments on whether there is any research we should consider regarding the impact that structured pay systems have on pay equity, and the impact that pay policies that allow organizations to set pay above the minimum rate of the rate range for new employees based on specified criteria have on pay equity. OPM received two comments that addressed this question. First, an agency suggested that OPM look at agencies that have converted to pay banded systems, such as demonstration projects under 5 U.S.C. chapter 47, to determine the benefits of such systems. Comment 34. The GS, prevailing rate, ALJ, and AAJ pay systems are all structured with grades or work levels and defined steps or pay rates within each grade or work level. It would be difficult to draw direct comparisons between pay-setting policies for pay banded systems (that combine multiple grades into a single

[9] Office of Personnel Management. ''Governmentwide Strategy for Advancing Pay Equality in the Federal Government.'' *https://www.opm.gov/policy-data-oversight/pay-leave/reference-materials/reports/Governmentwide-Strategy-on-Advancing-Pay-Equality-in-the-Federal-Government.pdf.*

[10] Office of Personnel Management. ''About Our Data (EHRI–SDM).'' *https://www.fedscope.opm.gov/datadefn/aehri_sdm.asp.*

[11] Foster, T., Murray-Close, M., Landivar, L., & de Wolf, M. ''An Evaluation of the Gender Wage Gap Using Linked Survey and Administrative Data,'' November 2020. *https://www.census.gov/library/working-papers/2020/adrm/CES-WP-20-34.html.*

[12] A reference at the end of a comment quotation or paraphrase provides the location of the item in the public record. (*i.e.,* the two-digit number associated with the location in the docket). Comments filed in response to the proposed rule are available at *https://www.regulations.gov/comment/OPM-2023-0005-00nn,* where nn is the comment number.

[13] Office of Personnel Management. ''Guidance for Agencies Conducting Gender Pay Data Analysis.'' *https://chcoc.gov/sites/default/files/Attachment-Agency%20Gender%20Data%20Analysis%20Guidance-rev_0.pdf.*

work level and/or have open salary ranges instead of step rates within a range) and the effect on pay equity. We do not have information on agency pay banding policies and practices nor has OPM conducted any pay equity analysis on agency pay banding systems or their policies and practices.

We also note that section 12(b) of E.O. 14035 requires agencies to review regulations and guidance and, as appropriate and consistent with applicable law, revise compensation practices for pay systems authorized outside of title 5 of the United States Code to address any pay inequities and advance equal pay. OPM will ask agencies to report any revisions to compensation practices made to implement the President's direction. Such reports may include information on beneficial compensation practices under alternative pay systems, such as pay banding systems.

Second, an organization shared two sources and stated that structured pay systems can help address pay gaps and are essential to attracting and retaining a talented and diverse workforce. Comment 61. One article summarized how implementing transparency and accountability procedures reduced the extent to which women and people of color received lower monetary performance-based rewards.[14] As OPM's regulatory changes affect certain structured pay systems with specified salaries rather than performance award determinations, this article is not directly applicable. As discussed in the proposed rule, however, we agree that pay transparency—as exists in Federal pay systems—can help reduce gender pay gaps and that written policies support agencies' consistent use of pay flexibilities.

The other article stated that, in developing a pay structure, ''grades enable flexibility and internal equity in an organization by providing a framework in which equivalent jobs are treated equally for pay purposes.'' [15] As explained in the proposed rule, the GS classification and pay system is designed with standardized classification criteria for determining the grade levels of positions, and each GS grade has a range of pay consisting of 10 step rates. The GS system has standardized pay-setting rules that help promote the equitable treatment among employees. The FWS has three main pay plans (Wage Grade (WG), Wage Leader (WL), and Wage Supervisor (WS)); the WG and WL pay plans have 15 grades and WS has 19. Each grade has five steps. The AAJ pay system has six rates of basic pay. An ALJ in level AL–3 also has six rates of basic pay. OPM agrees that these structured pay systems provide a framework that provides equal pay for work of an equal value, consistent with the merit system principle in 5 U.S.C. 2301(b)(3). Because structured pay systems minimize discriminatory influence on pay setting, OPM is not banning consideration of prior Federal pay when setting pay but is requiring agencies to establish policies that further promote equity in pay setting. OPM expects that, over time, any residual pay gaps in the Federal systems will shrink.

Classification

OPM received a few comments regarding how employees qualify for positions, how positions are classified, and how these decisions impact pay. One commenter requested that OPM require that agencies be more transparent about the pay for which new Federal employees qualify and specifically how the grade assessments are made or calculated. Comment 04. Another commenter similarly stated that ''clearly the source of inequity is in grade-setting, not step-setting as this rule targets.'' Comment 09. A third commenter stated, ''[t]his proposed rule appears to consider pay setting within a grade level, but it ignores another primary method of pay-setting in the government—grade level.'' Comment 20.

Although pay is often associated with position classification, position classification is based solely on work performed or the core duties and responsibilities of a position. The classification of positions recognizes levels of difficulty and responsibility in terms of the grade levels established in law at 5 U.S.C. 5104. While these grade-level definitions are used to determine grades that are linked to ranges of basic pay rates, those definitions are not based on pay factors or pay relationships. All OPM GS position classification standards are based on the difficulty and responsibility of the work at each level and the qualifications required to do that work. Under 5 U.S.C. 5107, Federal agencies are responsible for classifying their GS positions consistent with position classification standards issued by OPM. Similarly, under 5 U.S.C. 5346, agencies are responsible for grading their prevailing rate jobs consistent with the job grading standards issued by OPM. Therefore, similar or like positions and jobs across Federal agencies should be classified or graded in a consistent manner since they are evaluated against the same standards rather than position-to-position comparisons.

An agency also stated that ''a proposal to cease or significantly limit how Federal agencies can take into account past salary history must be paired with a wholesale reexamination of the GS pay scale and how hiring managers determine which qualifications meet which GS levels.'' Comment 21. The GS pay structure of 15 grades and 10 steps within each grade is defined in statute at 5 U.S.C. 5332(a)(2) and rates are adjusted in accordance with 5 U.S.C. 5303. The agency also recommended that OPM issue revised guidance on the minimum qualifications associated with each grade level. In May 2022, OPM issued updated guidance and qualifications policy including the General Schedule Qualifications Operating Manual.[16] Qualification requirements are aligned with classification policy for an occupational series. Similarly, OPM's Federal Wage System Qualifications provide guidance regarding the knowledge, skills, and abilities (KSAs) or job elements needed for jobs and provides a reference for assessing the qualifications of applicants for a particular grade.[17] Candidates for Federal employment and/or Federal employees may qualify for Federal jobs based on training, experience, education, and/or other requirements aligned with the position. Both the Manual and the FWS Qualifications provide detailed information to assist with aligning the qualifications of a candidate with the appropriate KSAs needed for jobs by grade, providing consistency between candidates, within an agency, and between agencies.

A commenter also expressed concern that ''to the extent that agencies are limited in their ability to set pay within GS levels, they are more likely to adjust the GS levels such that step 1 of the offered GS level is closer to the market rate.'' Comment 20. OPM cautions that the intentional misclassification of positions to manipulate recruitment,

[14] Castilla, E. ''Accounting for the Gap: A Firm Study Manipulating Organizational Accountability and Transparency in Pay Decisions,'' Organization Science, vol 26(2), March–April 2015, pages 311–333.

[15] Strategic Human Resource Management. ''Building a Market-Based Pay Structure from Scratch.'' *https://www.shrm.org/resourcesandtools/tools-and-samples/toolkits/pages/buildingamarket-basedpaystructurefromscratch.aspx.*

[16] Office of Personnel Management. ''Guidance Release—E.O. 13932; Modernizing and Reforming the Assessment and Hiring of Federal Job Candidates.'' *https://www.chcoc.gov/content/guidance-release-eo-13932-modernizing-and-reforming-assessment-and-hiring-federal-job.*

[17] Office of Personnel Management. ''Federal Wage System Qualifications.'' *https://www.opm.gov/policy-data-oversight/classification-qualifications/federal-wage-system-qualifications/#url=Overview.*

qualifications, and/or pay may be a prohibited personnel practice subject to review by the Office of Special Counsel.

Consideration of Salary History

Executive Order 14035 directed OPM to consider, as appropriate and consistent with applicable law, prohibiting the use of an applicant's salary history to set pay or when setting pay for a Federal employee. OPM has authority to issue regulations governing the GS, prevailing rate, AAJ, ALJ, SES, and SL/ST pay systems in 5 U.S.C. 5333, 5338, 5343, 5372, 5372b, 5376, 5382, and consistent with merit system principles established in law at 5 U.S.C. 2301. Relevant to this final rule is the requirement that all employees and candidates for employment receive fair and equitable treatment in all aspects of personnel management (5 U.S.C. 2301(b)(2)) and that equal pay should be provided for work of equal value, with ''appropriate consideration'' for both national and local rates paid by employers in the private sector (5 U.S.C. 2301(b)(3)).

Throughout the proposed rule and this final rule, OPM adheres to these authorities and merit system principles. We have identified the reasons—based on OPM data, Department of Labor data, examples of state salary history bans and their impacts on salary equity, research regarding the benefits of such bans, and other information—why salary history should not be a consideration in the pay-setting process for new Government employees.

OPM administers pay systems that have taken a variety of approaches to setting initial pay. The GS pay system specifically allows salary history as a factor to be considered when setting pay for an initial appointment in Federal service (or reappointment after a break in service). The prevailing rate pay systems allow agencies to set pay above a minimum rate based on ''special'' qualifications but provide no direction on what factors to consider when determining the step at which to set pay within the grade. The AAJ pay system allows agencies to offer an AAJ applicant with superior qualifications a higher than minimum rate of pay that is next above the applicant's existing pay or earnings, up to the maximum rate. The ALJ pay system allows agencies, with prior OPM approval, to pay an ALJ applicant with superior qualifications the rate of pay that is next above the applicant's existing pay or earnings up to the maximum rate. The SES and SL/ST pay systems provide a specific list of factors—which does not include salary history—that an agency must consider when setting initial pay.

OPM has determined that salary history should no longer be considered in setting pay for new Federal employees entering into the GS, prevailing rate, AAJ, ALJ, SES, and SL/ST pay systems. Accordingly, OPM is modifying the regulatory language for the GS pay system by removing salary history as a factor to consider in setting pay for newly appointed employees. Similarly, OPM is adding language to the prevailing rate systems, AAJ, ALJ, SES, and SL/ST pay system regulations to detail the factors that should be considered in setting pay and/or to make clear that salary history is no longer a permitted factor.

National unions, a local union, as well as multiple other organizations, Federal employees, and members of the public expressed strong support for many of the regulatory amendments in the proposed rule. One commenter reported an academic research study in which a description of the proposed salary history ban was shared with 1,605 Americans and found that about two-thirds of those surveyed favored the policy somewhat or strongly. *See* Comment 58. Commenters provided sources of information and data arguing against using salary history in the pay setting process. These commenters and the cited sources demonstrate multiple rationales supporting OPM's decision not to permit continued consideration of salary history in setting initial pay. The main rationales presented by commenters are discussed in the following sections along with consideration of countervailing comments.

Salary history does not demonstrate an individual's qualifications or fitness for a position. Commenters argued that past salary in a non-Federal job is not indicative of ability to perform in the Federal position. One organization wrote that ''prior salary is not an accurate measure of a job candidate's qualifications, skill, or ability to perform a job,'' referencing an Issue Brief from the Women's Bureau of the U.S. Department of Labor (DOL). Comment 56. A union commented that including salary history as an allowable consideration is at odds with the principles reflected in the current regulations. *See* Comment 44. The commenter explained that salary history ''does not directly reflect either the employee's superior qualifications or the agency's special needs,'' noting that those are the types of interests for which OPM regulations allow consideration. Id.

Another commenter also expressed concern that consideration of past salary information ''perpetuates the flawed assumption'' that a lower paid candidate is of lower quality. Comment 60. That commenter cited a study, which found that ''salary history is not an effective tool for assessing a candidate's value . . . because organizations do not accurately match pay to an employee's productivity'' and ''there [is] too much variation on the relationship between pay and performance.'' [18] Id. For example, candidates who have had a break in their career to serve as full-time caregivers to children or other family members may have a salary history that is lower than market value, but the candidate is well-qualified to perform the duties of the position. Id. Several other commenters also cited the example of lower pay for caregivers not being indicative of lower quality employees. *See, e.g.,* Comments 20, 33, 56.

Commenters raised the issue that variability in current pay may reflect the aspects of the current employer rather than any factors relevant to Federal employment. For example, an organization commented that ''those who take lower-paying jobs, such as those at non-profits or state and local government . . . should not be penalized [compared to those working for private sector employers].'' Comment 46.

Several commenters disagreed, contending that past pay can be indicative of superior skills and/or high performance. An agency recommended that OPM expand the criteria for determining an employee's salary based on qualifications to allow agencies to consider the ''whole of the individual and their experience'' rather than banning agencies from considering a candidate's salary history. Comment 34.

An individual commented that the rule was arbitrary and capricious because it is inconsistent with merit system principles at 5 U.S.C. 2301(b)(1) and 2301(b)(3), calling for equal pay for work of equal value. Comment 28. The commenter argues that the determination of ''relative ability, knowledge, and skills'' in ''fair and open competition'' means comparing individuals with others in a market, or competitive, economy, and that this requires a review of salary history because it is ''the price of a worker's labor per unit time.''

OPM disagrees with this analysis. As an initial matter, ''fair and open competition'' in 5 U.S.C. 2301(b)(1) does

[18] Adler, L. ''What's a Job Candidate Worth? Explaining Variation in Pay-Setting Practices, SOCARXIV (2020). *https://osf.io/preprints/socarxiv/ctu8m.*

not mean the Government should compare salaries vis-à-vis others in a market economy. It refers to the recruitment, selection, and advancement of qualified individuals based on merit (as opposed to, for example, political favor). More significantly, OPM disagrees that salary history is a consistently accurate proxy for worker value. Non-Federal employers can have widely varying compensation structures, policies, and funding. Lower paying jobs, such as non-profit organizations or entry-level professional positions, could have compensation packages that include non-salary benefits (*e.g.,* more generous leave or childcare flexibilities) that would be difficult to capture by only looking at past salary. Also, many higher paying jobs have an expectation or requirement of longer hours (as many are exempt from the overtime pay provisions of the Fair Labor Standards Act), such that the salary per hours worked would more closely resemble that of a lower paying job with a lower hours expectation or requirement. *See* Comments 20, 33, 44, 62, 68. But that nuance would not be captured by looking only at a monetary figure. In addition, OPM's regulations already allow—and will continue to allow—agencies to consider several factors including the level, type, or quality of the candidate's skills or competencies.

Agencies do not typically have access to the information that a previous non-Federal employer used to determine a job candidate's salary, whether the previous employer conducted any salary survey or labor market analysis when making pay-setting determinations, or how a candidate's employment history may have affected the previous employer's salary decisions. Under this final rule, agencies will set pay above the minimum of the rate range based on factor(s) such as the level, type, or quality of the candidate's skills or competencies, which will be more equitable and relevant than salary history.

Salary history bans break the cycle of pay discrepancies arising from discrimination and inequity and have positive impacts on pay gaps. Commenters noted that setting starting pay based on salary history can contribute to inequitable pay gaps. Citing a DOL Issue Brief, an organization noted that salary history may ''reflect past pay discrimination or other factors with gender-based implications.'' Comment 56. Therefore, setting starting pay based on past pay can compound the ''effects of discrimination and inequity,'' in part because starting salary can affect subsequent salary increases. Id. That commenter, citing a Harvard Business Review study, noted that ''nearly two-thirds'' of businesses found that pay disparities ''stemmed from reliance on salary history.'' Id. Another commenter also noted that prior salary history may reflect ''prior economic downturns in which women and minority workers are often harder hit.'' Comment 44.

Several commenters referenced a 2020 paper showing that implementing a salary history ban results in greater increases in salary for job changers for populations that have historically experienced discrimination. *See, e.g.,* Comments 51, 56, 61.[19] A Federal employee union expressed the view that the proposed approach would likely lead to an increase in pay for women and people of color. Comment 59. Another commenter argued that implementing a salary history ban would ''increase the diversity of our workforce and leadership.'' Comment 22. That commenter also argued that the proposed ban would ''provide greater footing to women and minority groups.'' Id. A Federal employee-run organization commented that ''in eliminating the use of salary history when setting pay the Government will emphasize its commitment to gender and racial equality while also reducing costly legal challenges to pay disparities.'' Comment 62. Similarly, an organization commented that the proposal would help to ''ensure that the Federal Government is in compliance with the Equal Pay Act.'' Comment 56.

In contrast, an agency expressed concern that prohibiting the consideration of salary history was not in line with the November 2021 Governmentwide DEIA Strategic Plan,[20] which discouraged ''solely'' relying on salary history to set pay. OPM believes the rule is consistent with the DEIA strategic plan. The DEIA strategic plan listed this suggestion among many policy examples the Government could adopt to ensure fair outcomes. Further, the President, through E.O. 14035 and E.O. 14069, directs OPM to consider prohibiting setting pay based on salary history, which OPM has concluded is appropriate.

Many of the comments arguing that salary history bans can reduce pay gaps cited the experiences of states and localities, noting that 21 states and 22 localities have enacted laws prohibiting the use of salary history in setting pay. *See, e.g.,* Comments 33, 56, 59, 60, 61. One organization cited to data from Colorado, Nevada, and Rhode Island in support of implementing a prohibition on considering a candidate's salary history. Comment 33. Several organizations further noted, citing multiple studies, that these salary bans have helped narrow pay gaps. *See, e.g.,* Comments 33, 60, 61. One of those organizations asserted that OPM's proposed changes would help bring the Federal Government in line with these states, localities, and private firms that have already taken steps to limit or ban employers from using an applicant's prior or current salary in determining pay. Comment 33.

In contrast, an agency commented that, OPM should not ''ban any pay flexibility across the board'' based on pay gaps specific to an agency, to certain occupations within an agency, or a limited number of agencies. Comment 34. It stated that agencies with such issues should ''seek to remedy those gaps or impose their own limits based on OPM authorities.'' Id. Further, some commenters questioned the existence of pay gaps (Comment 16) or the effectiveness of a salary history ban (Comments 18, 23), and argued that a salary history ban could harm women who earn a competitive wage (Comment 23). OPM does not believe that these comments warrant consideration of prior salary. The governing merit system principles are not unique to one agency, and OPM believes that eliminating consideration of prior salary is most consistent with those principles regardless of whether any agency or occupation currently has an inequitable pay gap. Additionally, even if a particular agency or occupation does not currently have a pay gap, that does not eliminate the possibility that a pay gap could develop if new hires have differing starting salary ranges for reasons unrelated to any merit system principles (including but not limited to prior discrimination); eliminating consideration of prior salary can help prevent inequities from developing in the future. No commenters provided data showing that a salary history ban is not an effective tool for eliminating inequitable pay gaps or preventing such gaps from occurring. OPM concludes that, based on the evidence, prohibiting consideration of salary history has been demonstrated to reduce pay gaps and, thus, is a valid tool for the Federal

[19] *See* Bessen, James E., Chen Meng, and Erich Denk. 2020. ''Perpetuating Inequality: What Salary History Bans Reveal About Wages.'' *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3628729.*

[20] The White House. ''Governmentwide Strategic Plan to Advance Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce,'' November 2021. *https://www.whitehouse.gov/wp-content/uploads/2021/11/Strategic-Plan-to-Advance-Diversity-Equity-Inclusion-and-Accessibility-in-the-Federal-Workforce-11.23.21.pdf.*

Government to implement for these pay systems.

Additional Considerations Regarding Setting Pay

Commenters raised several other considerations regarding the pay-setting processes at issue in this rule.

OPM proposed that, when setting pay above the minimum rate for an employee newly appointed to a GS, prevailing rate system, AAJ, and ALJ position, an agency would be required to consider how pay has been set for employees who had similar qualifications (based on the level, type, or quality of the appointee's skills or competencies or other qualities and experiences) and who have been newly appointed to positions that are similar to the appointee's position (based on the position's occupational series, grade level, organization, geographic location, or other job-relevant factors), if applicable. A commenter noted that ''this may have the effect of locking in low pay and creating disparities across teams or across agencies.'' Comment 20. The commenter suggested OPM ''provide a type of pay-setting authority that would allow an agency to remedy this by raising the pay for current employees to achieve equity with incoming employees.'' Id. There is no statutory authority for this suggested change. For example, 5 U.S.C. 5334 provides OPM with the authority to prescribe regulations regarding setting a GS employee's pay when an employee transfers from a non-GS position or another GS position, or upon demotion, reinstatement, reappointment, change in type of appointment, change in employment status, or change in grade. The law does not allow OPM to prescribe regulations regarding adjusting pay for existing employees to achieve equity.

An organization recommended that ''OPM provide additional guidance, including examples, to agencies about what constitutes 'similar work,' and how agencies should make determinations for employees doing 'similar work' who have different levels of experience.'' Comment 56. This final rule specifies that determinations regarding whether work is similar would be based on the position's occupational series, grade level, types of duties, or other job-relevant factors. While agencies will be responsible for making these determinations within these parameters, OPM will consider the need to provide further agency assistance on this issue in future implementing guidance.

Commenters noted that OPM proposed only banning the *consideration* of salary history in setting pay. Several organizations recommended that OPM explicitly ban agencies from asking for and discussing salary history with job candidates. *See, e.g.,* Comments 33, 56, 60, 61. The organizations also recommended that OPM guidance should clarify that agencies should not instead ask about an individual's salary expectation and that agencies should appropriately train relevant staff to ensure effective implementation of OPM's proposal. Id.

The regulations that OPM is amending relate to the factors agencies use in setting pay, not to agencies' conduct in the hiring process, but OPM agrees that agencies should not solicit salary history from job candidates. As an initial matter, agencies are prohibited from using this information, so there is simply no reason why agencies should request it, as there is no use for this information, if acquired. Moreover, doing so could suggest to a candidate that the agency intended to consider the information in violation of the regulation, which further militates against an agency from asking. Therefore, agencies should not request a candidate's salary history, and OPM will issue guidance saying the same. OPM will consider the scope and content of implementation guidance, trainings, and other means of sharing best practices following the publication of this rule.

We note, of course, that an agency has no control over what information a candidate may volunteer to provide and that a candidate could disclose their prior salary during the interview process. In the event of voluntary salary disclosure, agencies will continue to be prohibited from considering that information to set pay, regardless of how they learn that information.

With respect to candidates providing salary expectations, OPM notes that nothing in this rule limits candidates' ability to offer this information. Under this final rule, agencies can still set pay above the minimum rate (using factors other than salary history or a competing job offer). Information regarding candidates' salary expectations may help agencies effectively recruit and onboard these candidates by increasing minimum pay based on factors other than salary history or a competing job offer.

An agency was concerned that not allowing Federal agencies to consider salary when setting initial pay ''could lead to a biased pay-setting process and have unintended consequences.'' Comment 48. The commenter suggests that salary is a factor that helps to remove subjective bias. OPM disagrees that the changes could lead to a biased pay-setting process. Under the current regulations, agencies may consider one or more of the factors listed in the regulations when setting pay for a GS appointee with superior qualifications or for which the agency has a special need. Under the revised regulations for the GS pay system, agencies must consider the step at which pay has been set for employees who had similar qualifications and who have been newly appointed to positions that are similar to the candidate's position and at least one other factor listed in the regulations. Similarly, under the current prevailing rate regulations, an agency applying the special qualifications authority currently has no limitations. Under the revised regulations, OPM provides specific factors for an agency to consider, which will make pay setting less subjective and less prone to bias. Under the AAJ and ALJ pay systems, adjustments from the minimum rate for superior qualifications are currently based primarily on current pay. With the revisions in this final rule, AAJs and ALJs that are new to Federal employment or reappointed after a break in service may have pay set based on qualifications with consideration given to the pay received by AAJs or ALJs, respectively, with similar qualifications and in similar positions. This means that we expect a lower risk of bias because salary history, a factor known to perpetuate gender and racial/ethnic biases, is being removed from consideration.

Pay Systems Outside of Title 5

An agency noted that the proposed revisions would not apply to pay systems under authorities outside of title 5 of the United States Code and implied that implementing these changes for the title 5 pay systems but not for other pay systems would result in some sort of inequity. Comment 52. Another agency asked whether OPM's proposed regulatory changes would apply to employees under the Department of Defense Civilian Acquisition Workforce Personnel Demonstration Project (AcqDemo) or Science and Technology Reinvention Laboratories (STRL). Comment 57. OPM proposed revising the GS, prevailing rate system, AAJ, and ALJ regulations because OPM has authority to regulate pay setting for these systems under 5 U.S.C. 5333, 5338, 5343(c), 5372(c), and 5372b(b). The regulatory changes do not apply to AcqDemo, which is authorized under 10 U.S.C. 1762, or to STRL, which is authorized under 10 U.S.C. 4121, as the Department of Defense waived provisions of title 5 pertaining

to setting pay for GS employees under these demonstration projects' authorizing legislation and 5 U.S.C. chapter 47. *See* 82 FR 52104 and 87 FR 72462.

We note, however that under section 12(b) of E.O. 14035, the head of each agency that administers a pay system other than one established under title 5 of the United States Code must review the agency's regulations and guidance and, as appropriate and consistent with applicable law, revise compensation practices to address any pay inequities and advance equal pay. OPM will be requesting agency reports on any revisions to compensation practices made to implement the direction in E.O. 14035.

Impact on Recruitment

The commenters who categorically disagreed with the proposed rule and those commenters who only cited opposition to portions were largely concerned that prohibiting agencies from using a candidate's salary history to set pay would hurt the Federal Government's ability to recruit employees, especially for occupations for which non-Federal salaries exceed Federal salaries. *See, e.g.,* Comments 6, 8, 9, 18, 21, 23, 26, 35, 52, 57, 61.

Conversely, several commenters argued that prohibiting consideration of salary would improve recruitment because it forces consideration of more equitable factors in setting pay. *See, e.g.,* Comments 17, 33, 44, 51, 56. For example, one union noted that eliminating salary history refocuses ''consideration on . . . factors such as the nature and necessity of the job to the agency, disparities between Federal and non-Federal salaries for similar positions'' and comparability to pay received by similarly qualified candidates for similar positions. Comment 44. An organization, citing a working paper summarizing a field experiment, noted that ''[r]esearch shows that when employers are not able to rely on salary history to set pay, employers collect more information from candidates and ask more substantive and probing questions to evaluate an applicant for the job.'' Comment 56. Many commenters cited as a benefit the stronger emphasis on a candidate's knowledge and skills. *See, e.g.,* Comments 10, 57.

An organization commented that changing Federal Government hiring practices to be more equitable ''will likely result in economy-wide gains as the federal government will be better able to attract and hire a wider pool of workers.'' Comment 33. The organization also noted that the revised practices could improve retention, noting that ''removing salary history from the application and interview process can contribute to a sense of a fair and equitable organization culture that can lead to increased retention and talent attraction'' since ''workers who report a sense [of] unfairness in the workplace are more likely to voluntarily leave their job.'' Id.

An agency suggested that the salary history ban would improve its ability to recruit and retain ''highly skilled employees with specific technical expertise'' due to the perception of the Federal Government as an ideal employer. Comment 51. It argued that the ''halo effect'' of a salary history ban was an important tool for competing in tight labor markets. Id.

OPM agrees that this rule will have a positive impact on recruitment and believes that any recruitment challenges resulting from this rule will be minimal. Agencies will still be able to set pay above the minimum of the rate range to recruit new employees based on other applicable factors. For example, one of the factors agencies will be able to consider when setting pay under 5 CFR 531.212(c) is whether there are significant disparities between Federal and non-Federal salaries for the skills and competencies required in the position to be filled.

Several commenters, including an agency, expressed concern that the changes would slow down the pay-setting process or that agencies will be discouraged from using pay flexibilities because of the additional work required if use of salary history is prohibited in setting pay. *See* Comments 26, 41, 52. OPM disagrees that agencies will be discouraged from using the pay flexibilities that are being revised. Instead of being allowed to consider a candidate's salary history, an agency can, where a candidate's superior qualifications or an agency's special need merits setting pay above the minimum rate, consider one or more factors directly related to the position to be filled and how pay has been set for employees who had similar qualifications and who have been newly appointed to positions that are similar to the candidate's position, if applicable. This information should be readily available to agencies and will give agencies the ability to increase a candidate's starting pay as appropriate.

Competing Job Offers

OPM's proposal to allow agencies to consider a competing job offer when setting pay within limitations specified in the proposed rule received a significant number of comments.

One commenter said that it was ''arbitrary and capricious to propose that agencies may consider a competing offer but to ignore an applicant's current salary or salary history'' because ''their current compensation represents a competing offer to the Government's offer.'' Comment 20. That commenter argued that there are racial disparities with respect to who ''may be able to wait out longer for a competing [job] offer than others due to higher wealth.'' Id. Another commenter stated that allowing consideration of private sector job offers would be ''more available to beneficiaries of private sector discrimination than to those that have been treated unfairly, and those offers would precisely reflect the private sector salary history that the proposed rule disallows directly.'' Comment 32. A commenter expressed that relying on competing job offers in negotiation of pay ''only serve[s] to perpetuate pay disparities and should be eliminated.'' Comment 40. An organization commented that a competing job offer could be ''another reflection of past pay discrimination, bias, negotiation bias, or other factors with gender-based implications that are irrelevant to a candidate's skills, qualifications, or experience.'' Comment 56. Another organization stated that ''women and people of color likely have lower competing offers or may have none. Therefore, using this information to determine compensation could perpetuate inequality.'' Comment 61.

An organization recommended revising the regulations ''to require that the competing job offer be contemporaneous to the Federal offer at issue, and to require that the competing job offer be bona fide (as certified in writing by the applicant) and not, for example, be an offer that is made at the request of the applicant with no real intention of resulting in actual hiring for the purpose of affecting pay-setting in the hiring agency's job offer.'' Comment 49.

In contrast, one agency supported allowing agencies to consider competing job offers as necessary for the agency to compete with the private sector. Comment 57.

OPM is persuaded that the same principles that apply to consideration of salary history apply to consideration of a competing job offer. A competing job offer could, itself, be based on salary history. And, as noted by multiple commenters, an individual's current pay is effectively a competing offer. Setting pay based on the factors enumerated in this final rule is better suited to establishing equitable pay than comparison to a competing offer.

Because of the rationales for removing consideration of salary history and based on the comments received, OPM is revising this element of its proposed rule and, in this final rule, is removing a salary documented in a competing job offer from the list of factors that an agency may consider when setting pay above the minimum rate. OPM reiterates that agencies will be able to consider other applicable factors when setting pay above the minimum rate, such as significant disparities between Federal and non-Federal salaries for the required skills and competencies.

Comments Regarding Specific Pay Systems

SES & SL/ST Pay Systems

OPM's proposed rule explained that, although the SES and SL/ST pay systems are among the pay systems administered by OPM, OPM believed that it was not necessary to prohibit consideration of salary history in the SES and SL/ST pay systems because the regulations governing those pay systems provide a specific list of factors to consider when setting pay that does not include salary history. Further, the gender pay gap for these positions, based on September 2021 data, is less than one percent. OPM requested comments, however, on a wide range of topics to inform how OPM could best promote pay equity in its pay systems.

OPM received several comments objecting to OPM's proposal not to revise SES and SL/ST pay systems and advocating that these positions be treated the same as those in the GS, prevailing rate, AAJ, and ALJ pay systems. *See* Comments 07, 32, 47, 56, 62. After further consideration, OPM agrees and is amending the regulations for the SES and SL/ST pay systems to make explicit that salary history and competing job offers cannot be considered when setting pay for new entrants to Federal civilian positions.

The commenters that disagreed with excluding SES and SL/ST pay systems from these new rules argued that this exclusion created arbitrary inconsistency. Id. One commenter stated that ''exempting these [SES and SL/ST] positions from the strict prohibition on considering an applicant's salary history appears arbitrary and would create unnecessary inconsistencies in the regulations.'' Comment 56. Another commenter voiced support for the use of salary history, generally, describing it as ''a factor that is helpful for setting the starting pay'' but supported either a total inclusion or total exclusion of the use of salary history across pay systems, stating that the exclusion of SES and SL/ST ''shows prejudice in applications of this policy.'' Comment 07.

Commenters also objected to the exclusion of SES and SL/ST from this rule on the basis that any gender/racial pay gap, even below one percent, should be addressed. Comments 56, 62. A Federal employee-run organization stated that ''[t]he salary history ban is a critical step towards shrinking unjust and inequitable salary gaps, which is why we encourage OPM to include all positions (including Senior Executive Service jobs) unless OPM can provide compelling reasons for their exclusion.'' Comment 62. Similarly, when commenting on the existing pay gap for SES and SL/ST positions, an organization stated that ''[a]bsent evidence that prohibiting consideration of salary history for SES, SL, and ST positions would increase the pay gap for those positions, the fact that the pay gap is small does not provide an adequate justification for failing to apply rules designed to promote equity to these positions.'' Comment 56. OPM did not receive any comments in support of this aspect of the proposed rule.

OPM agrees with the commenters that the SES and SL/ST pay regulations should be revised consistent with changes being made to the pay-setting rules for other pay systems. Although the SES and SL/ST systems currently do not include salary history as a factor when setting pay for individuals receiving their first appointment as a civilian employee of the Federal Government, they also do not specify that the list of factors is exhaustive. That is, the SES and SL/ST pay regulations mandate what must be considered when setting an initial rate of pay—to include merit-based factors such as the nature and quality of the individual's experience, qualifications, accomplishments, and current responsibilities, which could be read to allow for the consideration of additional factors such as salary history. 5 CFR 534.404; 5 CFR 534.506. Similarly, agencies currently have broad discretion in setting pay for an individual being reappointed to the SES following a break in SES service and for reappointment to an SL or ST position. 5 CFR 534.404(i); 5 CFR 534.506(c).

OPM agrees with commenters that consideration of salary history for SES and SL/ST positions presents the same concerns as for the GS, prevailing rate, AAJ, and ALJ pay systems. Further, even though the SES and SL/ST pay systems do not have a significant pay gap, eliminating consideration of salary history information, as discussed above, is most consistent with merit system principles and can help prevent inequitable pay discrepancies from arising. Salary history also is unlikely to reflect an individual's qualifications or fitness for a position relative to the qualifications of other new appointees. Therefore, we are adding language to the SES and SL/ST pay regulations explicitly prohibiting the use of salary information for appointees who are entering the Federal Government for the first time and prohibiting the use of non-Federal salary information upon reappointment to an SES, SL, or ST position.

Unlike the GS, prevailing rate, AAJ, and ALJ pay systems for which OPM is adding a requirement for agencies to implement policies for setting pay for current and former Federal employees, OPM is not adding a similar provision for the SES and SL/ST pay systems. The regulations for SES pay already require agencies to have a plan for setting and adjusting rates for SES members. 5 CFR 534.404(g). With respect to setting initial pay, plans must provide for transparency in pay setting, may consider the executive's scope of authority and level of responsibility in the agency, and must consider the distribution of pay rates within the SES rate range. Id. Similarly, the SL/ST pay system regulations require an agency to have written procedures for setting pay. 5 CFR 534.505. The procedures must provide for transparency in pay setting. Id. These written SES and SL/ST plans already address the pay-setting issues this final rule requires agencies to develop for the GS, prevailing rate, AAJ and ALJ pay systems.

General Schedule Pay Setting

OPM received a number of comments related specifically to the General Schedule pay system and the General Schedule regulations. While some of these comments implicate issues that affect each of the pay systems at issue in this final rule, we address the General Schedule-specific comments here.

An agency suggested modifying or eliminating 5 CFR 531.211(a), which requires that pay be set at the minimum rate. Comment 30. OPM cannot eliminate this regulation because it implements the law in 5 U.S.C. 5333. The statute states, ''New appointments shall be made at the minimum rate of the appropriate grade'' and provides OPM with authority to prescribe regulations to allow setting pay above the minimum rate of the grade based on considerations such as existing pay, the candidate's unusually high or unique qualifications, or a special need of the Government for the candidate's services. While the statute authorizes regulations

that provide pay-setting flexibility, the default is to have pay set at the minimum of the grade. Also, while the statute refers to consideration of ''existing pay,'' it is listed as an example of what OPM regulations may consider. As discussed in this final rule and the proposed rule, OPM has determined to prohibit consideration of existing pay or salary history when setting pay above the minimum rate of a GS grade.

An agency questioned the applicability of 5 CFR 531.212 to nonappropriated fund instrumentality (NAFI) employees who move to GS positions. Comment 52. As stated in 5 CFR 531.212(a)(4), employees who move from a NAFI position to a GS position with a break in service of 3 days or less and without a change in agency are not eligible to have pay set under 5 CFR 531.212 because their NAFI employment is considered employment by the Federal Government. Such NAFI employees are covered by the regulations in 5 CFR 531.216, which allow consideration of a NAFI employee's highest previous rate when setting pay. NAFI employees who are not covered by 5 CFR 531.216 (*i.e.,* those who have a break in service of more than 3 days or a change in agency upon movement to a GS position) may be eligible to have their pay set under the GS superior qualifications and special needs pay-setting authority at 5 CFR 531.212, as revised by this final rule.[21]

An agency was concerned that OPM does not ''have the agency data to accurately state whether salary history was the basis for justifying [setting pay above step 1 in the GS system] or whether it was one of the other eight factors considered.'' Comment 45. The agency recommended ''[mandating] . . . that setting pay above step 1 cannot be based solely on salary history,'' that agencies ''communicate to applicant/candidate/selectee that they are not required to provide any salary history,'' and that ''OPM request the data/information they are lacking to make a more informed decision regarding the proposed removal of this factor.'' Comment 52. Another commenter also suggested that OPM collect more data. OPM does not believe that it is practical to ask agencies to submit the written documentation of their justifications to use the superior qualifications and special needs pay-setting authority that is required by 5 CFR 531.212(e) when it was used for over 9,000 GS employees in fiscal year 2021. In 2013, some agencies reported that their policy on this authority required the use of a job candidate's existing salary, or that existing salary must be considered when setting pay of a new GS employee. While OPM revised its fact sheet on the authority in 2015 to remind agencies that existing salary is only one factor an agency may use when setting pay under this authority, the regulations have not changed since that time so agency policies may not have changed either. OPM will update its guidance on setting pay to reflect the changes made by this final rule.

A Federal employee-run organization ''agree[d] that it is prudent for agencies to consider the wages of existing comparable peers when setting a new employee's pay'' but encouraged ''OPM to clarify that agencies should not look at the actual salary a comparable peer made when starting, but rather the *grade* and *step* the peer was originally given.'' Comment 62 (emphasis added). The organization suggested revising 5 CFR 531.212(c)(1) to replace ''How pay has been set for'' with ''Which grade and step had been given to'' and replacing ''have'' with ''had'' in the paragraph reading ''How pay has been set for employees who had similar qualifications (based on the level, type, or quality of the candidate's skills or competencies or other qualities and experiences) and who have been newly appointed to positions that are similar to the candidate's position (based on the position's occupational series, grade level, organization, geographic location, or other job-relevant factors), if applicable.'' Id. Another organization similarly supported ''requiring the hiring agency to search comparative pay of current employees at the hiring agency when setting pay for new hires, with measures taken to account for differences in locality pay and post-hire merit-based pay increases, such as within-grade increases and quality step increases.'' Comment 49. The proposed rule accounts for the grade level and geographic location (which would account for differences in locality pay and other location-based payments applicable to GS employees) of the position. However, OPM has clarified in this final rule that agencies must consider the step at which pay has been set for employees who had similar qualifications and who have been newly appointed to positions that are similar to the candidate's position.

Another organization commented that consideration of labor market factors to set a higher than minimum rate can maintain pay inequities. The regulations in 5 CFR 531.212 allow an agency to consider ''existing labor market conditions and employment trends, including the availability and quality of candidates for the same or similar positions.'' Comment 61. The organization writes that ''workers who enter during a competitive labor market could earn a higher wage than workers who perform the same job but entered during a less competitive labor market'' and that ''this is fundamentally at odds with the notion of equal pay,'' and ''when the affected workers are women or people of color, this approach can exacerbate gender and racial pay inequities.'' Id. We are not revising the regulations in response to this comment. This factor—which an agency has discretion to consider—recognizes that it may be difficult to recruit employees during a competitive labor market, especially when the agency has a special need for the candidate's services and may need to set pay at a higher rate in the rate range. Agencies will be required to consider how pay has been set for employees who had similar qualifications (based on the level, type, or quality of the candidate's skills or competencies or other qualities and experiences) and who have been newly appointed to positions that are similar to the candidate's position (based on the position's occupational series, grade level, organization, geographic location, or other job-relevant factors), if applicable. This required factor will better advance pay equity.

A commenter asked, with respect to 5 CFR 531.212(e) for the GS pay system, whether it would be permissible for agencies to create a uniform policy by which a certain step is always assigned, such as step 4, for candidates with similar qualifications for similar positions. Comment 14. The commenter suggested that this would ensure that all candidates that benefit from the regulation always have their pay set the same to reduce variability in outcomes. Id. OPM notes that agencies may create such policies if the agency also approves and documents each determination to use the authority consistent with 5 CFR 531.212(e).

OPM proposed adding in 5 CFR 531.221 that an agency must establish a policy regarding use of the GS maximum payable rate (MPR) rule that included elements specified in the proposed rule, such as considering how pay has been set for employees performing similar work in the organization (based on the position's occupational series, grade level, types of duties, or other job-relevant factors). One agency suggested requiring agencies in most circumstances to provide a salary offer no lower than the highest rate of pay the employee

[21] OPM has a fact sheet on NAFI employees moving to GS positions, which is based on the law in 5 U.S.C. 5334(f).

previously received in another Federal job (the employee's highest previous rate or HPR). OPM is not making this change. An agency's decision to use the MPR rule or how to set pay under the MPR rule may be influenced by different factors, such as budget, and under this final rule must reflect consideration of how pay has been set for employees performing similar work in support of pay equity. Under the regulations, agencies will list these factors in their policies. Agencies may establish policies under which they will always set pay at the employee's MPR.

A commenter recommended additional revisions, including that OPM require that agencies post and maintain their MPR policies on their websites and that agency decisions regarding any exceptions to these policies be made on a centralized basis. OPM declines to add these requirements to the rule. OPM will be issuing implementation guidance separately, which will include best practices.

The same commenter also recommended that OPM permit agencies to set an employee's salary up to 15 percent higher than an employee's highest previous rate in recognition that some Federal agencies have the independent statutory authority to provide benefits that are greater than those provided under title 5 of the United States Code to most Federal employees. This recommendation is beyond the scope of this rulemaking. This rule is not intended to address pay discrepancies resulting from independent agency authority to provide alternative compensation and benefits.

Prevailing Rate Pay Setting

OPM did not receive any comments specific to the prevailing rate pay systems regulations. Accordingly, OPM is adopting its proposals with two changes, as described above. First, as discussed in the Competing Job Offers section, in this final rule, an agency will not be able to consider a competing job offer when setting pay for a new prevailing rate pay system employee. Second, we are also clarifying that agencies must consider the ''step'' at which pay has been set (instead of ''pay'') for employees who had similar qualifications and who have been newly appointed to positions that are similar to the candidate's position.

Administrative Appeals Judge Pay Setting

Under 5 CFR 534.604, an agency may offer an AAJ applicant with prior Federal service a rate up to the lowest rate of basic pay of the AAJ pay system that equals or exceeds the employee's highest previous rate of basic pay in a Federal civil service position, not to exceed the rate of basic pay for AA–6. OPM proposed adding that an agency must establish a policy regarding use of this provision that includes elements specified in the regulations, including that the policy must require consideration of how pay has been set for other AAJs if the agency decides to use this authority.

Also under the AAJ pay-setting regulations, an agency may offer an AAJ applicant with superior qualifications who is not a current Federal employee a higher than minimum rate when such a rate is clearly necessary to meet the needs of the Government. An agency may pay a higher than minimum rate of pay that is next above the applicant's existing pay or earnings, up to the maximum rate AA–6. OPM proposed several revisions to this authority, including allowing agencies to set pay at any rate within the AAJ pay system. OPM proposed adding language requiring an agency to document the superior qualifications of the applicant, the need of the Government for the applicant's services, consideration of how pay has been set for AAJs who had similar qualifications (based on the level, type, or quality of the appointee's skills or competencies or other qualities and experiences) and have been newly appointed to positions that are similar to the applicant's position (based on the position's occupational series, grade level, organization, geographic location, or other job-relevant factors), if applicable, and an explanation of the factors that were used to justify the rate at which the employee's pay is set. Factors an agency could consider include the success of recent efforts to recruit for the same or similar AAJ positions or significant disparities between Federal and non-Federal salaries for the skills and competencies required in the position to be filled. This documentation would allow an agency to evaluate for equity purposes how pay has been set and reconstruct the action if necessary.

An organization supported OPM's proposal to require agencies to document the superior qualifications of AAJs when setting pay above the minimum rate. Comment 61.

As discussed in prior sections, in this final rule, an agency will not be permitted to consider an applicant's or former AAJ's salary history or a salary documented in a competing job offer. OPM is modifying its proposed regulatory text to make clear that, when setting pay for a former AAJ, an agency may set pay using either the highest previous Federal rate of pay (which necessarily considers salary history) or the superior qualifications authority; however, if an agency uses the superior qualifications authority, then the agency may not consider salary history. OPM is adopting the remainder of its proposal without change.

Administrative Law Judge Pay Setting

Under 5 CFR 930.205, upon appointment to a position at level AL–3, an ALJ is paid at the minimum rate unless the agency chooses to set pay at a higher rate based on prior service or superior qualifications. OPM proposed revising § 930.205 to add that, before an agency sets pay based on the ALJ's highest previous Federal rate of basic pay, the agency must establish a policy that includes certain elements specified in the regulations, including that the policy must require consideration of how pay has been set for other ALJs if the agency decides to use this authority.

OPM also proposed revisions to the regulations on setting pay based on the ALJ applicant's superior qualifications in § 930.205. Agencies would be able to submit a request to OPM to set pay at any rate within the AL–3 level. Agencies' requests to OPM would be required to include: (1) the applicant's or former ALJ's superior qualifications; (2) how pay has been set for ALJs who had similar qualifications (based on the level, type, or quality of the appointee's skills or competencies or other qualities and experiences) and have been newly appointed to positions that are similar to the ALJ's position (based on the position's occupational series, grade level, organization, geographic location, or other job-relevant factors), if applicable; and (3) the proposed rate of basic pay and justification for that rate. Agencies would not be able to consider an applicant's or former ALJ's salary history or the salary in a competing job offer. Other factors an agency could consider include the success of recent efforts to recruit for the same or similar ALJ positions or significant disparities between Federal and non-Federal salaries for the skills and competencies required in the position to be filled. OPM also proposed minor revisions to reflect changes resulting from Executive Order 13843 ''Excepting Administrative Law Judges from the Competitive Service,'' signed July 10, 2018.[22] For example, OPM proposed to modify the language of § 930.202 to remove the reference to a ''certificate of eligibles'' to reflect that ALJ positions are now excepted service.

[22] 83 FR 32755 (July 10, 2018).

An organization noted that ''the past practice of relying upon salary history has, in certain instances, limited the starting salary potential of newly hired ALJs without fairly considering the experience and expertise these newly hired individuals would bring to the position.'' Comment 36. The organization stated it supports the goal of ''[increasing] pay equity by removing reliance on salary history as a central factor for setting pay, while retaining the use of past Federal salary as the minimum starting salary for a newly hired ALJ with a history of Federal employment.'' Id. The organization also requested that OPM consider ''taking steps to adjust. . . the maximum salary of a Federal ALJ [to be] equivalent to the salary paid to a Federal magistrate or bankruptcy judge.'' Id. OPM is not adopting this recommendation. The President determines the appropriate adjustment for each level in the ALJ pay system by executive order. *See* 5 U.S.C. 5372(b)(4).

Another organization supported OPM's proposal to require agencies to document the superior qualifications of ALJs when setting pay above the minimum rate. Comment 61.

As discussed in prior sections, in this final rule, an agency will not be able to consider an applicant's or former ALJ's salary history (defined as existing salary or prior salary) or a salary documented in a competing job offer when setting pay based on an applicant's superior qualifications. OPM is adopting the remaining aspects of its proposal without change.

Expected Impact of This Final Rule

A. Statement of Need

OPM is issuing this rule pursuant to its authority to issue regulations governing the GS, prevailing rate, AAJ, ALJ, SES, and SL/ST pay systems in 5 U.S.C. 5333, 5338, 5343, 5372, 5372b, 5376, and 5382. The purpose of this final rule is to advance pay equity consistent with merit system principles and position the Federal Government as a model employer while reaping the benefits that this policy will have for the economy and efficiency of the Government workforce. This rule is also consistent with diversity, equity, inclusion, and accessibility principles. Based on September 2021 EHRI data covering nonseasonal, full-time, permanent Executive branch employees, gender and racial pay gaps persist. On average for all race/ethnicity groups combined, women are paid 94 cents for every dollar paid to a man—a gender pay gap of 6 percent. This raw, unadjusted gender pay gap is before considering any factors that might explain the gap, such as occupation.

Because salary history is not always a good proxy for worker value, experience, and expertise and setting pay based on a candidate's salary history could perpetuate a pay rate that was inequitable, the Federal Government is taking steps to address the treatment of salary history and establish policies that support equitable pay determinations anticipating that these policies in turn will also support certain economies and efficiencies for the Federal Government. Currently, certain regulations allow agencies to consider a candidate's salary history or use a competing salary offer as a factor in setting initial pay. Agencies are not required by OPM's current regulations to consider the assigned grades and steps for employees performing similar work or candidates who had similar qualifications, if applicable, when using pay-setting flexibilities. Nor are agencies required to have policies regarding use of an employee's highest previous Federal rate to set pay.

OPM invited comments on whether there are additional ways that the Federal Government can be a model employer with respect to pay equity and received several responses. A union recommended that OPM ''emphasize pay equity and ensure employee qualifications and the needs of agencies struggling to hire and retain qualified employees are both adequately considered in pay-setting decisions.'' Comment 44. The union's recommendations are generally consistent with this final rule. An organization recommended that OPM ''add language formally stating that the Federal Government intends to serve as a model employer with respect to pay equity. . . maintain oversight and track how these pay-setting authorities are employed. . . [and] continue to use the General Schedule or other similar regimented pay schedules.'' Comment 49. We note that OPM's strategic plan for fiscal years 2022–2026 already states that ''OPM strives for the Federal Government to be a model employer where every Federal job provides fair pay and benefits that reflect the diverse needs of the workforce.'' [23] This final rule does not modify OPM's current oversight responsibilities regarding the use of pay-setting flexibilities and does not eliminate any Governmentwide pay system, such as the GS system, which would require a statutory change.

Several commenters offered other suggestions for ways the Federal Government could improve pay equity. These included examining veterans' preference, ''performing a market analysis and paying civil servants fair wages,'' and shortening the required waiting period that is required to advance to the next higher step or rate or reducing the number of steps in the GS pay system or, more generally, reforming how agencies set pay upon promotion. Comments 58, 02, 08, 48, respectively.

These suggestions would require a statutory change—

- Veterans' preference is provided by 5 U.S.C. 2108 and 2108a.
- GS, FWS, AAJ, and ALJ pay schedules are typically adjusted annually as provided by the statutes that govern those pay systems, which include consideration of changes in the cost of labor or, in the case of the FWS, prevailing rates (5 U.S.C. 5303, 5304, 5304a, 5343, 5372b, and 5372).
- The waiting periods that are required to advance to the next higher step or rate and the number of steps in the GS pay system are specified in 5 U.S.C. 5335.
- Pay setting upon promotion for GS employees is governed by 5 U.S.C. 5334.

Commenters also suggested regulating pay-banding systems more strictly, fully implementing the Federal Employees Pay Comparability Act (FEPCA) of 1990, allowing agencies to establish developmental programs that allow for ''retained pay'' when changing career fields, and providing current Federal employees with more information on promotions including specific benchmarks that employees must achieve to move between pay levels. Comments 09, 18, 34, 56, respectively.

OPM does not administer any pay banding systems—they are administered by the agency that has the pay banding system under its independent statutory pay authority or under a demonstration project authority, following provisions under 5 U.S.C. chapter 47. OPM has prescribed criteria under 5 U.S.C. 9509 for the U.S. Department of the Treasury to follow in exercising its authority to establish one or more pay banding systems covering all or any portion of the Internal Revenue Service workforce.[24] Any such system is administered by the U.S. Department of the Treasury and is outside the scope of this final rule.

[23] Office of Personnel Management. ''Goal 1: Position the federal government as a model employer.'' *https://www.opm.gov/about-us/strategic-plan/goal-1-position-the-federal-government-as-a-model-employer./*

[24] 65 FR 79433 (Dec. 19, 2000).

Several other of the above recommendations are also outside the scope of this final rule—

- With regard to the FEPCA recommendation, on August 31, 2023, the President determined that it was appropriate to exercise his authority to set alternative pay adjustments for 2024 pursuant to 5 U.S.C. 5303(b) and 5 U.S.C. 5304a. These alternative pay adjustments mean FEPCA will continue to not be implemented fully.[25]
- OPM regulations at 5 CFR 536.301(a)(5) provide for retained pay when an agency places an employee in a formal employee development program that is generally utilized Governmentwide, such as the Recent Graduates Program. Agencies have discretion to determine whether to use formal employee development programs generally utilized Governmentwide to fill their positions.
- Information on classification and qualifications for GS and FWS positions is available on OPM's website.[26]

Commenters also suggested prohibiting applicants from placing pay on their resumes, prohibiting agencies from asking about gaps in employment, and considering how many hours a candidate works in a non-Federal position when setting pay. *See, e.g.,* Comments 09, 23, 60, 20.

This final rule does not address what topics may be discussed during salary negotiations, including what information a job candidate may share with an agency on an employment application or resume, as an agency cannot completely control what information a job candidate may provide. See the 'Additional Considerations Regarding Setting Pay' section for further discussion. Instead, this final rule focuses on the agency's action by removing from consideration any salary history information it may receive. Because OPM is requiring agencies not to consider salary history, the number of hours a candidate works in a non-Federal position becomes irrelevant, since there is no reason to standardize salary information (for example, annualizing a non-Federal hourly rate to compare with annual salaries).

Another suggestion was to take strong disciplinary action against managers who discriminate when setting pay to deter deliberate pay discrimination from occurring. Comment 49. An employee's violation of an agency's regulations or policies may cause the employee's agency to take disciplinary or corrective action using well-established tools available to agencies for addressing performance issues and misconduct. If an individual fails to follow pay-setting policy, it could be a performance or misconduct issue addressable under 5 U.S.C. chapters 43 or 75.

B. Impact

The rule will impact pay setting for new Federal hires in the affected pay systems when agencies exercise discretionary authority to set pay within the rate range. The rule may also impact pay setting for current Federal employees for certain personnel actions as agencies review or develop policies addressing use of an employee's highest previous rate of pay received in a previous Federal civilian position.

Based on data regarding non-seasonal, full-time permanent Executive branch employees reported to OPM's EHRI database as of September 2021, there were more than 1.3 million GS employees, approximately 160,000 FWS (the largest pay system under the prevailing rate systems) appropriated fund employees,[27] 8,000 SES, 900 SL positions, 400 ST positions, 1,700 ALJs, and 63 AAJs in the Federal Government. This included approximately 97,000 new hires in the GS pay system, 13,000 new FWS appropriated fund hires, 700 new hires in the SES pay system, 24 new SL hires, 10 new ST hires, 17 new hires in the ALJ pay system, and 3 new hires in the AAJ pay system.

In fiscal year 2021, 9.5 percent of new GS employees (9,216 individual pay actions/authorizations) had their pay set using the superior qualifications and special needs pay-setting authority in 5 CFR 531.212. With respect to the prevailing rate pay system, agencies used the authority in 5 CFR 532.403(b) to set pay above the minimum rate of the appropriate grade for around 210 appointees with special qualifications. During the same period, one agency set pay above the minimum rate for an ALJ applicant based on their superior qualifications under 5 CFR 930.205(f)(2) with OPM approval.[28] No agencies reported setting pay under 5 CFR 534.604 based on an AAJ's superior qualifications.

Because this pay authority is delegated to agencies and agencies' written justifications for its use are not reported to EHRI, OPM does not have information regarding which factor or factors were used to justify the rate at which each new employee's pay is set under the GS superior qualifications and special needs pay-setting authority or similar prevailing rate, ALJ, and AAJ pay-setting authorities. As a result, we are not able to predict with specificity how the regulations will affect the rate at which pay is set for candidates based on their special or superior qualifications or a special agency need.

Although OPM does not have data on the specific factors agencies used to justify use of these pay-setting authorities, OPM reviewed hiring and pay data from fiscal year 2021, which demonstrated the extent to which agencies set pay under the GS superior qualifications and special needs pay-setting authority, the occupations for which these pay authorities are used, and how use of these authorities varied by gender. Looking more specifically at the 9.5 percent of new GS employees (9,216 individual pay actions/authorizations) who had their pay set using the superior qualifications and special needs pay-setting authority in 5 CFR 531.212, 21.5 percent of those were authorized for employees in the 06XX Medical, Hospital, Dental, and Public Health occupational family, 17.4 percent were authorized for employees in the 08XX Engineering and Architecture occupational family, 12.1 percent were authorized for employees in the 03XX General Administrative, Clerical, and Office Services occupational family, and 10.6 percent were authorized for employees in the 22XX Information Technology occupational family. The authority was used more frequently (on a percentage basis) for men than for women: 11.2 percent of non-seasonal full-time permanent GS new hires who were men had their pay set using the superior qualifications and special needs pay-setting authority, but only 7.9 percent of non-seasonal full-time permanent GS hires who were women had their pay set using the superior qualifications and special needs pay-setting authority.

Of the four occupational families that had the majority of the superior qualifications and special needs pay-setting authorizations, the two occupational families that were overwhelmingly male dominated (08XX Engineering and Architecture and 22XX Information Technology) are also the occupational families that had the

[25] The White House. ''Letter to the Speaker of the House and President of the Senate on the Alternative Plan for Pay Adjustments for Civilian Federal Employees.'' *https://www.whitehouse.gov/briefing-room/presidential-actions/2023/08/31/letter-to-the-speaker-of-the-house-and-the-president-of-the-senate-on-the-alternative-plan-for-pay-adjustments-for-civilian-federal-employees-2/.*

[26] Office of Personnel Management. ''Classification and Qualifications.'' *https://www.opm.gov/policy-data-oversight/classification-qualifications/.*

[27] Nonappropriated fund FWS prevailing rate employees are not reported to EHRI.

[28] Agencies must seek OPM pre-approval to use this pay-setting flexibility for ALJs. 5 CFR 930.205.

greatest percentage of new hires with pay set under the superior qualifications and special needs pay-setting authority. In the 08XX occupational family (Engineering and Architecture), 21 percent of new hires were women, and 79 percent of new hires were men. About 29 percent of new hires in the 08XX occupational family had their pay set using the superior qualifications and special needs pay-setting authority. In the 22XX occupational family (Information Technology), 24 percent of new hires were women, and 76 percent of new hires were men. About 22 percent of new hires in the 22XX occupational family had their pay set using the superior qualifications and special needs pay-setting authority. Conversely, in the 06XX occupational family (Medical, Hospital, Dental, and Public Health), 79 percent of new hires were women, and 21 percent of new hires were men, but only about 9 percent of new hires had their pay set using the superior qualifications and special needs pay-setting authority. Similarly, in the 03XX occupational family (General Administrative, Clerical, and Office Services), 54 percent of new hires were women, and 46 percent of new hires were men, but only about 8 percent of new hires had their pay set under the superior qualifications and special needs pay-setting authority.

OPM does not collect data on agency use of the other pay flexibilities that this regulation will revise (that is, the GS maximum payable rate rule in 5 CFR 531.221–223, the authority in 5 CFR 532.405 to set pay for a prevailing rate employee based on their highest previous rate, the authority in 5 CFR 534.604 to set pay based on an AAJ applicant's Federal highest previous rate of basic pay, or the authority in 5 CFR 930.205(f)(1) to set pay based on an ALJ applicant's highest previous Federal rate of basic pay). Because OPM is not prohibiting the use of an employee's highest previous Federal rate of pay to set pay, OPM does not anticipate that the regulatory changes in this final rule will result in a change in how frequently these pay flexibilities are used.

OPM invited comments on what data the Federal Government should consider when measuring the effects of greater pay equity achieved through a salary history ban, including effects on Federal worker turnover.

A professional organization stated that OPM should consider possible data sources such as exit interviews and Equal Employment Opportunity Commission (EEOC) data on pay discrimination cases. Comment 49. OPM does not collect exit interview data or data on EEO complaints, which are collected and maintained at agencies. An overview of the Federal Sector EEOC complaint process is available on EEOC's website.[29] Employees can appeal agency decisions to EEOC, but such data would not be complete and may not be readily available. EEOC provides annual reports on the Federal Workforce,[30] but it is summary-level data that is not specific enough to inform OPM's analyses of these regulatory changes. The organization also suggested that OPM should consider latitudinal studies across a sample of agencies to determine if there are differences between different hiring agencies and between different facilities on how frequently these authorities are invoked, and if there are any demographic disparities for subject employees in when and how these authorities are invoked. Id. As explained in the proposed rule, OPM analyzes the use of pay flexibilities by occupation and gender. OPM could also examine the use of pay flexibilities by racial/ethnic group. Pay flexibilities are discretionary so there may be differences between agencies' use of these authorities.

Also in response to OPM's request for comment, an agency suggested that the Federal Government should consider labor costs. Comment 57. The agency stated that ''agencies may be paying more without salary history'' and that ''the Federal Government should focus on career progression or upward mobility and associated pay increases after a person enters civil service rather than starting salary.'' Id. When completing Management Directive 715 for the EEOC, agencies already explore all levels of the workforce to determine if EEO groups have the same opportunities for career advancement.[31] An organization recommended comparing the salaries of newly hired Federal employees after OPM's proposal is enacted, with a control group of employees that would have been subject to the rule had it been in effect at time of hire, to isolate the effects of a salary history ban on wages, pay equity, and worker turnover. Comment 33. As these are discretionary pay authorities, it would be unworkable to identify a control group of employees that could be appropriately compared to employees in which the discretionary pay authorities had been used.

C. Costs

This rule will affect the operations of more than 80 Federal agencies—ranging from cabinet-level departments to small independent agencies—that have employees under the GS, prevailing rate, ALJ, AAJ, SES, and SL/ST pay systems. We estimate that this rule will require individuals employed by these agencies to spend time reviewing the rule and updating agency policies and procedures for the pay flexibilities. For this cost analysis, the assumed average salary rate of Federal employees performing this work will be the rate in 2023 for GS–14, step 5, from the Washington, DC, locality pay table ($150,016 annual locality rate and $71.88 hourly locality rate). We assume the total dollar value of labor, which includes wages, benefits, and overhead, is equal to 200 percent of the wage rate, resulting in an assumed labor cost of $143.76 per hour.

We estimate that, in the first year following publication of this final rule, compliance with this rule would require an average of 160 hours of work by employees with an average hourly cost of $143.76 per hour. This would result in estimated costs in that first year of implementation of about $23,000 per agency, and about $1.8 million Governmentwide. There are costs associated with administering the pay flexibilities in this rule, such as surveying and comparing similar positions, but not necessarily an increase in administrative costs for agencies that are already using these pay flexibilities.

A labor organization expressed concern that agency HR professionals may not have the necessary training to set pay based on the factors enumerated in the regulations. Comment 41. The organization recommended that OPM provide mandatory training and generate detailed worksheets to help generate justifications for pay setting. Id. OPM appreciates this suggestion and will consider the scope and content of implementation guidance, trainings, and other means of sharing best practices following the publication of this rule.

Another individual commented that OPM did not account for the cost of the increased wages that the commenter expects will be paid out because of the proposal. Comment 28. The commenter suggested that the cost impact of the proposed rule could be in excess of $570 million if the rule is successful in

[29] Equal Employment Opportunity Commission. ''Overview of Federal Sector EEO Complaint Process.'' *https://www.eeoc.gov/federal-sector/overview-federal-sector-eeo-complaint-process.*

[30] Equal Employment Opportunity Commission. ''Federal Sector Reports''. *https://www.eeoc.gov/federal-sector/reports.*

[31] Equal Employment Opportunity Commission. ''Instructions to Federal Agencies for EEO MD–715.'' *https://www.eeoc.gov/federal-sector/management-directive/instructions-federal-agencies-eeo-md-715-1.*

eliminating pay gaps. The commenter seems to assume that the rule would directly result in increases in pay for existing employees to close pay gaps. As noted in the prior section, the purpose of this rule is consistent with Executive Orders and OPM statutes and regulations, to remove from the pay-setting process consideration of a variable the agency has found to be inequitable. OPM, however, does not have authority to raise the pay for current employees to achieve equity with incoming employees. This rule does not purport to systematically increase existing pay and therefore cannot be the proximate cause of commenter's claimed increased costs to the Government.

D. Benefits

This final regulation provides the opportunity for the Federal Government to experience the benefits that certain states have found after enacting salary history bans, which includes benefits in economy and efficiency such as promoting equitable pay, improving wages and job mobility for workers who began their careers during a recession, and creating hiring efficiencies such as improved recruitment and retention. The Federal Government may also experience benefits related to increased equity and fairness within the Federal workforce.

Salary history bans can help close inequitable pay gaps that disadvantage women, workers of color, and workers who began their career during a recession. By enhancing equal treatment and compensation of similarly situated workers, salary history bans could lead to increased job satisfaction, commitment, and motivation among workers. This may help attract and retain a diverse and qualified workforce, and result in improved job performance and enhanced productivity for the employer. In addition to these economic gains, the Federal Government may see cost savings through reduced turnover, saving time and money from avoiding new hiring searches and new employee trainings. Salary history bans can also increase efficiencies by enhancing employers' talent pools.[32] In addition, by curbing inequitable pay decisions, a salary history ban can promote the values of equity, human dignity, and fairness within the Federal workforce described in E.O. 13563. Salary history bans can also promote more equitable and fairer pay-setting practices that are based on workers' skills, experience, or meeting a special agency need and eliminate reliance on the pay decisions of previous employers for which there is no context and that may have been arbitrary or potentially discriminatory.

OPM invited comments on whether there is any social science research or other evidence OPM should consider that suggests that limiting reliance on salary history advances equity and/or has other workplace benefits including for the employer.

Many commenters referenced a variety of social science research papers and data that show positive effects of salary history bans. *See, e.g.,* Comments 31, 33, 56, 61, 68. One commenter shared three articles regarding gender differences in negotiations. The first article reported on an experiment that found significant gender differences when men and women asked for more money as compensation for playing a game in the absence of overt prescriptions to negotiate.[33] Framing the situations as opportunities for negotiation was particularly intimidating to women. By contrast, framing situations as opportunities for asking was much less intimidating to women, as this language is viewed as more polite and role-consistent. The next article reported on an experiment that found that men benefitted more than women from having a strong alternative when negotiating a compensation package, which supported the author's hypothesis that women suffer a backlash from male and female negotiation partners when women negotiate assertively.[34] The authors suggest that ''managers looking to reduce gender gaps in the workplace may want to install guidelines and processes to minimize the possibility that such backlash occurs.'' Id. The third article reported on experiments in which ''evaluators penalized female candidates more than male candidates for initiating negotiations [for higher compensation].'' [35] These articles suggest that removing consideration of salary history may advance gender pay equity because it will help promote a level playing field between men and women in salary negotiations.

An organization and an individual suggested that OPM review pay discrimination litigation relating to Federal employees and data regarding private sector pay discrimination to determine the potential benefit of this rule in helping to avoid a category of pay lawsuits. Comments 27, 62. The EEOC has a fact sheet on notable EEOC litigation involving pay discrimination.[36] The commenters did not identify specific precedents, but OPM identified several cases that resulted in restrictions on considering prior salary in various contexts. In *Rizo* v. *Yovino,* the Ninth Circuit found that relying on prior wages when setting pay would perpetuate a wage disparity between men and women. 950 F.3d 1217 (9th Cir. 2020) (en banc). In a consent decree settling a pay discrimination suit, a bank agreed not to inquire about applicants' prior earnings history during the hiring process. *EEOC* v. *First Metropolitan Financial Services, Inc.,* 1:18–cv–177 (N.D. Miss. March 18, 2021). Similarly, in *EEOC* v. *Cummins, Inc., d/b/a Cummins Business Services,* the company agreed not to rely solely on prior salary in determining compensation. 3:17–cv–01306 (M.D. Tenn. Mar. 29, 2019). *EEOC* v. *Covenant Medical Center, Inc.,* resulted in a consent decree to equalize pay where a woman had been paid less than two male peers based on one man's prior salary history and the other man's negotiation of pay (where the woman had not been permitted to negotiate pay). *EEOC* v. *Covenant Medical Center, Inc.,* 2:20–cv–10662 (E.D. Mich. Sept. 2, 2020).

Similarly, the organization referenced an academic report, which noted that asking candidates to disclose their salary history can ''embed any previously encountered pay inequities into an employee's starting pay with a new employer.'' [37] These cases and report provide further information indicating that limiting reliance on salary history to set pay has positive benefits.

E. Regulatory Alternatives

Executive Orders 12866, 13563, and 14094 direct agencies to assess available

[32] National Women's Law Center. ''Asking for Salary History Perpetuates Pay Discrimination from Job to Job.'' March 2022. *https://nwlc.org/wp-content/uploads/2020/12/Asking-for-Salary-History-2022.pdf.*

[33] Small, D., Gelfand, M., Babcock, L., and Gettman, H. ''Who Goes to the Bargaining Table? The Influence of Gender and Framing on the Initiation of Negotiation.'' Journal of Personality and Social Psychology, 2007, Vol. 3, No. 4, 600–613.

[34] Dallanls, J., Zlatev, J., Halevy, N., and Neale, M. ''The Dynamics of Gender and Alternatives in Negotiation.'' Journal of Applied Psychology, 2021, Vol. 106, No. 11, 1655–1672.

[35] Bowles, H., Babcock, L., and Lai, L. ''Social Incentives for Gender Differences in the Propensity to Initiate Negotiations: Sometimes it Does Hurt to Ask.'' Organizational Behavior and Human Decision Processes, 2007, Vol. 103, 84–103.

[36] Equal Employment Opportunity Commission. ''Fact Sheet: Notable EEOC Litigation Involving Pay Discrimination.'' *https://www.eeoc.gov/fact-sheet-notable-eeoc-litigation-involving-pay-discrimination.*

[37] National Academies of Sciences, Engineering, and Medicine. ''Evaluation of Compensation Data Collected Through the EEO–1 Form.'' *https://nap.nationalacademies.org/catalog/26581/evaluation-of-compensation-data-collected-through-the-eeo-1-form.*

regulatory alternatives and to select regulatory approaches that maximize net benefits.

As discussed, agencies are required to set pay at the minimum of the rate range for new GS, prevailing rate, AAJ, and ALJ employees unless the agency chooses to set pay above the minimum based on one of the pay flexibilities that are available in regulations. To advance pay equity for new hires, one regulatory alternative OPM considered was eliminating pay flexibilities to set pay above the minimum rate of the applicable rate range. This option, however, would have been detrimental to agencies and job candidates. Agencies use pay flexibilities to set pay above the minimum rate to recruit candidates with superior qualifications or when agencies have a special need for the candidate's services. Agencies risk candidates rejecting employment if the offered salary does not meet their expectations.

Another option was to allow agencies to set pay based on a candidate's salary history if provided voluntarily and without prompting. OPM invited comments on what the advantages and disadvantages would be of prohibiting Federal agencies from relying on prior salary history, if the candidate voluntarily provided it, and possible justifications for allowing an exception to the prior salary history prohibition. OPM asked whether such an exception would be consistent with the goals of this regulation. OPM received many comments in response.

Most commenters were in favor of prohibiting Federal agencies from relying on prior salary history even if the candidate voluntarily provides it. One commenter stated that allowing an exception would be ''counterproductive [to] the goal of reducing or eliminating the gender pay gap . . . [because] many academic studies have shown that males will engage in salary negotiation about four times as often as females.'' Comment 18. Organizations similarly commented that men are more likely to disclose their salaries than women.

A commenter said that ''allowing private sector compensation to be considered when a candidate voluntarily supplies that information replicates private sector discrimination because candidates treated unfairly in the private sector will have no helpful salary history information to volunteer.'' Comment 32. A union and an organization stated that allowing voluntary disclosure of salary history would ''perpetuate current inequalities in the Federal workforce.'' Comment 44. An organization stated that allowing an exception would make the rule ''pointless'' and would provide ''no added independent benefit.'' Comment 46.

Two organizations agreed with OPM that ''a strict prohibition on considering salary history allows for more effective administration of the regulations and avoids confusion.'' Comment 56. An organization stated that ''allowing reliance on voluntary disclosure would tend to benefit those who have sufficient awareness of Federal hiring processes to know that this flexibility is potentially available and is likely to harm those who have less extensive experience or networks, a group that likely disproportionately includes women, people of color, and other traditionally marginalized candidates.'' Comment 56. The organization also shared results from a study that found that women are disproportionately penalized for declining to disclose their salaries whereas men are disproportionately rewarded.[38] Id. Another organization stated that reliance on prior salary is unnecessary because ''the Federal Government's pay-setting practices allow for consideration of a broad range of factors in determining appropriate pay setting.'' Comment 60.

One agency suggested that possible justifications for allowing an exception to the prior salary prohibition are that 5 U.S.C. 2301(b)(3) allows for ''appropriate consideration of both national and local rates paid by employers in the private sector'' and ''allows for competitiveness in hiring.'' Comment 09. The agency suggested limiting agencies to setting pay at the lowest step that equals or exceeds the candidate's salary history. Id. Another agency also stated that ''salary history, if available, should be factored when setting initial pay for an external candidate'' because otherwise ''individual hiring managers [may] randomly select a step or salary rate'' and setting a candidate's salary above their salary history would result in an ''increase in costs to taxpayers.'' Comment 57.

We find the reasons for prohibiting Federal agencies from considering prior salary history even if the candidate voluntarily provides it more compelling than the reasons for allowing an exception to the prior salary history prohibition. Agencies would still be able to set pay above step 1 to be competitive based on factors specified in the regulations, including significant disparities between Federal and non-Federal salaries for the skills and competencies required in the position to be filled. OPM is retaining its proposed approach of prohibiting agencies from considering prior salary history even if the candidate voluntarily provides it.

Lastly, OPM could maintain the status quo and not propose regulations to change salary determinations based on salary history. As explained throughout the proposed rule and this final rule, banning salary history as a consideration when setting pay promotes greater pay equity consistent with merit system principles. Because the Federal Government should serve as a model employer in establishing policies that advance pay equity, regulatory change is needed to help advance pay equity for Federal employees.

In evaluating the regulatory alternatives, OPM considered the information it had available regarding the pay gaps in Federal employment. Many factors, including disparities in salary history, may contribute to the overall gender and race/ethnicity pay gaps in the Federal Government. For example, more women than men occupy positions classified at lower GS grades with lower pay, while more men than women occupy positions classified at higher GS grades with higher pay and in higher-paying Senior Executive Service positions. Data indicated that, for each GS grade, women and men had close to the same average position in range (average step position). Factors such as length in service, quality step increases, and—most significantly for this regulation—how pay is set upon personnel actions such as appointment or promotion affect an employee's step position. OPM also found that the size of the gender pay gap varied by occupation.[39]

OPM's findings regarding Federal pay gaps are consistent with research on pay gaps in the national workforce. A November 2020 study[40] focused on national pay gaps and found that the gender pay gap varied significantly by occupation. There was no gender pay gap in some occupations, but gender pay gaps as large as 45 percent in others. The researchers found larger gender pay gaps in occupations that were more competitive and hazardous, occupations that reward longer hours of work, and those that have a larger proportion of women workers.

OPM's discussion in the proposed rule regarding the calculation and

[38] Payscale. ''Is Asking for Salary History . . . History?'' *https://www.payscale.com/research-and-insights/salary-history/.*

[39] 88 FR 30251, 30253 (May 11, 2023).

[40] Foster, T., Murray-Close, M., Landivar, L., & de Wolf, M. ''An Evaluation of the Gender Wage Gap Using Linked Survey and Administrative Data,'' November 2020. *https://www.census.gov/library/working-papers/2020/adrm/CES-WP-20-34.html.*

presentation of Federal Government pay gaps received multiple comments. One commenter requested more detailed data, such as data by occupational series. Comment 15. The commenter expressed that the public should have access to more detailed data behind our calculations in the proposed rule. A national union that supported the proposed rule asked OPM to examine ''potential clusters of inequity, whether it is within certain position series or grades, or individual agencies'' as part of its pay equity analyses. Comment 59. An agency commented that the Federal Government already has a diverse workforce and that women earn salaries that are the same as or higher than salaries earned by men when comparing both genders in the same position.

An organization cited international pay equity regulations, such as those in the European Union, as an example of a ''comprehensive approach,'' which requires reporting pay gap data in an open and transparent manner. Comment 31. OPM reviewed the European Union pay transparency regulations but concluded that requiring agencies to conduct and report on pay gap analyses is not within the scope of this rulemaking.

Another organization had several recommendations including that OPM: (1) update its multivariate regression-decomposition analysis using 2022 or 2023 data; (2) take an intersectional approach when updating its analysis; (3) break out Asian and Native Hawaiian/Pacific Islander employees into separate groups rather than combining them; (4) use medians instead of means; and (5) examine worker characteristics including supervisory status, education level, geography, tenure, age, and disability status. Comment 33. An international professional and technical union asked OPM to ''undertake an annual review of gender-based and racial/ethnic-based bias in median pay, matched for positions and seniority.'' Comment 64.

These data analysis recommendations raise several issues that are beyond the scope of this rule. Certain data from EHRI is available to the public on FedScope.[41] However, complete raw data is not available due to concerns about identifying employees at the individual level.[42] OPM has been reviewing 2022 data and plans to release a report in the coming months that will summarize pay gap information by gender and race/ethnicity and will present pay gap data for key worker characteristics such as pay system, grade (where applicable), occupation, agency, and age. OPM also plans to release detailed 2022 pay gap data with that report. OPM combines Asian and Native Hawaiian/Pacific Islander ethnic groups due to small sample sizes. OPM uses average, instead of median, salaries, in part, because means are readily available in OPM's EHRI[43] data system. Average salaries are an appropriate metric because a mean reflects the salary of all employees rather than focusing on a typical employee. OPM notes that the risks normally associated with using an average salary as a metric are minimal because Federal salaries have statutory pay limitations, which decrease the occurrence of outliers that would influence average salaries. Although OPM will continue to monitor and evaluate data regarding pay gaps based on gender or race/ethnicity, this final rule is not being promulgated simply to address potential pay gaps; this final rule is based on OPM's broader determination that eliminating consideration of prior salary history is the best way to implement the governing merit system principles.

F. Implementation

OPM invited comments on what information agencies should provide on the pay-setting flexibilities and at what stage in the hiring process agencies should provide this information. A union stated that ''information on how pay-setting flexibilities influence the final salary a candidate may be offered in job announcements and on agency websites helps candidates make better informed decisions when deciding whether to apply for such opportunities and what information to disclose during the application process.'' Comment 44. Similarly, several commenters recommended that OPM require agencies to provide this information in job announcements. Comments 44, 56. An agency stated that ''agencies should not solicit candidates to negotiate pay when hiring.'' Comment 57. An organization suggested that ''hiring agencies should be required to give applicants notice and the opportunity to submit to [the] agency pay-setting authorities documentation of any job offers or data on comparative pay for non-Federal positions that the applicant may have'' at the initial offer stage. Comment 49. Then ''only after receipt and review of any response from the applicant (or the passing of the deadline with no response) should the hiring agency finalize the starting pay offer grade and step for the position being offered.'' Id. OPM appreciates the responses received but declines to impose specific requirements for job announcements. OPM will consider these comments and suggestions in developing recommended best practices. In addition, as discussed in the Competing Job Offers section, OPM is revising the regulations in this final rule such that an agency will no longer be able to set pay based on a competing job offer.

Commenters recommended that OPM address other implementation issues. An agency, an organization, and a union recommended that hiring managers and human resources staff be trained on these regulatory changes. Comments 33, 41, 43. The union also recommended that OPM ''develop a standard form that would guide HR practitioners and/or hiring managers in developing a well-supported justification for pay-setting.'' Comment 41. The union suggested that agencies should provide service credit for the non-Federal work experience towards determining the step or rate at which to set the candidate's pay. Id. An organization suggested that OPM provide guidance ''on standards for what constitutes an effective comparative pay information search.'' Comment 49. The organization recommended that OPM ''modify the USAJOBS website and its standard forms for Federal job applications to eliminate rote requests for . . . prior salaries for non-Federal positions as part of detailing their employment histories.'' Id. OPM will review the USAJOBS website as OPM supports implementation of this final rule.

This final rule covers approximately 1.5 million Federal employees in the GS, prevailing rate, AAJ, ALJ, SES, and SL/ST pay systems combined who are employed in more than 80 Federal agencies. OPM's pay-setting regulations for the pay systems covered by this final rule prescribe broad criteria and limitations that agencies must apply in developing and implementing their own agency-specific pay-setting policies and procedures. OPM's regulations do not address the form or content of offers of employment that agencies make to candidates, nor do they address the process by which agencies engage with candidates. For these reasons, agency pay setting, job offer, and candidate communication policies, procedures, and practices may vary widely.

This final rule has a 60-day effective date. OPM recognizes, however, that agencies may need implementing

[41] *https://www.fedscope.opm.gov/.*

[42] *See* the FedScope Data Release Policy at *https://www.fedscope.opm.gov/download_Data%20Release%20Policy.pdf.*

[43] Office of Personnel Management, ''About Our Data (EHRI–SDM).'' *https://www.fedscope.opm.gov/datadefn/aehri_sdm.asp.*

guidance and additional time to modify their own policies and procedures and provide new instructions to their human resources professionals and hiring managers regarding setting pay and making pay offers in compliance with this final rule. To accommodate the scope of coverage and range of agency policies and practices this final rule will affect and to minimize disruptions to ongoing agency hiring processes where offers of pay have already been made to candidates, OPM is allowing additional time for agencies to implement this final rule. During this time, agencies should take steps to revise their policies and procedures. As soon as practicable, any new offers for employment including salary information for GS, FWS, ALJ, AAJ, SES, SL, ST positions and new pay-setting decisions for such positions based on an employee's previous Federal salary should reflect the requirements in this final rule. Agencies must be in full compliance with the final rule by October 1, 2024. OPM considers ''full compliance'' to refer to the pay setting decision as documented in the required justifications for use of these pay flexibilities—not necessarily the final processing of the personnel action. Therefore, these justifications that are approved on or after October 1, 2024, must be in full compliance. In accordance with 5 U.S.C. 7116(a)(7), this final rule cannot override any collective bargaining agreement in effect prior to the effective date of this regulation. Such collective bargaining agreement would need to come into compliance with this government wide regulation when the agreement is due to be renegotiated or expires.

G. Severability

If any of the provisions of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, it shall be severable from its respective section(s) and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances. For example, if a court were to invalidate any portion of this proposed rule as finalized imposing procedural requirements on agencies with respect to one pay system, the other portions of the rule—including the portions applying to each of the other affected pay systems—would independently remain workable and valuable. In enforcing the pay equity provisions of this rule, OPM will comply with all applicable legal requirements.

Regulatory Flexibility Act

The Director of OPM certifies that these regulations will not have a significant economic impact on a substantial number of small entities because they will apply only to Federal agencies and employees.

Regulatory Review

OPM has examined the impact of this rule as required by Executive Orders 12866, 13563, and 14094, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public, health, and safety effects, distributive impacts, and equity). This rule is considered a ''significant regulatory action'' under section 3(f) of Executive Order (12866).

E.O. 13132, Federalism

This regulation will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this final rule does not have sufficient federalism implications to warrant preparation of a Federalism Assessment.

E.O. 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in section 3(a) and (b)(2) of Executive Order 12988.

Unfunded Mandates Reform Act of 1995

This final rule will not result in the expenditure by State, local or tribal governments of more than $100 million annually. Thus, no written assessment of unfunded mandates is required.

Congressional Review Act

OMB's Office of Information and Regulatory Affairs has determined this is not a major rule as defined by the Congressional Review Act (5 U.S.C. 804(2)).

Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35)

This regulatory action will not impose any reporting or recordkeeping requirements under the Paperwork Reduction Act.

List of Subjects in Title 5 CFR Parts 531, 532, 534, and 930

Administrative practice and procedure, Computer technology, Freedom of information, Government employees, Hospitals, Law enforcement officers, Motor vehicles, Reporting and recordkeeping requirements, Students, Wages.

Office of Personnel Management.

Stephen Hickman,

Federal Register Liaison.

Accordingly, OPM is amending 5 CFR parts 531, 532, 534, and 930 as follows:

PART 531—PAY UNDER THE GENERAL SCHEDULE

■ 1. The authority citation for part 531 continues to read as follows:

Authority: 5 U.S.C. 5115, 5307, and 5338; sec. 4 of Public Law 103–89, 107 Stat. 981; and E.O. 12748, 56 FR 4521, 3 CFR, 1991 Comp., p. 316; Subpart B also issued under 5 U.S.C. 5303(g), 5305, 5333, 5334(a) and (b), and 7701(b)(2); Subpart D also issued under 5 U.S.C. 5335 and 7701(b)(2); Subpart E also issued under 5 U.S.C. 5336; Subpart F also issued under 5 U.S.C. 5304, 5305, and 5941(a); E.O. 12883, 58 FR 63281, 3 CFR, 1993 Comp., p. 682; and E.O. 13106, 63 FR 68151, 3 CFR, 1998 Comp., p. 224.

Subpart B—Determining Rate of Basic Pay

■ 2. In § 531.212—

■ a. Revise paragraph (c) introductory text;

■ b. Remove paragraph (c)(2);

■ c. Redesignate paragraph (c)(1) as (c)(2)(i) and paragraphs (c)(3) through (c)(10) as (c)(2)(ii) through (c)(2)(ix);

■ d. Add a new paragraph (c)(1) and new paragraph (c)(2) introductory text;

■ e. Revise newly redesignated paragraph (c)(2)(ix); and

■ f. Revise paragraph (e)(2)(ii).

The revisions and additions read as follows:

§ 531.212 Superior qualifications and special needs pay-setting authority.

* * * * *

(c) *Pay rate determination.* To determine the step at which to set an employee's payable rate of basic pay using the superior qualifications and special needs pay-setting authority, an agency must consider:

(1) The step at which pay has been set for employees who had similar qualifications (based on the level, type, or quality of the candidate's skills or competencies or other qualities and experiences) and who have been newly appointed to positions that are similar to the candidate's position (based on the position's occupational series, grade level, organization, geographic location, or other job-relevant factors), if applicable; and

(2) One or more of the following factors, as applicable in the case at hand:

* * * * *

(ix) Other relevant factors, except that an agency may not consider the candidate's salary history (*i.e.,* existing salary or prior salary) or a salary from a competing job offer.

* * * * *

(e) * * *

(2) * * *

(ii) An explanation of the factors and supporting documentation under paragraph (c) of this section which were used to justify the rate at which the employee's pay is set. The written documentation must explain how the factors directly relate to the rate approved; and

* * * * *

■ 3. In § 531.221, add paragraph (a)(6) to read as follows:

§ 531.221 Maximum payable rate rule.

(a) * * *

(6) Before setting pay under this section, an agency must establish a policy on its use of the maximum payable rate rule that includes—

(i) Designation of officials with the authority to approve and set pay under this section;

(ii) Any situations in which the agency must use the authority;

(iii) Any situations in which the agency may exercise its discretion in using the authority;

(iv) Consideration of the step at which pay has been set for other employees performing similar work in the organization (based on the position's occupational series, grade level, types of duties, or other job-relevant factors) and any other factors the designated official(s) may or must consider in determining the step at which to set the employee's pay between the employee's entitlement under any other applicable pay-setting rule and the employee's maximum payable rate; and

(v) Documentation and recordkeeping requirements sufficient to allow reconstruction of the action.

* * * * *

PART 532—PREVAILING RATE SYSTEMS

■ 4. The authority citation for part 532 continues to read as follows:

Authority: 5 U.S.C. 5343, 5346; § 532.707 also issued under 5 U.S.C. 552.

Subpart D—Pay Administration

■ 5. In § 532.403, revise paragraph (b) to read as follows:

§ 532.403 New appointments.

* * * * *

(b) An agency may make a new appointment at a rate above the minimum rate of the appropriate grade in recognition of an appointees' special qualifications. In determining the rate at which to set the appointee's pay:

(1) An agency must consider how the step has been set for employees who had similar qualifications (based on the level, type, or quality of the appointee's skills or competencies or other qualities and experiences) and who have been newly appointed to positions that are similar to the appointee's position (based on the position's occupational series, grade level, organization, geographic location, or other job-relevant factors), if applicable;

(2) An agency may not consider the appointee's pay history (*i.e.,* existing pay or prior pay) or a pay rate from a competing job offer; and

(3) An agency must consider other relevant factors (*e.g.,* the level, type, or quality of the appointee's skills or competencies; or significant disparities between Federal and non-Federal salaries for the skills and competencies required in the position to be filled).

* * * * *

■ 6. In 532.405, add paragraph e to read as follows:

§ 532.405 Use of highest previous rate.

* * * * *

(e) Before setting pay under this section, an agency must establish a policy regarding use of employees' highest previous rates. The policy must include the following elements:

(1) Designation of officials with the authority to approve and set pay under this section;

(2) Any situations in which the agency must use an employee's highest previous rate;

(3) Any situations in which the agency may exercise its discretion in using an employee's highest previous rate;

(4) Consideration of the step at which pay has been set for other employees performing similar work in the organization (based on the position's occupational series, grade level, types of duties, or other job-relevant factors) and any other factors the designated official(s) may or must consider in determining the step at which to set the employee's pay between the employee's entitlement under any other applicable pay-setting rule and the employee's highest previous rate; and

(5) Documentation and recordkeeping requirements sufficient to allow reconstruction of the action.

PART 534—PAY UNDER OTHER SYSTEMS

■ 7. The authority citation for part 534 continues to read as follows:

Authority: 5 U.S.C. 1104, 3161(d), 5307, 5351, 5352, 5353, 5376, 5382, 5383, 5384, 5385, 5541, 5550a, sec. 1125 of the National Defense Authorization Act for FY 2004, Pub. L. 108–136, 117 Stat. 1638 (5 U.S.C. 5304, 5382, 5383, 7302; 18 U.S.C. 207); and sec. 2 of Pub. L. 110–372, 122 Stat. 4043 (5 U.S.C. 5304, 5307, 5376).

Subpart D—Pay and Performance Awards Under the Senior Executive Service

■ 8. In § 534.404—

■ a. Amend paragraph (a) by adding a sentence to the end of the paragraph; and

■ b. Amend paragraph (i)(1) by adding a sentence to the end of the paragraph.

The revisions read as follows:

§ 534.404 Setting and adjusting pay for senior executives.

(a) * * * When making a first appointment (regardless of tenure) as a civilian employee of the Federal Government, an agency may not consider the individual's salary history (*i.e.,* existing salary or prior salary) or a salary from a competing job offer.

* * * * *

(i) * * *

(1) * * * When setting pay upon reappointment to the SES, an agency may not consider the individual's non-Federal salary history (*i.e.,* existing salary or prior salary) or a salary from a competing job offer.

* * * * *

Subpart E—Pay for Senior-Level and Scientific or Professional Positions

■ 9. In § 534.506, revise paragraphs (a) and (c)(1) to read as follows:

§ 534.506 Setting a rate of basic pay upon appointment.

(a) An authorized agency official may set the rate of basic pay of an individual who is not currently an SL or ST appointee of the agency at any rate within the applicable rate range under § 534.504(a) upon appointment to an SL or ST position in the agency, subject to the requirements of this section. In setting a new senior professional's rate of basic pay, an agency must consider the nature and quality of the individual's experience, accomplishments, and any unique skills, qualifications, or competencies the individual possesses as they relate to requirements of the senior professional position and its impact on

the agency's performance. When making a first appointment (regardless of tenure) as a civilian employee of the Federal Government, an agency may not consider the individual's salary history (*i.e.,* existing salary or prior salary) or a salary from a competing job offer. Rates of basic pay above the rate for level III of the Executive Schedule, but less than or equal to the rate for level II of the Executive Schedule, generally are reserved for those newly appointed senior professionals who possess superior leadership, scientific, professional or other competencies necessary to address key program and mission requirements, as determined by the agency through its strategic human capital planning process.

* * * * *

(c)(1) Consistent with the agency's written procedures and paragraph (a) of this section, except as provided in paragraph (c)(2) of this section, an authorized agency official may set pay upon reappointment of a former SL or ST employee at any rate of basic pay within the pay range that applies to the SL or ST position under § 534.504(a). When setting pay, the agency may not consider the individual's non-Federal salary history (*i.e.,* existing salary or prior salary) or a salary from a competing job offer.

* * * * *

Subpart F—Pay for Administrative Appeals Judge Positions

■ 10. In § 534.604—

■ a. Revise paragraph (b);

■ b. Redesignate paragraphs (c) and (d) as paragraphs (f) and (g), respectively; and

■ c. Add new paragraphs (c) and (d) and paragraph (e).

The revision and additions read as follows:

§ 534.604 Pay administration.

* * * * *

(b) Upon initial appointment, an agency must set the rate of basic pay of an administrative appeals judge at the minimum rate AA–1 of the administrative appeals judge pay system, except as provided in paragraphs (c), (d), and (e) of this section.

(c) An agency must set the pay of an employee under the General Schedule pay system who is appointed to an administrative appeals judge position without a break in service at the lowest rate of basic pay of the administrative appeals judge pay system that equals or exceeds the rate of basic pay the employee received immediately prior to such appointment, not to exceed the rate of basic pay for AA–6. If the resulting basic pay increase is less than one-half of the dollar value of the employee's next within-grade increase, the agency must set the employee's rate of basic pay at the next higher rate of basic pay in the basic rate range of the administrative appeals judge pay system, not to exceed the rate of basic pay for AA–6.

(d) An agency may offer an administrative appeals judge applicant with prior Federal service a rate up to the lowest rate of basic pay of the administrative appeals judge pay system that equals or exceeds the employee's highest previous rate of basic pay in a Federal civil service position, not to exceed the rate of basic pay for AA–6. Before setting pay under this paragraph, an agency must establish a policy that includes the following elements:

(1) Designation of officials with the authority to approve and set pay under this paragraph (d);

(2) Whether use of this authority is discretionary or mandatory;

(3) The factors the designated officials may or must consider in determining the rate at which to set the applicant's pay and which must include consideration of the rate of basic pay set for other administrative appeals judges (based on the level, type, or quality of the appointee's skills or competencies or other qualities and experiences); and

(4) Documentation and recordkeeping requirements sufficient to allow reconstruction of the action.

(e) An agency may offer an administrative appeals judge applicant (including a former administrative appeals judge) with superior qualifications who is not a current Federal employee a higher than minimum rate up to the maximum rate AA–6 when such a rate is clearly necessary to meet the needs of the Government. Superior qualifications for applicants include, but are not limited to, having legal practice before the hiring agency, having practice in another forum with legal issues of concern to the hiring agency, or having an outstanding reputation among others in the field. An agency must document all of the following:

(1) The superior qualifications of the applicant;

(2) The need of the Government for the applicant's services;

(3) Consideration of how pay has been set for administrative appeals judges who had similar qualifications (based on the level, type, or quality of the applicant's skills or competencies or other qualities and experiences) and who have been newly appointed to positions that are similar to the applicant's position (based on the position's occupational series, organization, geographic location, or other job-relevant factors), if applicable; and

(4) An explanation of the factors which were used to justify the rate at which the employee's pay is set, except an agency may not consider the applicant's salary history (*i.e.,* existing salary or prior salary) or a salary from a competing job offer.

* * * * *

PART 930—PROGRAMS FOR SPECIFIC POSITIONS AND EXAMINATIONS (MISCELLANEOUS)

Subpart B—Administrative Law Judge Program

■ 11. The authority citation for subpart B continues to read as follows:

Authority: 5 U.S.C. 1104(a), 1302(a), 1305, 3105, 3301, 3304, 3323(b), 3344, 4301(2)(D), 5372, 7521, and E.O. 10577, 3 CFR, 1954–1958 Comp., p. 219.

■ 12. In § 930.201, revise paragraph (e)(5) to read as follows:

§ 930.201 Coverage.

* * * * *

(e) * * *

(5) Approve personnel actions related to pay for administrative law judges under § 930.205(c), (g), (h), and (k);

* * * * *

■ 13. In § 930.205—

■ a. In paragraph (e), remove the words ''paragraph (f)'' and add ''paragraphs (f) and (g)'' in their place;

■ b. Revise paragraph (f);

■ c. Redesignate paragraphs (g) through (j) as paragraphs (h) through (k), respectively; and

■ d. Add a new paragraph (g).

The revision and addition read as follows:

§ 930.205 Administrative law judge pay system.

* * * * *

(f) When an applicant to an administrative law judge position at AL–3 has prior Federal service, the agency may set pay at a higher than minimum rate up to the lowest rate of basic pay that equals or exceeds the applicant's highest previous Federal rate of basic pay, not to exceed the maximum rate F. Before setting pay under this paragraph, an agency must establish a policy regarding use of this pay-setting authority that includes the following elements:

(1) Designation of officials with the authority to approve and set pay under this paragraph;

(2) Whether use of this authority is discretionary or mandatory;

(3) The factors the designated officials may or must consider in determining the rate at which to set the applicant's pay, which must include how the rate of basic pay has been set for other administrative law judges; and

(4) Documentation and recordkeeping requirements sufficient to allow reconstruction of the action.

(g) With prior OPM approval, an agency may offer a higher than minimum rate, up to the maximum rate F, to an administrative law judge applicant or a former administrative law judge with superior qualifications who is eligible for appointment to a position at AL–3. An agency request to OPM must include:

(1) A description of the superior qualifications (as defined in § 930.202) of the applicant or former administrative law judge;

(2) How pay has been set for administrative law judges who had similar qualifications (based on the level, type, or quality of the applicant's or former administrative law judge's skills or competencies or other qualities and experiences) and who have been newly appointed to positions that are similar to the administrative law judge's position (based on the position's occupational series, organization, geographic location, or other job-relevant factors), if applicable; and

(3) The proposed rate of basic pay and a justification for that rate, except an agency may not consider an applicant's or former administrative law judge's salary history (*i.e.,* existing salary or prior salary) or a salary from a competing job offer.

* * * * *

[FR Doc. 2024–01337 Filed 1–29–24; 8:45 am]

BILLING CODE 6325–39–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 984

[Doc. No. AMS–SC–23–0030]

Walnuts Grown in Califfornia; Decreased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule implements a recommendation from the California Walnut Board (Board) to decrease the assessment rate established for the 2023–2024 and subsequent marketing years. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Effective February 29, 2024.

FOR FURTHER INFORMATION CONTACT: Joshua R. Wilde, Marketing Specialist, or Barry Broadbent, Acting Chief, West Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA; Telephone: (503) 326–2724, or Email: *Joshua.R.Wilde@usda.gov* or *Barry.Broadbent@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–8085, or Email: *Richard.Lower@usda.gov.*

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, amends regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This rule is issued under Marketing Agreement and Order No. 984, both as amended (7 CFR part 984), regulating the handling of walnuts grown in California. Part 984 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Board locally administers the Order and is comprised of growers and handlers of California walnuts operating within the area of production, and a public member.

The Agricultural Marketing Service (AMS) is issuing this rule in conformance with Executive Orders 12866, 13563, and 14094. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 14094 reaffirms, supplements, and updates Executive Order 12866 and further directs agencies to solicit and consider input from a wide range of affected and interested parties through a variety of means. This proposed action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review.

This rule has been reviewed under Executive Order 13175—Consultation and Coordination with Indian Tribal Governments, which requires Federal agencies to consider whether their rulemaking actions would have Tribal implications. AMS has determined that this rule is unlikely to have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the Order now in effect, California walnut handlers are subject to assessments. Funds to administer the Order are derived from such assessments. It is intended that the assessment rate will be applicable to all assessable California walnuts for the 2023–2024 marketing year, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the U.S. Department of Agriculture (USDA) a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This rule decreases the assessment rate for California walnuts handled under the Order from $0.0125 per inshell pound, the rate that was initially established for the 2023–2024 and subsequent marketing years, to $0.011 per inshell pound.

Section 984.68 authorizes the Board, with the approval of AMS, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members of the Board are familiar with the Board's needs and with the costs of goods and services in their local area and are able to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting, and all directly affected persons have an opportunity to participate and provide input.

On September 21, 2021, at the request of the Board, AMS issued a temporary

moratorium on the enforcement of the Order's grading and assessment requirements as the Board considered multiple amendments to modify the Federal marketing order for California walnuts through the formal rulemaking process. On April 19 and 20, 2022, AMS held a public hearing on the proposed amendments, including a recommendation by the Board to establish an assessment rate of $0.0125 per inshell pound of walnuts. The Board recommended the assessment rate of $0.0125 per inshell pound to ensure the Board would have the ability to collect assessments to generate funds needed to sustain Board activities and programs moving forward. The Board determined $0.0125 as appropriate given the available data at that time and with the understanding that a rate change may be necessary if updated market data indicates such an adjustment is necessary after the completion of the formal rulemaking. The formal rulemaking completed when a final rule published in the **Federal Register** on August 21, 2023 (88 FR), and effective September 20, 2023, an assessment rate of $0.0125 per inshell pound of walnuts was established.

Prior to the publication of the final rule, the Board met on June 9, 2023, and unanimously recommended 2023–2024 marketing year expenditures of $16,811,250 and recommended amending the 2023–2024 marketing year assessment rate to $0.011 per inshell pound of California walnuts handled. By comparison, the 2022–2023 budgeted expenditures were $5,275,000 and the 2021–2022 budgeted expenditures were $18,892,500.

Assessments are applied uniformly on all handlers, and some of the costs may be passed on to growers. The assessment rate of $0.0125 per inshell pound of walnuts along with non-assessment revenue is sufficient to cover the upcoming marketing year's budgeted expenditures; however, during Board meetings, industry members expressed that the cost of production is greater than grower revenue and that growers are struggling. The Board then deliberated on a rate that would provide a cost relief for handlers (and by extension to walnut growers) while balancing the Board's assessment income with budgeted expenses for the 2023–2024 and subsequent marketing years.

The Board ultimately recommended decreasing the assessment rate to $0.011 per inshell pound. The assessment rate of $0.011 per inshell pound is $0.0015 lower than the rate established by the August 21, 2023, final rule, with an effective date of September 20, 2023. The Board believes the decreased assessment rate will balance assessment income with budgeted expenditures and provide some financial relief to walnut growers after industry members expressed concern over the increasing cost of production as outpacing grower revenue, leading to tighter operating margins.

For the 2021–2022 through 2022–2023 marketing years, the Board has operated using available financial reserves to meet its expenses. The Board expects to enter the 2023–2024 marketing year with a reserve balance of approximately $10,043,811, which is within the maximum permitted under § 984.69 of the Order of approximately two marketing years' budgeted expenses. The Board projects handler receipts of 700,000 tons (1.4 billion pounds) of assessable California walnuts for the 2023–2024 marketing year, which is the same quantity that was projected for the 2022–2023 marketing year.

The major expenditures budgeted by the Board for the 2023–2024 marketing year include $10,588,750 for domestic marketing; $2,472,500 for employee expenses; $1,700,000 for production research; $725,000 for grades and standards activities; $585,000 for industry crop/acreage reporting; $350,000 for office expenses; and $390,000 for other operating expenses. For comparison, there were no Board-authorized expenses for domestic marketing for the 2022–2023 marketing year due to the moratorium. Instead, the Board authorized reserve funding during the 2022–2023 marketing year for budgeted expenses, which included $1,894,000 for employee expenses; $1,700,000 for production research; $725,000 for grades and standard activities; $184,000 for industry crop/acreage reporting; $282,000 for office expenses; and $284,000 for operating expenses.

The Board derived the recommended assessment rate by considering anticipated expenses, the estimated volume of assessable walnuts, and the amount of funds available in the authorized reserve. The expected 700,000 tons (1.4 billion pounds) of California walnuts from the 2023–2024 marketing year crop will generate $15,400,000 in assessment revenue at the decreased assessment rate (1.4 billion pounds multiplied by the $0.011 assessment rate). The remaining $1,411,250 needed to cover budgeted expenditures will come from an approved administrative services agreement with the California Walnut Commission, which shares staff and office expenses with the Board. The income generated from assessments, along with non-assessment revenue, should be sufficient to meet the Board's budgeted program expenditures of $16,811,250.

Prior to arriving at this budget and assessment rate recommendation, the Board considered information from various sources, such as the Board's Executive Committee. The Board discussed various alternatives to its recommended action, including maintaining the current assessment rate of $0.0125 per inshell pound of assessable walnuts and decreasing the assessment rate by a different amount. However, the Board determined that the decreased assessment rate will effectively achieve the Board's goals of covering budgeted expenses for the 2023–2024 marketing year and maintaining adequate funds in its financial reserve while providing a cost relief to handlers, which may be passed on to growers.

The assessment rate will continue in effect indefinitely unless modified, suspended, or terminated by AMS upon recommendation and information submitted by the Board or other available information.

Although this assessment rate will be in effect for an indefinite period, the Board will continue to meet prior to or during each marketing year to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Board meetings are available from the Board or AMS. Board meetings are open to the public and interested persons may express their views at these meetings. AMS would evaluate Board recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The Board's 2023–2024 marketing year budget, and those for subsequent marketing years, will be reviewed and, as appropriate, approved by AMS.

Final Regulatory Flexibility Analysis

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

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about

through group action of essentially small entities acting on their own behalf.

There are approximately 4,500 walnut growers in the production area and 80 handlers subject to regulation under the Order. Small agricultural growers of California walnuts are defined by the Small Business Administration (SBA) as those having annual receipts of less than $3,750,000 (NAICS Code 111335), and small agricultural service firms are defined as those whose annual receipts are less than $34,000,000 (NAICS Code 115114) (13 CFR 121.201).

Data from USDA's National Agricultural Statistics Service (NASS), indicate a three-year average value of utilized walnut production of $1.069 billion for the most recent seasons for which data is available (2019–2020 through 2021–2022 marketing years). Dividing that figure by the number of walnut growers (4,400) yields an average annual crop value per grower of approximately $243,045. This figure is well below the SBA small agricultural walnuts producer threshold of $3,750,000 in annual sales. Assuming a normal distribution, this provides evidence that a large majority of walnut growers would likely be considered small agricultural producers according to the SBA definition. Additionally, data from NASS's 2017 Agricultural Census show that 86 percent of California farms growing walnuts at the time had walnut sales of less than $1 million.

Based on information from the Board, approximately 70 percent of California's walnut handlers shipped assessable walnuts valued under $34 million during the 2022–2023 marketing year and would, therefore, be considered small handlers according to the SBA definition. In light of the foregoing, it is reasonable to conclude that a substantial majority of both walnut growers and handlers would be considered small business entities according to current SBA definitions.

This rule decreases the assessment rate collected from handlers for the 2023–2024 and subsequent marketing years from $0.0125 to $0.011 per inshell pound of California walnuts. Authority for this action can be found under § 984.68 of the Order. The Board unanimously recommended 2023–2024 marketing year expenditures of $16,811,250 and an assessment rate of $0.011 per inshell pound of California walnuts. The assessment rate of $0.011 is $0.0015 lower than the current rate. The Board expects the industry to handle 700,000 tons (1.4 billion pounds) of California walnuts during the 2023–2024 marketing year. Thus, the $0.011 per inshell pound assessment rate will provide $15,400,000 in assessment income (1.4 billion pounds multiplied by $0.011). The Board also expects to receive $1,411,250 from an administrative services agreement with the California Walnut Commission. Income derived from these sources will be adequate to meet budgeted expenditures for the 2023–2024 marketing year.

The major expenditures budgeted by the Board for the 2023–2024 marketing year include $10,588,750 for domestic marketing; $2,472,500 for employee expenses; $1,700,000 for production research; $725,000 for grades and standards activities; $585,000 for industry crop/acreage reporting; $350,000 for office expenses; and $390,000 for other operating expenses. For comparison, there were no Board-authorized expenses for domestic marketing for the 2022–2023 marketing year while assessment collection was temporarily suspended. The other 2022–2023 marketing year budgeted expenses were $1,894,000; $1,700,000; $725,000; $184,000; $282,000; and $284,000 respectively.

The Board recommended decreasing the assessment rate in order to provide relief to California walnut growers while still generating adequate income to cover all of the Board's budgeted expenses for the 2023–2024 marketing year. Prior to arriving at this budget and assessment rate recommendation, the Board considered information from various sources and discussed various alternatives to its recommended action. These included maintaining the current assessment rate of $0.0125 per inshell pound of assessable walnuts and decreasing the assessment rate by a different amount. However, the Board determined that the decreased assessment rate will effectively achieve the Board's goals of covering budgeted expenses for the 2023–2024 marketing year and maintaining adequate funds in its financial reserve. This action will maintain the Board's reserve balance at a level that the Board believes is appropriate and is compliant with the provisions of the Order.

Based upon information from NASS, the grower price reported for walnuts in the 2021 crop year was $1,410 per ton ($0.71 per pound). To determine the estimated assessment revenue as a percentage of the total grower revenue, we calculate the assessment rate ($0.011 per inshell pound) divided by the grower price ($0.71 per pound) and multiply that number by 100. Therefore, estimated assessment revenue as a percentage of total grower revenue for the 2023–2024 marketing year will be about 1.5 percent.

This action decreases the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to growers. However, these costs are expected to be offset by the benefits derived by the operation of the Order.

The Board's meetings are widely publicized throughout the production area. The California walnut industry and all interested persons are invited to attend the meetings and participate in Board deliberations on all issues. Like all Board meetings, the June 9, 2023, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Finally, interested persons were invited to submit comments on this rule, including the regulatory and information collection impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995, (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0178, Vegetable and Specialty Crops. No changes in those requirements will be necessary as a result of this rule. Should any changes become necessary, they would be submitted to OMB for approval.

This rule will not impose any additional reporting or recordkeeping requirements on either small or large California walnut handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide decreased opportunities for citizen access to Government information and services, and for other purposes.

AMS has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

A proposed rule concerning this action was published in the **Federal Register** on October 27, 2023 (88 FR 73763). Copies of the proposed rule were also mailed or sent via email to all walnut handlers. A copy of the proposed rule was made available through the internet by AMS via *https://www.regulations.gov*. A 30-day comment period ending November 27, 2023, was provided for interested persons to respond to the proposal. AMS received one comment in support

of the decreased assessment rate. Accordingly, no changes have been made to the rule as proposed.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *https://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendations submitted by the Board and other available information, AMS has determined that this rule tends to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 984

Marketing agreements, Nuts, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Agricultural Marketing Service amends 7 CFR part 984 as follows:

PART 984—WALNUTS GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 984 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 984.347 is revised to read as follows:

§ 984.347 Assessment rate.

On and after September 1, 2023, an assessment rate of $0.011 per inshell pound is established for California walnuts.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2024–01609 Filed 1–29–24; 8:45 am]

BILLING CODE P

FARM CREDIT ADMINISTRATION

12 CFR Parts 619 and 627

RIN 3052–AD48

Conservators and Receivers

AGENCY: Farm Credit Administration.

ACTION: Notification of effective date.

SUMMARY: The Farm Credit Administration (FCA) issued a final rule that amended our conservators and receiver regulations for Farm Credit System (FCS) banks, associations, service corporations, and the Federal Farm Credit Banks Funding Corporation (Funding Corporation).

DATES: This final rule was published on November 24, 2023 (88 FR 82238), is effective as of January 17, 2024.

FOR FURTHER INFORMATION CONTACT:

Technical information: Jason Moore, Associate Director, Office of Regulatory Policy, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4414, TTY (703) 883–4056; or

Legal Information: Karen Hunter, Attorney Advisor, or Richard A. Katz, Senior Counsel, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TTY (703) 883–4056.

SUPPLEMENTARY INFORMATION: On November 9, 2023, FCA issued a final rule that amended our regulations governing the appointment of the Farm Credit System Insurance Corporation (FCSIC) as the conservator or receiver of FCS banks, associations, service corporations, and the Funding Corporation. The final rule ensures that FCA conservatorship and receivership regulations are consistent with section 5412 of the Agricultural Improvement Act of 2018, which added section 5.61C to the Farm Credit Act of 1971, as amended(12 U.S.C. 2277a-10c), to strengthen, update and clarify FCSIC's powers as the conservator or receiver of these above-mentioned FCS institutions. Additionally, the final rule consolidates and reorganizes FCA's conservatorship and receivership regulations so they are easier to understand and use. Finally, FCA made conforming amendments to its definitional regulations in Part 619 to exempt bridge System banks from other FCA regulations that apply to viable and solvent FCS banks.

In accordance with 12 U.S.C. 2252(c)(1), the effective date of the rule is no earlier than 30 days from the date of publication in the **Federal Register** during which either or both Houses of Congress are in session. Based on the records of the sessions of Congress, the effective date of the regulations is January 17, 2024.

Dated: January 24, 2024.

Ashley Waldron,

Secretary to the Board, Farm Credit Administration.

[FR Doc. 2024–01738 Filed 1–29–24; 8:45 am]

BILLING CODE 6705–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2023–2439; Special Conditions No. 25–852–SC]

Special Conditions: Gulfstream Aerospace Corporation Model GVIII–G700 and GVIII–G800 Series Airplanes; Operation Without Normal Electrical Power

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Gulfstream Aerospace Corporation (Gulfstream) Model GVIII–G700 and GVIII–G800 series airplanes. These airplanes will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. This design feature is an electronic flight-control system, the functions of which are dependent upon the electrical power-generation and distribution systems, whereby the loss of all electrical power may be catastrophic to the airplane. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Gulfstream on January 30, 2024. Send comments on or before March 15, 2024.

ADDRESSES: Send comments identified by Docket No. FAA–2023–2439 using any of the following methods:

- *Federal eRegulations Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

• *Docket:* Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Dan Poblete, Aircraft Systems, AIR–623, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 3960 Paramount Boulevard, Suite 100, Lakewood, California 90712; telephone 562–627–5335, fax 562–627–5210; email *daniel.d.poblete@faa.gov.*

SUPPLEMENTARY INFORMATION: The substance of these special conditions has been published in the **Federal Register** for public comment in several prior instances with no substantive comments received. Therefore, the FAA finds, pursuant to 14 CFR 11.38(b), that new comments are unlikely, and notice and comment prior to this publication are unnecessary.

Privacy

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 *www.regulations.gov,* including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact received about these special conditions.

Confidential Business Information

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 these special conditions contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to these special conditions, 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 the indicated comments will not be placed in the public docket of these special conditions. Send submissions containing CBI to the individual listed in the For Further Information Contact section above. Comments the FAA receives, which are not specifically designated as CBI, will be placed in the public docket for these special conditions.

Comments Invited

The FAA invites interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

The FAA will consider all comments received by the closing date for comments and will consider comments filed late if it is possible to do so without incurring delay. The FAA may change these special conditions based on the comments received.

Background

On December 31, 2019, Gulfstream applied for an amendment to Type Certificate No. T00015AT to include the new Model GVIII–G700 and GVIII–G800 series airplanes. These airplanes, which are derivatives of the Model GVI currently approved under Type Certificate No. T00015AT, are twin-engine, transport-category airplanes, with seating for 19 passengers, and a maximum take-off weight of 107,600 pounds (GVIII–G700) and 105,600 pounds (GVIII–G800).

Type Certification Basis

Under the provisions of title 14, Code of Federal Regulations (14 CFR) 21.101, Gulfstream must show that the Model GVIII–G700 and GVIII–G800 series airplanes meet the applicable provisions of the regulations listed in Type Certificate No. T00015AT, or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Gulfstream Model GVIII–G700 and GVIII–G800 series airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Gulfstream Model GVIII–G700 and GVIII–G800 series airplanes must comply with the exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with 14 CFR 11.38, and they become part of the type certification basis under § 21.101.

Novel or Unusual Design Features

The Gulfstream Model GVIII–G700 and GVIII–G800 series airplanes will incorporate the following novel or unusual design feature:

This design feature is an electronic flight-control system, the functions of which are dependent upon the electrical power-generation and distribution systems, whereby the loss of all electrical power may be catastrophic to the airplane. These special conditions retain the level of safety offered by § 25.1351(d).

Discussion

The Gulfstream Aerospace Corporation Model GVIII–G700 and GVIII–G800 airplanes incorporate a fly-by-wire flight-control system that requires a continuous source of electrical power to keep the flight-control system operable. The current regulation, § 25.1351(d), Amendment 25–72, ''Operation without normal electrical power,'' states that the airplane must be operated safely in visual-flight-rules conditions for a period of not less than five minutes after loss of all normal electrical power. This rule was structured around a traditional design of mechanical control cables for flight control that allowed time for the crew to remedy an electrical failure, start the engine(s) if necessary, and re-establish some or all of the electrical power-generation capability.

To maintain the same level of safety associated with traditional designs, the Model GVIII–G700 and GVIII–G800 airplane's design must not be time limited in its operation when the airplane is without its normal source of engine- or auxiliary-power-unit-generated electrical power. Service experience has shown that the loss of all electrical power generated by an airplane's engine generators or auxiliary power unit (APU) is not extremely improbable. Likewise, regulations

require the applicant to demonstrate that the airplane has the power required for continued safe flight and landing with the use of its emergency electrical power systems. These emergency electrical power systems must be able to power all loads considered essential for continued safe flight and landing.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to the Gulfstream Model GVIII–G700 and GVIII–G800 series airplanes. Should Gulfstream apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only a certain novel or unusual design feature on Gulfstream Model GVIII–G700 and GVIII–G800 series of airplanes. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702, and 44704.

The Special Conditions

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Gulfstream Model GVIII–G700 and GVIII–G800 series airplanes.

Because the total loss of normal, generated, electrical power in two-engine airplanes is not extremely improbable, and because the loss of all electrical power may be catastrophic to airplanes equipped with an electronic flight-control system, the following special conditions apply to Gulfstream Model GVIII–G700 and GVIII–G800 airplanes.

(a) In lieu of § 25.1351(d), the following special conditions apply:

(1) Gulfstream must show, by test or a combination of test and analysis, that the airplane is capable of continued safe flight and landing with all normal electrical power sources inoperative, as prescribed by paragraphs (1)(i) and (1)(ii), below. For purposes of these special conditions, normal sources of electrical-power generation do not include alternate power sources such as the battery, ram-air turbine, or independent power systems such as the flight-control permanent-magnet generating system. In showing capability for continued safe flight and landing, Gulfstream must account for systems capability, effects on crew workload and operating conditions, and the physiological needs of the flightcrew and passengers for the longest diversion time for which Gulfstream is seeking approval.

(i) In showing compliance with this requirement, Gulfstream must account for common-cause failures, cascading failures, and zonal physical threats.

(ii) Gulfstream may consider the ability to restore operation of portions of the electrical power generation and distribution system if it can be shown that unrecoverable loss of those portions of the system is extremely improbable. The design must provide an alternative source of electrical power for the time required to restore the minimum electrical-power generation capability required for safe flight and landing. Gulfstream may exclude unrecoverable loss of all engines when showing compliance with this requirement.

(2) Regardless of electrical-power generation and distribution-system recovery capability shown under special condition (1), above, sufficient electrical-system capability must be provided to:

(i) Allow time to descend, with all engines inoperative, at the speed that provides the best glide distance, from the maximum operating altitude to the top of the engine-restart envelope, and

(ii) Subsequently allow multiple start attempts of the engines and auxiliary power unit (APU). The design must provide this capability in addition to the electrical capability required by existing part 25 requirements related to operation with all engines inoperative.

(3) The airplane emergency electrical-power system must be designed to supply:

(i) Electrical power required for immediate safety, which must continue to operate without the need for crew action following the loss of the normal electrical power, for a duration sufficient to allow reconfiguration to provide a non-time-limited source of electrical power.

(ii) Electrical power required for continued safe flight and landing for the maximum diversion time.

(4) If the applicant uses APU-generated electrical power to satisfy the requirements of these special conditions, and if reaching a suitable runway for landing is beyond the capacity of the battery systems, then the APU must be able to be started under any foreseeable flight condition prior to the depletion of the battery, or the restoration of normal electrical power, whichever occurs first. Flight tests must demonstrate this capability at the most critical condition.

(i) The applicant must show that the APU will provide adequate electrical power for continued safe flight and landing.

(ii) The airplane flight manual (AFM) must incorporate abnormal procedures that direct the pilot to take appropriate actions to activate the APU after loss of normal engine-driven generated electrical power.

(5) As part of showing compliance with these special conditions, the tests to demonstrate loss of all normal electrical power must also take into account the following:

(i) The assumption that the failure condition occurs during night instrument meteorological conditions (IMC) at the most critical phase of the flight, relative to the worst possible electrical-power distribution and equipment-loads-demand condition.

(ii) After an unrestorable loss of normal engine-driven generated electrical power, the airplane engine-restart capability is provided, and operations are continued in IMC.

(iii) The airplane is demonstrated to be capable of continued safe flight and landing. The duration of this capability must be computed based on the maximum diversion-time capability for which the airplane is being certified. The applicant must account for airspeed reductions resulting from the associated failure or failures.

(iv) The airplane must provide adequate indication of loss of normal electrical power to direct the pilot to the abnormal procedures, and the AFM must incorporate abnormal procedures that will direct the pilot to take appropriate actions.

Issued in Kansas City, Missouri, on January 24, 2024.

Patrick R. Mullen,

Manager, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2024–01740 Filed 1–29–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2023–2438; Special Conditions No. 25–848–SC]

Special Conditions: Gulfstream Aerospace Corporation Model GVIII–G700 and GVIII–G800 Series Airplanes; Installation of Large Non-Structural Glass in the Passenger Compartment

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comment.

SUMMARY: These special conditions are issued for the Gulfstream Aerospace Corporation (Gulfstream) Model GVIII–G700 and GVIII–G800 series airplanes. These airplanes will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. This design feature is the installation of large, non-structural glass items in the passenger cabin. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Gulfstream on January 30, 2024. Send comments on or before March 15, 2024.

ADDRESSES: Send comments identified by Docket No. FAA–2023–2438 using any of the following methods:

Federal eRegulations Portal: Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.

Mail: Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

Hand Delivery or Courier: Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Fax: Fax comments to Docket Operations at 202–493–2251.

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Myra Kuck, Cabin Safety, routing symbol AIR–624, Technical Policy Branch, Policy and Standards Division, Aircraft Certification Service, Federal Aviation Administration, 3960 Paramount Blvd., Lakewood, CA 90712; telephone and fax 405–666–1059; email *Myra.J.Kuck@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The substance of these special conditions has been published in the **Federal Register** for public comment in several prior instances with no substantive comments received. Therefore, the FAA finds, pursuant to 14 CFR 138(b), that new comments are unlikely, and notice and comment prior to this publication are unnecessary.

Privacy

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in title 14 CFR 11.35, the FAA will post all comments received without change to *www.regulations.gov,* including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact received about these special conditions.

Confidential Business Information

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 these special conditions contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to these special conditions, 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 the indicated comments will not be placed in the public docket of these special conditions. Send submissions containing CBI to the individual listed in the For Further Information Contact section above. Comments the FAA receives, which are not specifically designated as CBI, will be placed in the public docket for these special conditions.

Background

On December 31, 2019, Gulfstream applied for an amendment to Type Certificate No. T00015AT to include the new Model GVIII–G700 and GVIII–G800 series airplanes. These airplanes, which are derivatives of the Model GVI currently approved under Type Certificate No. T00015AT, are twin-engine, transport-category airplanes, with maximum seating for 19 passengers, and a maximum take-off weight of 107,600 pounds (GVIII–G700) and 105,600 pounds (GVIII–G800).

Type Certification Basis

Under the provisions of title 14, Code of Federal Regulations (14 CFR) 21.101, Gulfstream must show that the Model GVIII–G700 and GVIII–G800 series airplanes meet the applicable provisions of the regulations listed in Type Certificate No. T00015AT, or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (*e.g.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Gulfstream Model GVIII–G700 and GVIII–G800 series airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Gulfstream Model GVIII–G700 and GVIII–G800 series airplanes must comply with the exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with 14 CFR 11.38, and they become part of the type certification basis under § 21.101.

Novel or Unusual Design Features

The Gulfstream Model GVIII–G700 and GVIII–G800 airplanes will

incorporate the following novel or unusual design feature:

Installation of large, non-structural glass items in the passenger cabin. Possible installations of large non-structural glass items include, but are not limited to, the following items:

- Glass partitions
- Glass floor installations
- Glass attached to the ceiling
- Glass parts integrated in the stairway
- Wall or Door mounted mirrors and glass panels
- Mirrors as part of a door blow out panel
- Glass plate installed in a doorframe
- Washstand with glass-panel
- Mirrored bulkheads
- Partial partitions with transparent glass decorative features

The installation of these glass items in the passenger compartment, which can be occupied during taxi, take-off, and landing (TT&L), is a novel or unusual design feature with respect to the installed material. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for these design features.

Discussion

The use of glass results in trade-offs between the one unique characteristic of glass, its capability for undistorted or controlled light transmittance, or transparency, and the negative aspects of the material. Glass, in its basic form as annealed, untreated sheet, plate or float glass, when compared to metals, is extremely notch-sensitive, has a low fracture resistance, has a low modulus of elasticity and can be highly variable in its properties. While reasonably strong, it is nonetheless not a desirable material for traditional airplane applications because it is heavy (about the same density as aluminum), and when it fails, it breaks into extremely sharp fragments that have the potential for injury and have been known to be lethal. Thus, the use of glass traditionally was limited to windshields, and instrument or display transparencies. The regulations in 14 CFR 25.775 only address, and likewise only recognize, the unique use of glass in windshield or window applications where no other material will serve. This regulation does address the adverse properties of glass, but pilots occasionally are injured from shattered glass windshields.

The FAA divides other uses of glass in the passenger cabin into four groups. These groups were created to address the practical and functional uses of glass. The four groups are as follows:

1. The first group is glass items installed in rooms or areas in the cabin that are not occupied during taxi, takeoff, and landing (TT&L), and a person does not have to enter or pass through the room or area to get to any emergency exit.

2. The second group is glass integrated into a functional device operation of which is dependent upon the characteristics of glass, such as instrument or indicator protective transparencies, or monitor screens such as liquid crystal displays, or plasma displays. This group may be installed in any area in the cabin regardless of occupancy during TT&L. Acceptable means of compliance for these items may depend on the size and specific location of the device containing the glass.

3. The third group is small glass items installed in occupied rooms or areas during TT&L, or rooms or areas that a person does not have to enter or pass through to get to any emergency exit. The FAA defines a small glass item as less than 8.8 lbs (4kg) in mass.

4. The fourth group is large glass items, the subject of these special conditions, installed in occupied rooms or areas during TT&L, or rooms or areas that a person must enter or pass through to get to an emergency exit. A large glass item is defined as 8.8 lbs (4kg) and greater in mass. Groups of glass items that collectively weigh 4kg or more would also be included. The mass is based on the amount of glass that becomes hazardous in high inertial loads.

The glass items in groups one, two, and three are restricted to applications where the potential for injury is either highly localized (such as flight-instrument faces) or the location is such that injury due to failure of the glass is unlikely, for example mirrors in lavatories, because these installations necessitate the use of glass. These glass items typically are addressed in a ''Method of Compliance'' issue paper for each project based on existing part 25 regulations, or in established policy. These issue papers identify specific tests that could include abuse loading and ball-impact testing. In addition, these items are subject to the inertia loads contained in § 25.561 and maximum positive-differential pressure for items like video monitors to meet § 25.789.

The items in group four are much larger and heavier than have been previously approved and raise additional safety concerns. These large, heavy glass panels, primarily installed as architectural features, were not envisioned in the regulations. The unique aspects of glass, with the potential to become highly injurious or lethal objects during emergency landing, minor crash conditions, or in-flight, warrant a unique approach to certification that addresses the characteristics of glass that prevented its use in the past. These special conditions were developed to ensure that airplanes with large glass features in passenger cabins provide the same level of safety as airplanes using traditional, lightweight materials. The FAA reiterates this intention in the text of the special conditions by qualifying their use for group four glass items.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to the Gulfstream Model GVIII–G700 and GVIII–G800 series airplanes. Should Gulfstream apply at a later date for a change to the type certificate to include another model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, these special conditions would apply to the other model as well.

Conclusion

This action affects only a certain novel or unusual design feature on Gulfstream Model GVIII–G700 and GVIII–G800 series of airplanes. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702, and 44704.

The Special Conditions

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Gulfstream Model GVIII–G700 and GVIII–G800 series airplanes.

For large glass items (a single item, or a collective group of glass items, that weigh 4 kg or more in mass) installed in passenger-occupied rooms or areas during taxi, takeoff, and landing, or installed in rooms or areas that occupants must enter or pass through to

access any emergency exit, the glass installations on the Gulfstream Model GVIII–G700 and GVIII–G800 series airplanes must meet the following conditions:

1. Material Fragmentation—The glass used must be tempered or otherwise treated to ensure that when fractured, it breaks into small pieces with relatively dull edges. The glass component installation must retain all glass fragments to minimize the danger from flying glass shards or pieces. The applicant must demonstrate this by impact and puncture testing and testing to failure.

2. Strength—The glass component must be strong enough to meet the load requirements for all flight and landing loads including any of the applicable emergency landing conditions in subparts C & D of 14 CFR part 25. In addition, glass components that are located such that they are not protected from contact with cabin occupants must not fail due to abusive loading, such as impact from occupants stumbling into, leaning against, sitting on, or performing other intentional or unintentional forceful contact. The effect of design details such as geometric discontinuities or surface finish *e.g.,* embossing, etching, etc., must be assessed.

3. Retention—The glass component, as installed in the airplane, must not come free of its restraint, or mounting system in the event of an emergency landing. Both the directional loading and rebound conditions must be assessed. The effect of design details such as geometric discontinuities or surface finish *e.g.,* embossing, etching, etc., must be assessed.

4. Instructions for Continued Airworthiness—The instructions for continued airworthiness must reflect the fastening method used and must ensure the reliability of the methods used (*e.g.,* life limit of adhesives, or clamp connection). Inspection methods and intervals must be defined based upon adhesion data from the manufacturer of the adhesive or actual adhesion test data, if necessary.

Issued in in Kansas City, Missouri, on January 24, 2024.

Patrick R. Mullen,

Manager, Technical Policy Branch, Policy and Standards Division, Aircraft Certification Service.

[FR Doc. 2024–01739 Filed 1–29–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2023–2442; Special Conditions No. 25–850–SC]

Special Conditions: Gulfstream Aerospace Corporation Model GVIII–G700 and GVIII–G800 Series Airplanes; Limit Pilot Forces for Side-Stick Controllers

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Gulfstream Aerospace Corporation (Gulfstream) Model GVIII–G700 and GVIII–G800 series airplanes. These airplanes will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport-category airplanes. This design feature is a side-stick controller for one-hand operation requiring wrist motion only, not arms. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Gulfstream on January 30, 2024. Send comments on or before March 15, 2024.

ADDRESSES: Send comments identified by Docket No. FAA–2023–2442 using any of the following methods:

- *Federal eRegulations Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.
- *Docket:* Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Todd Martin, Airframe Section, AIR–622, Technical Policy Branch, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone 206–231–3210; email *Todd.Martin@faa.gov.*

SUPPLEMENTARY INFORMATION: The substance of these special conditions has been published in the **Federal Register** for public comment in several prior instances with no substantive comments received. Therefore, the FAA finds, pursuant to title 14, Code of Federal Regulations (14 CFR) 11.38(b), that new comments are unlikely, and notice and comment prior to this publication are unnecessary.

Privacy

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in title 14 CFR 11.35, the FAA will post all comments received without change to *www.regulations.gov,* including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact received about these special conditions.

Confidential Business Information

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 these special conditions contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to these special conditions, 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 the indicated comments will not be placed in the public docket of these special conditions. Send submissions containing CBI to Todd Martin, Airframe Section, AIR–622, Technical Policy Branch, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198;

email *Todd.Martin@faa.gov.* Comments the FAA receives, which are not specifically designated as CBI, will be placed in the public docket for these special conditions.

Comments Invited

The FAA invites interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

The FAA will consider all comments received by the closing date for comments and will consider comments filed late if it is possible to do so without incurring delay. The FAA may change these special conditions based on the comments received.

Background

On December 31, 2019, Gulfstream applied for an amendment to Type Certificate No. T00015AT to include the new Model GVIII–G700 and GVIII–G800 series airplanes. These airplanes, which are derivatives of the Model GVI currently approved under Type Certificate No. T00015AT, are twin-engine, transport-category airplanes, with maximum seating for 19 passengers, and a maximum take-off weight of 107,600 pounds (GVIII–G700) and 105,600 pounds (GVIII–G800).

Type Certification Basis

Under the provisions of 14 CFR 21.101, Gulfstream must show that the Model GVIII–G700 and GVIII–G800 series airplanes meet the applicable provisions of the regulations listed in Type Certificate No. T00015AT, or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (*e.g.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Gulfstream Model GVIII–G700 and GVIII–G800 series airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Gulfstream Model GVIII–G700 and GVIII–G800 series airplanes must comply with the exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with 14 CFR 11.38, and they become part of the type certification basis under § 21.101.

Novel or Unusual Design Feature

The Gulfstream Model GVIII–G700 and GVIII–G800 series airplanes will incorporate the following novel or unusual design feature:

A side-stick controller for one-hand operation requiring wrist motion only, not arms.

Discussion

The Gulfstream Model GVIII–700 and GVIII–800 series airplanes are equipped with side-stick controllers instead of conventional wheel or control stick controllers. Side-stick controllers are designed to be operated using only one hand. The requirements of § 25.397(c), which define limit pilot forces and torques for conventional wheel or stick controllers, are not adequate for side-stick controllers because pilot forces are applied to side-stick controllers with only the wrist, not arms. Special conditions are necessary to specify the appropriate loading conditions for side-stick controllers.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to the Gulfstream Model GVIII–G700 and GVIII–G800 series airplanes. Should Gulfstream apply at a later date for a change to the type certificate to include another model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only a certain novel or unusual design feature on Gulfstream Model GVIII–G700 and GVIII–G800 series airplanes. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702, and 44704.

The Special Conditions

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued, in lieu of the aileron-control and elevator-control forces specified in § 25.397(c), as part of the type certification basis for Gulfstream Aerospace Corporation Model GVIII–G700 and GVIII–G800 series airplanes.

For Gulfstream Aerospace Corporation Model GVIII–G700 and GVIII–G800 series airplanes equipped with side-stick controls designed for forces to be applied by one wrist and not arms, the limit pilot forces are as follows.

(a) For all components between and including the side-stick control-assembly handle and its control stops:

Pitch	Roll
Nose up, 200 lbs force.	Nose left, 100 lbs force.
Nose down, 200 lbs force.	Nose right, 100 lbs force.

(b) For all other components of the side-stick control assembly, but excluding the internal components of the electrical sensor assemblies, to avoid damage to the control system as the result of an in-flight jam:

Pitch	Roll
Nose up, 125 lbs force.	Nose left, 50 lbs force.
Nose down, 125 lbs force.	Nose right, 50 lbs force.

Issued in Kansas City, Missouri, on January 24, 2024.

Patrick R. Mullen,

Manager, Technical Innovation Policy Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2024–01741 Filed 1–29–24; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1420

[CPSC Docket No. 2017–0032]

Amendment to Standard for All-Terrain Vehicles

Correction

In Rule document 2024–01309 beginning on page 4188 in the issue of Tuesday, January 23, 2024, make the following correction:

§ 1420.3 [Corrected]

■ On page 4195, in the third column, in the 8th and 9th lines, the heading ''§ 1420.1 Requirements for four-wheel ATV's'' should read ''§ 1420.3 Requirements for four-wheel ATV's''.

[FR Doc. C1–2024–01309 Filed 1–29–24; 8:45 am]

BILLING CODE 0099–10–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2023–F–5500]

Food Additives Permitted in Feed and Drinking Water of Animals; Chromium Propionate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of chromium propionate as a source of chromium in turkey feed. This action is in response to a food additive petition filed by Kemin Industries, Inc.

DATES: This rule is effective January 30, 2024. See section V for further information on the filing of objections. Either electronic or written objections and requests for a hearing on the final rule must be submitted by February 29, 2024.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 29, 2024. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting objections. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–F–5500 for ''Food Additives Permitted in Feed and Drinking Water of Animals; Chromium Propionate.'' Received objections, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies in 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 objections. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your objections and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Wasima Wahid, Center for Veterinary Medicine (HFV–221), Food and Drug Administration, 12225 Wilkins Avenue, Rockville, MD 20852, 240–402–5857, *wasima.wahid@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the **Federal Register** of July 27, 2023 (88 FR 48406), FDA announced that we had filed a food additive petition (animal use) (FAP 2318) submitted by Kemin Industries, Inc.; 1900 Scott Ave., Des Moines, IA 50317. The petition proposed that the regulations for food additives permitted in feed and drinking water of animals be amended to provide for the safe use of chromium propionate as a source of chromium in turkey feed.

II. Conclusion

FDA concludes that the data establish the safety and utility of chromium

propionate as a source of chromium in turkey feed and that the food additive regulations should be amended as set forth in this document.

III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and documents we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 571.1(h), we will delete from the documents any materials that are not available for public disclosure.

IV. Analysis of Environmental Impact

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The Agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

V. Objections and Hearing Requests

If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

■ 1. The authority citation for part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

■ 2. In § 573.304, revise the section heading and paragraphs (b)(1), (d)(3)(i), and (e)(2)(ii)(A) to read as follows:

§ 573.304 Chromium propionate.

* * * * *

(b) * * *

(1) In complete feed for broiler chickens and growing turkeys at a level not to exceed 0.2 milligrams (mg) of chromium from chromium propionate per kilogram feed.

* * * * *

(d) * * *

(3) * * *

(i) A level of 0.2 ppm in complete feed for broiler chickens and growing turkeys.

* * * * *

(e) * * *

(2) * * *

(ii) * * *

(A) For feed for broiler chickens and growing turkeys, ''Chromium from all sources of supplemental chromium cannot exceed 0.2 parts per million of the complete feed.''

* * * * *

Dated: January 25, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01796 Filed 1–29–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

Procedure and Administration

CFR Correction

This rule is being published by the Office of the Federal Register to correct an editorial or technical error that appeared in the most recent annual revision of the Code of Federal Regulations.

■ In Title 26 of the Code of Federal Regulations, Parts 300 to 499, revised as of April 1, 2023, amend section 301.6721–1 by reinstating paragraph (b)(6) to read as follows:

§ 301.6721–1 Failure to file correct information returns.

* * * * *

(b) * * *

(6) *Application to returns not due on February 28, or March 15.* For returns that are not due on February 28 or March 15 (for example, Forms 8300 reporting certain cash payments of $10,000 or more), the penalty is $15 if the failure is corrected within 30 days. If the failure is corrected after 30 days, the penalty is $50 rather than $30. There is no period during which the penalty is reduced to $30 under paragraph (b)(2) of this section.

* * * * *

[FR Doc. 2024–01924 Filed 1–29–24; 8:45 am]

BILLING CODE 0099–10–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0020]

RIN 1625–AA00

Safety Zone; North Pacific Ocean, Dutch Harbor, AK

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

ACTION: Amendment to temporary final rule; reduction in size of safety zone.

SUMMARY: The Coast Guard is amending the temporary safety zone for the M/V GENIUS STAR XI navigable waters from 1 nautical mile radius to a ½ nautical mile radius. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by a fire onboard the M/V GENIUS STAR XI. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Western Alaska (COTP).

DATES: This rule is effective without actual notice from January 30, 2024, through March 6, 2024. For the purposes of enforcement, actual notice will be used from January 19, 2024, until January 30, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2024–0020 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 about this rule, call or email LT William Mason, Sector Anchorage, AK Waterways Management Division, U.S. Coast Guard; telephone

907–428–4100, email *sectoranchorage@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 under authority in 5 U.S.C. 553(b)(B). This statutory 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.'' The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because publishing an NPRM would be impracticable because of the urgent need to establish a safety zone as soon as possible to enhance public safety given the dangers associated with a vessel recently on fire.

Also, 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 a recent fire onboard the M/V GENIUS STAR XI and the emergency operations taking place.

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, Western Alaska, has determined that potential hazards associated with ongoing response activities for a recent vessel fire and the hazardous materials onboard the vessel will be a safety concern for anyone within a ½ nautical mile radius of the M/V GENIUS STAR XI. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone from the potential hazards created by the vessel fire. The duration of the rule is necessary due to the challenges associated with getting materiel and personnel to the vessel given its remote location.

IV. Discussion of the Rule

This rule establishes an amended safety zone from January 19, 2024, through March 6, 2024. The safety zone will be reduced from the previous 1 nautical mile radius, to a ½ nautical mile radius and will cover all navigable waters of the M/V GENIUS STAR XI within the Captain of the Port Zone Western Alaska in the vicinity of the Port of Dutch Harbor, Alaska. The M/V GENIUS STAR XI, IMO 9622710, is a 410-foot General cargo ship with a white superstructure and a black hull.

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 the safety of emergency operators in the vicinity of the M/V GENIUS STAR XI. The small size and short duration of this safety zone combined with anticipated limited vessel traffic is expected to minimally restrict vessel movements. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via available local means about the zone, and the rule will allow vessels to seek permission under certain conditions to enter the zone from the COTP or a designated representative.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting only 60 days based on the response operations for the fire onboard the M/V GENIUS STAR XI and will prohibit entry within ½ nautical mile of the vessel. 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 is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Revise § 165.T17–0020, added at 89 FR 1457 (January 10, 2024), to read as follows:

§ 165.T17–0020 Safety Zone; North Pacific Ocean, Dutch Harbor, AK.

(a) *Location.* The following is a safety zone: All navigable waters within a ½ nautical mile radius of the M/V GENIUS STAR XI within the Captain of the Port Zone Western Alaska in the vicinity of the Port of Dutch Harbor, Alaska.

(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 Western Alaska (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you shall 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 Marine VHF channel 16 or by calling the USCG Command Center at 907–428–4100. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from January 19, 2024, through March 6, 2024.

Dated: January 19, 2024.

C.A. Culpepper,

Captain, U.S. Coast Guard, Captain of the Port Western Alaska.

[FR Doc. 2024–01857 Filed 1–26–24; 4:15 pm]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2023–0630; FRL–11617–01–R9]

Finding of Failure To Submit State Implementation Plan Submissions for the 2012 Fine Particulate Matter National Ambient Air Quality Standards; California; Los Angeles-South Coast Air Basin

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to find that California has failed to submit state implementation plan (SIP) elements required under the Clean Air Act (CAA or ''Act'') to implement the 2012 national ambient air quality standards (NAAQS) for fine particulate matter ($PM_{2.5}$) (''2012 $PM_{2.5}$ NAAQS'') in the Los Angeles-South Coast Air Basin (''South Coast''). California was required to submit a SIP that meets the Serious area plan requirements for a reasonable further progress demonstration, quantitative milestones, an attainment demonstration, and contingency measures for the 2012 $PM_{2.5}$ NAAQS by December 31, 2023. The State submitted the required SIP elements, but subsequently withdrew its submission. If the EPA has not affirmatively found that the State has submitted a complete SIP to correct these deficiencies within 18 months of this finding, the offset sanctions will apply in the area. If within six additional months the EPA has still not affirmatively determined that the State has submitted a complete SIP to correct the deficiencies, the highway funding sanction will apply in the area. No later than two years after the EPA makes this finding, if the State has not submitted and the EPA has not approved each of the required SIP elements, the EPA must promulgate a Federal implementation plan (FIP) to address the remaining requirements.

DATES: The effective date of this action is February 29, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2023–0630. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Ginger Vagenas, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 972–3964 or by email at *vagenas.ginger@epa.gov*.

SUPPLEMENTARY INFORMATION: Section 553 of the Administrative Procedure Act (APA), U.S.C. 553(b)(B), provides that an agency may issue a rule without providing notice and an opportunity for public comment when that agency finds for good cause that notice and public procedure are impracticable, unnecessary, or contrary to public interest. The EPA has determined that there is a good cause for issuing this finding without prior proposal and opportunity for comment because there is little or no judgment involved for the EPA to make a finding of failure to submit SIPs or elements of SIPs required by the CAA, where states have not submitted a required SIP revision, made incomplete submissions, or, as in this case, withdrawn an existing submission by the date specified by the statute. In such circumstances, the EPA finds that notice and public procedures are unnecessary and that this constitutes good cause under 5 U.S.C. 553(b)(B).

Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

Table of Contents

I. Background

Airborne particulate matter (PM) can be composed of a complex mixture of particles in both solid and liquid form. Particulate matter can be of different sizes, commonly referred to as ''coarse'' and ''fine'' particles. Fine particles, in general terms, are PM with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers. For this reason, particles of this size are referred to as $PM_{2.5}$.

Under section 109 of the Act, the EPA is required to establish primary (health-based) and secondary (welfare-based) NAAQS for each pollutant for which the EPA has issued air quality criteria. The EPA first promulgated annual and 24-hour NAAQS for $PM_{2.5}$ in July 1997 [1] and then revised the 24-hour $PM_{2.5}$ NAAQS in October 2006.[2] Most recently, on December 14, 2012, the EPA revised the primary annual $PM_{2.5}$ standard by lowering the level from 15.0 to 12.0 micrograms per cubic meter of air ($\mu g/m^3$) to provide increased protection against health effects associated with long- and short-term $PM_{2.5}$ exposures. The EPA did not revise the secondary annual $PM_{2.5}$ standard, which remains at 15.0 $\mu g/m^3$.[3] In addition, the EPA retained the level and form of the primary and secondary 24-hour $PM_{2.5}$ standards to continue to provide supplemental protection against health and welfare effects associated with short-term $PM_{2.5}$ exposures.

Promulgation of a revised NAAQS triggers a requirement for the EPA to designate areas of the country as nonattainment, attainment, or unclassifiable for the standards. As prescribed by CAA section 188(a), areas designated as nonattainment for a $PM_{2.5}$ NAAQS are initially classified as Moderate. The designation and initial classification for the South Coast as Moderate nonattainment for the 2012 $PM_{2.5}$ NAAQS became effective on April 15, 2015.[4]

Nonattainment areas for $PM_{2.5}$ are subject to the general nonattainment area planning requirements of CAA section 172 and to the PM-specific planning requirements of CAA sections 188–189. On August 24, 2016, the EPA established a final implementation rule (''$PM_{2.5}$ SIP Requirements Rule'') outlining the attainment planning and control requirements for current and future $PM_{2.5}$ NAAQS.[5] The $PM_{2.5}$ SIP Requirements Rule also established the due date for Moderate area $PM_{2.5}$ SIP submissions as no later than 18 months from the effective date of area designations.[6] Accordingly, the areas designated as nonattainment for the 2012 $PM_{2.5}$ NAAQS (with an effective date of April 15, 2015) were required to submit Moderate area attainment plans to EPA no later than October 15, 2016.

On April 27, 2017, California submitted the ''Final 2016 Air Quality Management Plan'' (''2016 Plan''), as adopted on March 3, 2017, by the Governing Board for the South Coast Air Quality Management District (SCAQMD or ''District'') to the EPA to address CAA requirements associated with the 2012 $PM_{2.5}$ standard.[7] The 2016 Plan included a demonstration, consistent with the requirements of CAA section 189(a)(1)(B), that attainment of the 2012 $PM_{2.5}$ standard by the December 31, 2021, Moderate area attainment date was impracticable, despite the implementation of required control measures.[8] The 2016 Plan also included a request that the EPA reclassify the nonattainment area from Moderate to Serious, and included a Serious area attainment demonstration, an emissions inventory, attainment related plan elements, and control measure provisions.[9] Effective December 9, 2020, we approved or conditionally approved the portions of the 2016 Plan that addressed the CAA Moderate area requirements for the 2012 $PM_{2.5}$ NAAQS in the South Coast nonattainment area and reclassified the South Coast as a Serious nonattainment area under CAA section 188(b)(1).[10]

Our final action on the 2016 Plan's Moderate area requirements and reclassification of the nonattainment area to Serious also noted that the submitted 2016 Plan included Serious area planning elements for the 2012 $PM_{2.5}$ NAAQS and stated that we would evaluate and act on them through subsequent rulemakings as appropriate.[11] At the same time, our final action explained that our reclassification of the South Coast nonattainment area from Moderate to Serious for the 2012 $PM_{2.5}$ NAAQS triggered statutory and regulatory timelines for submittal of Serious area planning elements. Specifically, we stated that section 189(b)(2) of the CAA requires a state to submit the required best available control measure (BACM) provisions no later than 18 months after the effective date of final reclassification (*i.e.,* June 9, 2022). Because an effective BACM evaluation requires an up-to-date emissions inventory and an evaluation of the precursor pollutants that must be controlled to provide for expeditious attainment, we also required the State to submit the emissions inventory required

[1] 62 FR 38652 (July 18, 1997).

[2] 71 FR 61143 (October 17, 2006).

[3] 78 FR 3086 (January 15, 2013).

[4] 80 FR 2206 (January 15, 2015).

[5] Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements; Final rule; 81 FR 58010 (August 24, 2016).

[6] 40 CFR 51.1003(a)(1).

[7] 85 FR 71264 (November 9, 2020). For additional background, see the associated proposed rulemaking at 85 FR 40026 (July 2, 2020).

[8] Id. at 71266.

[9] Id. at 71268.

[10] 85 FR 71264.

[11] Id. at 71268.

under CAA section 172(c)(3) and any optional precursor demonstrations by this same date. In addition, we established a deadline of December 31, 2023, for the submittal of the attainment demonstration and all other attainment-related plan elements.[12]

On March 29, 2023, the State of California and the District notified the EPA of their determination that the portions of the 2016 Plan relating to Serious area planning elements for the 2012 $PM_{2.5}$ NAAQS were no longer appropriate for inclusion in the SIP and requested that those portions of the submittal be considered withdrawn.[13] [14] Shortly thereafter, we issued a finding that California had failed to submit the BACM and emissions inventory (EI) plan elements that were due on June 9, 2022.[15] The remaining plan elements, which were due on December 31, 2023, are the subject of this action.

II. Consequences of Findings of Failure To Submit

For plan requirements under part D, title I of the CAA, such as those for $PM_{2.5}$ nonattainment areas, if the EPA finds that a state has failed to make the required SIP submission, then CAA section 179 establishes specific consequences, including the eventual imposition of mandatory sanctions for the affected area. Additionally, such a finding triggers an obligation under CAA section 110(c) for the EPA to promulgate a FIP no later than two years from the effective date of the finding, if the affected state has not submitted, and the EPA has not approved, the required SIP submissions.

If the EPA has not affirmatively determined that a state has submitted a complete SIP addressing the deficiency that is the basis for these findings within 18 months of the effective date of this rulemaking, pursuant to CAA sections 179(a) and (b) and 40 CFR 52.31, the emissions offset sanction identified in CAA section 179(b)(2) will apply to the affected nonattainment area. If the EPA has not affirmatively determined that the state has submitted a complete SIP addressing the deficiency that is the basis for these findings within six months after the offset sanction is imposed, the highway funding sanction will apply in the affected nonattainment area, in accordance with CAA section 179(b)(1) and 40 CFR 52.31. The State must make the required SIP submission and the EPA must take final action to approve the submission within two years of the effective date of this finding; otherwise, the EPA is required to promulgate a FIP to address the relevant requirements. This is required pursuant to CAA section 110(c) for the affected nonattainment area.

Based upon the withdrawal of the Serious area plan elements submitted with the 2016 Plan as described in section I of this rulemaking, the EPA is finding that California has failed to make the following required submittals for the 2012 $PM_{2.5}$ NAAQS for the South Coast nonattainment area: (1) reasonable further progress demonstration, (2) quantitative milestones, (3) attainment demonstration, and (4) contingency measures. These required elements were due on December 31, 2023. With this finding, section 179 of the CAA starts sanctions clocks and a FIP clock. California may avoid these sanctions by taking timely action to remedy this finding. The clock governing the CAA's imposition of sanctions for these areas will stop and sanctions will not take effect if the EPA finds that the State has made a complete SIP submission addressing the reasonable further progress demonstration, quantitative milestones, attainment demonstration, and contingency measures requirements for this area within 18 months of the date of this finding. Similarly, the EPA is not required to promulgate a FIP if California makes the required SIP submissions and the EPA takes final action to approve the submissions within two years of this finding of failure to submit a required SIP. In sum, the CAA does not require sanctions or a FIP if the State and the EPA take timely action to remedy this finding.

III. Final Action

In this action, the EPA is finding that California has failed to submit certain Serious area SIP elements for the 2012 $PM_{2.5}$ NAAQS required under subpart 4 of part D of title I of the CAA. Specifically, following the March 2023 withdrawal, the EPA finds that California failed to submit the elements that were due no later than December 31, 2023, including an attainment demonstration, a reasonable further progress plan, quantitative milestones, and contingency measures. The consequences of this finding are discussed in Section II of this action.

IV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at *http://www2.epa.gov//laws-regulations/laws-and-executive-orders.gov*.

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

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

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the provisions of the PRA because it does not impose additional requirements beyond those imposed by state law.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities beyond those imposed by state law.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action does not impose additional requirements beyond those imposed by state law. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, will result from this action.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government.

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[12] 85 FR 71268. The Serious area SIP elements for the 2012 $PM_{2.5}$ NAAQS include provisions to assure that best available control measures (including best available control technology) shall be implemented no later than four years after the area is reclassified, a base year emissions inventory, an attainment projected emissions inventory, an attainment demonstration with air quality modeling, a reasonable further progress (RFP) demonstration, quantitative milestones, contingency measures, and a nonattainment new source review (NNSR) program with the major source threshold set at 70 tons per year. CAA section 189(b).

[13] Letter dated March 8, 2023, from Sarah Rees, Ph.D., Deputy Executive Officer, Planning, Rule Development & Implementation, South Coast Air Quality Management District to Michael Benjamin, D. Env., Chief, Air Quality Planning and Science Division, California Air Resources Board.

[14] Letter dated March 29, 2023, from Michael Benjamin, Chief, Air Quality Planning and Science Division, California Air Resources Board to Martha Guzman, Regional Administrator, EPA Region IX.

[15] 88 FR 34093 (May 26, 2023), effective June 26, 2023.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175, because this action does not apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and will not impose substantial direct compliance costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive order. This action is not subject to Executive Order 13045 because it does impose additional requirements beyond those imposed by state law.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. EPA defines environmental justice (EJ) as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

The EPA did not perform an EJ analysis and did not consider EJ in this action. Consideration of EJ is not required as part of this action because the EPA is performing a non-discretionary duty to find that a required State submission was not timely submitted, and there is no information in the record inconsistent with the stated goals of E.O. 12898 of achieving environmental justice for people of color, low-income populations, and indigenous peoples.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

L. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 1, 2024. Filing a petition for reconsideration by the Administrator of this final action does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Administrative practice and procedures, Air pollution control, Approval and promulgation of implementation plans, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

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

Dated: January 23, 2024.

Martha Guzman Aceves,

Regional Administrator, Region IX.

[FR Doc. 2024–01691 Filed 1–29–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[EPA–HQ–OW–2023–0541; FRL–11620–01–OW]

Expedited Approval of Alternative Test Procedures for the Analysis of Contaminants Under the Safe Drinking Water Act; Analysis and Sampling Procedures

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action announces the Environmental Protection Agency's (EPA's) approval of alternative testing methods for use in measuring the levels of contaminants in drinking water to determine compliance with national primary drinking water regulations. The Safe Drinking Water Act authorizes EPA to approve the use of alternative testing methods through publication in the **Federal Register**. EPA is using this streamlined authority to make 93 additional methods available for analyzing drinking water samples. This expedited approach provides public water systems, laboratories, and primacy agencies with more timely access to new measurement techniques and greater flexibility in the selection of analytical methods, thereby reducing monitoring costs while maintaining public health protection.

DATES: This action is effective January 30, 2024.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2023–0541. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Teresa Wells, Technical Support Branch, Standards and Risk Management Division, Office of Ground Water and Drinking Water (MS 140), Environmental Protection Agency, 26 West Martin Luther King Drive, Cincinnati, OH 45268; telephone number: (513) 569–7128; email address: *wells.teresa@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

Public water systems are the regulated entities required to measure contaminants in drinking water samples. In addition, EPA Regions as well as States and Tribal governments with authority to administer the regulatory program for public water systems under the Safe Drinking Water Act (SDWA) may measure contaminants in water samples. When EPA sets a monitoring requirement in its national primary drinking water regulations for a given contaminant, the agency also establishes (in the regulations) standardized test procedures for analysis of the contaminant. This action makes alternative testing methods available for particular drinking water contaminants beyond the testing methods currently established in the regulations. EPA is providing public water systems, required to test water samples, with a choice of using either a test procedure already established in the existing regulations or an alternative testing method that has been approved in this action or in prior expedited approval actions. Categories and entities that may ultimately be affected by this action include:

Category	Examples of potentially regulated entities	NAICS [1]
State, local, & Tribal governments	State, local, and Tribal governments that analyze water samples on behalf of public water systems required to conduct such analysis; State, local, and Tribal governments that directly operate community and non-transient non-community water systems required to monitor.	924110
Industry	Private operators of community and non-transient non-community water systems required to monitor.	221310
Municipalities	Municipal operators of community and non-transient non-community water systems required to monitor.	924110

[1] North American Industry Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be interested in this action. Other types of entities not listed in the table could also have some interest. To determine whether your facility is affected by this action, you should carefully examine the applicability language in the *Code of Federal Regulations* (CFR) at 40 CFR 141.2 (definition of a public water system). If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Abbreviations and Acronyms Used in This Action

CFR: *Code of Federal Regulations*
EPA: United States Environmental Protection Agency
NAICS: North American Industry Classification System
QC: Quality Control
SDWA: The Safe Drinking Water Act
VCSB: Voluntary Consensus Standard Bodies

II. Background

A. What is the purpose of this action?

In this action, EPA is approving 93 analytical methods for determining contaminant concentrations in drinking water samples collected under SDWA. Regulated entities required to sample and monitor may use either the testing methods already established in existing regulations or the alternative testing methods being approved in this action or in prior expedited approval actions. The new methods are listed along with other methods similarly approved through previous expedited actions in 40 CFR part 141, appendix A to subpart C and on EPA's drinking water methods website at *https://www.epa.gov/dw analyticalmethods.*

B. What is the basis for this action?

When EPA determines that an alternative analytical method is ''equally effective'' (*i.e.,* as effective as a method that has already been promulgated in the regulations), SDWA allows EPA to approve the use of the alternative testing method through publication in the **Federal Register** (see section 1401(1) of SDWA). EPA is using this streamlined approval authority to make 93 additional methods available for determining contaminant concentrations in drinking water samples collected under SDWA. EPA has determined that, for each contaminant or group of contaminants listed in section III of this preamble, the additional testing methods being approved in this action are as effective as one or more of the testing methods already approved in the regulations for those contaminants. Section 1401(1) of SDWA states that the newly approved methods ''shall be treated as an alternative for public water systems to the quality control and testing procedures listed in the regulation.'' Accordingly, this action makes these additional 93 analytical methods legally available as options for meeting EPA's monitoring requirements.

This action does not add regulatory language, but does, for informational purposes, update an appendix to the regulations at 40 CFR part 141 that lists all methods approved under section 1401(1) of SDWA. Accordingly, while this action is not a rule, it is updating CFR text and therefore is being published in the ''Final Rules'' section of the **Federal Register**.

III. Summary of Approvals

EPA is approving 93 methods that are equally effective relative to methods previously promulgated in the regulations. By means of this action, these 93 methods are added to appendix A to subpart C of 40 CFR part 141.

A. Methods Developed by Voluntary Consensus Standard Bodies (VCSB)

1. ASTM International. EPA compared the most recent version of one ASTM International method for determination of radium-226 by radon emanation to the earlier version of the method that is currently approved in 40 CFR 141.25(a). Changes between the earlier approved version and the most recent version of the method are described more fully in Smith 2023. The revisions involve primarily editorial changes (*e.g.,* updated references, definitions, terminology, procedural clarifications, and reorganization of text). The revised method is the same as the approved version with respect to sample collection and handling protocols, sample preparation, analytical methodology, and method performance data; thus, EPA finds it is equally effective relative to the approved method.

EPA is thus approving the use of the following ASTM method for radium-226 as listed in the following table:

ASTM revised version	Approved method	Contaminant	Regulation citation
D 3454–21 (ASTM 2021)	D 3454–97 (ASTM 1997)	Radium-226	40 CFR 141.25(a).

The ASTM method is available from ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959 or *https://www.astm.org.*

2. Standard Methods for the Examination of Water and Wastewater (Standard Methods). The 24th edition of *Standard Methods for the Examination of Water and Wastewater* (APHA 2023) was published in 2023. EPA compared 90 methods in the 24th edition to earlier versions of those methods that are currently approved in 40 CFR parts 141 and 143. Changes between the approved version and the version of each method published in the 24th edition are summarized in Smith and Wendelken (2023) and Best (2023). The revisions primarily involve editorial changes (*e.g.,* correction of errors, procedural clarifications and reorganization of text). The methods in the following table are the same as the earlier approved versions with respect to the sample handling protocols, analytical procedures and method performance data. For these reasons, EPA has concluded that the versions in the 24th edition are equally effective relative to the currently approved versions in the regulations. Therefore, EPA is approving the use of 90 Standard Methods in the 24th edition for the contaminants and their respective regulations listed in the following table:

Standard methods, 24th edition (APHA 2023)	Approved method	Contaminant	Regulation citations
2120 B	2120 B–01, online version (APHA 2001a).	Color	40 CFR 143.4(b).
2130 B	2130 B–01, online version (APHA 2001b).	Turbidity	40 CFR 141.74(a)(1).
2150 B	2150 B–97, online version (APHA 1997a).	Odor	40 CFR 143.4(b).
2320 B	2320 B–97, online version (APHA 1997b).	Alkalinity	40 CFR 141.23(k)(1).
2510 B	2510 B–97, online version (APHA 1997c).	Conductivity	40 CFR 141.23(k)(1).
2540 C	2540 C–97, online version (APHA 1997d).	Total Dissolved Solids	40 CFR 143.4(b).
2550	2550–00, online version (APHA 2000a)	Temperature	40 CFR 141.23(k)(1).
3111 B	3111 B–99, online version (APHA 1999a).	Calcium, copper, magnesium, nickel, sodium, iron, manganese, silver, zinc.	40 CFR 141.23(k)(1); 40 CFR 143.4(b).
3111 D	3111 D–99, online version (APHA 1999a).	Barium, aluminum	40 CFR 141.23(k)(1); 40 CFR 143.4(b).
3112 B	3112 B–99, online version (APHA 1999b).	Mercury	40 CFR 141.23(k)(1).
3113 B	3113 B, 19th Edition (APHA 1995)	Antimony, arsenic, barium, beryllium, cadmium, chromium, copper, lead, nickel, selenium, aluminum, iron, manganese, silver.	40 CFR 141.23(k)(1); 40 CFR 143.4(b).
3114 B	3114 B–97, online version (APHA 1997e).	Arsenic, selenium	40 CFR 141.23(k)(1).
3120 B	3120 B–99, online version (APHA 1999c).	Barium, beryllium, calcium, chromium, copper, magnesium, nickel, silica, aluminum, iron, manganese, silver, zinc.	40 CFR 141.23(k)(1); 40 CFR 143.4(b).
3500-Ca B	3500-Ca B–97, online version (APHA 1997f).	Calcium	40 CFR 141.23(k)(1).
3500-Mg B	3500-Mg B–97, online version (APHA 1997g).	Magnesium	40 CFR 141.23(k)(1).
4110 B	4110 B–00, online version (APHA 2000b).	Fluoride, nitrate, nitrite, ortho-phosphate, chloride, sulfate.	40 CFR 141.23(k)(1); 40 CFR 143.4(b).
4500-Cl D,F,G,H	4500-Cl D,F,G,H–00, online versions (APHA 2000c).	Free chlorine	40 CFR 141.74(a)(2); 40 CFR 141.131(c)(1).
4500-Cl D,E,F,G,I	4500-Cl D,E,F,G,I–00, online versions (APHA 2000c).	Total chlorine	40 CFR 141.74(a)(2); 40 CFR 141.131(c)(1).
4500-Cl D,F,G	4500-Cl D,F,G–00, online versions (APHA 2000c).	Combined chlorine	40 CFR 141.131(c)(1).
4500-Cl^- B,D	4500-Cl^- B,D–97, online versions (APHA 1997h).	Chloride	40 CFR 143.4(b).
4500-ClO_2 C	4500-ClO_2 C–00, online version (APHA 2000d).	Chlorine dioxide	40 CFR 141.74(a)(2).
4500-ClO_2 E	4500-ClO_2 E–00, online version (APHA 2000d).	Chlorine dioxide	40 CFR 141.74(a)(2); 40 CFR 141.131(c)(1).
4500-ClO_2 E	4500-ClO_2 E–00, online version (APHA 2000d).	Chlorite	40 CFR 141.131(b)(1).
4500–CN^- C,E,F,G	4500–CN^- C,E,F,G, 20th Edition (APHA 1998).	Cyanide	40 CFR 141.23(k)(1).
4500–F^- B,C,D,E	4500–F^- B,C,D,E–97, online versions (APHA 1997i).	Fluoride	40 CFR 141.23(k)(1).

Standard methods, 24th edition (APHA 2023)	Approved method	Contaminant	Regulation citations
4500–H^+ B	4500–H^+ B–00, online version (APHA 2000e).	pH	40 CFR 141.23(k)(1).
4500–NO_3^- D	4500–NO_3^- D–00, online version (APHA 2000f).	Nitrate	40 CFR 141.23(k)(1).
4500–NO_3^- E,F	4500–NO_3^- E,F–00, online versions (APHA 2000f).	Nitrate, nitrite	40 CFR 141.23(k)(1).
4500–NO_2^- B	4500–NO_2^- B–00, online version (APHA 2000g).	Nitrite	40 CFR 141.23(k)(1).
4500–O_3 B	4500–O_3 B–97, online version (APHA 1997j).	Ozone	40 CFR 141.74(a)(2).
4500–P E,F	4500–P E,F, 19th Edition, (APHA 1995)	Ortho-phosphate	40 CFR 141.23(k)(1).
4500-SiO_2 C,D,E	4500-SiO_2 C,D,E–97, online versions (APHA 1997k).	Silica	40 CFR 141.23(k)(1).
4500–SO_4^{2-} C,D,E,F	4500–SO_4^{2-} C,D,E,F, 19th Edition (APHA 1995).	Sulfate	40 CFR 143.4(b).
5310 B,C.	5310 B,C–00, online versions (APHA 2000h).	Dissolved and Total Organic Carbon	40 CFR 141.131(d).
5540 C	5540 C–00, online version (APHA 2000i)	Foaming agents	40 CFR 143.4(b).
5910 B	5910 B–00, online version (APHA 2000j)	UV Absorption at 254 nm	40 CFR 141.131(d).
6251 B	6251 B–94, online version (APHA 1994)	HAA5	40 CFR 141.131(b)(1).
6610 B	EPA Method 531.2, Rev. 1.0 (USEPA 2001).	Carbofuran, oxamyl	40 CFR 141.24(e)(1).
6640 B	EPA Method 515.4, Rev. 1.0 (USEPA 2000).	2,4–D; 2,4,5–TP; Dalapon; Dinoseb; Pentachlorophenol; Picloram.	40 CFR 141.24(e)(1).
6651 B	6651 B, 20th Edition, (APHA 1998)	Glyphosate	40 CFR 141.24(e)(1).
7110 B	7110 B–00, online version (APHA 2000k).	Gross alpha and gross beta	40 CFR 141.25(a).
7110 C	7110 C–00, online version (APHA 2000k).	Gross alpha	40 CFR 141.25(a).
7110 D	EPA Method 900.0 (USEPA 1980)	Gross alpha and gross beta	40 CFR 141.25(a).
7120	7120–97, online version (APHA 1997l)	Gamma emitters (includes radioactive cesium and iodine).	40 CFR 141.25(a).
7500-Cs B	7500-Cs B–00, online version (APHA 2000l).	Radioactive Cesium and Gamma emitters.	40 CFR 141.25(a).
7500-^{3}H B	7500-^{3}H B–00, online version (APHA 2000m).	Tritium	40 CFR 141.25(a).
7500–I B	7500–I B–00, online version (APHA 2000n).	Radioactive Iodine and Gamma emitters	40 CFR 141.25(a).
7500–I C,D	7500–I C,D–00, online versions (APHA 2000n).	Radioactive Iodine	40 CFR 141.25(a).
7500-Ra B,C	7500-Ra B,C–01, online versions (APHA 2001c).	Radium-226	40 CFR 141.25(a).
7500-Ra D	7500-Ra D–01, online version (APHA 2001c).	Radium-228	40 CFR 141.25(a).
7500-Ra E	GA Method (2004)	Radium-226 and Radium-228	40 CFR 141.25(a).
7500-Sr B	7500-Sr B–01, online version (APHA 2001d).	Strontium-89 and Strontium-90	40 CFR 141.25(a).
7500–U B,C	7500–U B,C–00, online versions (APHA 2000o).	Uranium	40 CFR 141.25(a).
9221 A,C	9221 A,C, 20th Edition, (APHA 1998)	Total coliforms	40 CFR 141.74(a)(1).
9221 B	9221 B, 20th Edition, (APHA 1998)	Total coliforms	40 CFR 141.74(a)(1) 40 CFR 141.852(a)(5) [B.1, B.2, B.3, B.4].
9221 D	9221 D, 20th Edition, (APHA 1998)	Total coliforms	40 CFR 141.852(a)(5) [D.1, D.2, D.3].
9221 E	9221 E, 20th Edition, (APHA 1998)	Fecal coliforms	40 CFR 141.74(a)(1).
9221 F	9221 F, 20th Edition, (APHA 1998)	*E. coli*	40 CFR 141.402(c)(2) 40 CFR 141.852(a)(5) [F.1].
9222 A	9222 A 20th Edition, (APHA 1998)	Total coliforms	40 CFR 141.74(a)(1).
9222 B,C	9222 B,C, 20th Edition, (APHA 1998)	Total coliforms	40 CFR 141.74(a)(1) 40 CFR 141.852(a)(5).
9222 D	9222 D, 20th Edition, (APHA 1998)	Fecal coliforms	40 CFR 141.74(a)(1).
9222 H	9222 G, 20th Edition, (APHA 1998)	*E. coli*	40 CFR 141.852(a)(5).
9222 I	9222 G, 20th Edition, (APHA 1998)	*E. coli*	40 CFR 141.402(c)(2) 40 CFR 141.852(a)(5).
9222 J	m-ColiBlue24 Test (Hach Company 1999).	Total coliforms	40 CFR 141.852(a)(5).
9222 J	m-ColiBlue24 Test (Hach Company 1999).	*E. coli*	40 CFR 141.402(c)(2) 40 CFR 141.852(a)(5).
9223 B	9223 B, 20th Edition (APHA 1998)	Total coliforms	40 CFR 141.74(a)(1); 40 CFR 141.852(a)(5).

Standard methods, 24th edition (APHA 2023)	Approved method	Contaminant	Regulation citations
9223 B	9223 B, 20th Edition (APHA 1998)	*E. coli*	40 CFR 141.402(c)(2); 40 CFR 141.852(a)(5).
9230 B	9230 C, 20th Edition (APHA 1998)	Enterococci	40 CFR 141.402(c)(2).
9230 C	9230 C, 20th Edition (APHA 1998)	Enterococci	40 CFR 141.402(c)(2).
9230 D	(Budnick 1996)	Enterococci	40 CFR 141.402(c)(2).

The 24th edition can be obtained from the American Public Health Association (APHA), 800 I Street NW, Washington, DC 20001–3710. Approved online versions are available at *http://www.standardmethods.org.*

B. Methods Developed by Vendors

1. Hach Method 10312—Spectrophotometric Measurement of Fluoride in Finished Drinking Water Aluminum-Chromeazurol S complex (AL–CAS) Using Planar Reagent-filled Cuvettes (Hach 2022a). Hach Method 10312 uses a reagent solution containing an intensely colored aluminum-chromeazurol S complex. The presence of fluoride in the sample removes aluminum from the complex, releasing the free chromeazurol S ion. The free chromeazurol S ion has peak absorbance in a different region of the visible spectrum. The quantifiable change in absorbance is directly proportional to the fluoride concentration. Test results are measured at 427 nm using a colorimeter.

Approved methods for fluoride are listed at 40 CFR 141.23(k)(1). The performance characteristics of Hach Method 10312 were compared to the performance characteristics of the approved Standard Methods 4500–F D (Standard Methods 1997i). The validation study report (Hach 2022b) summarizes the results obtained from three different facilities and laboratories. Method detection limits and method limits, precision and accuracy performance in high and low ionic strength water, and matrix spike studies were determined at all sites.

EPA has determined that Hach Method 13012 is equally effective relative to Standard Methods 4500–F D. The basis for this determination is discussed in Adams 2023a. Therefore, EPA is approving the Hach Method 10312 for determining fluoride in drinking water. A copy of the method is available from Hach Company, 5600 Lindbergh Drive, Loveland, Colorado 80539.

2. Yokogawa Method 820—Measurement of Turbidity in Drinking Water by Right Angle Scattered Light Turbidity Analyzer (Yokogawa 2022a). Yokogawa Method 820 uses a right-angle scattering turbidimeter with an LED light source with a peak emitting wavelength between 650 and 670 nm. The method is based upon a comparison of the intensity of light scattered by the sample under defined conditions with the intensity of light scattered by a standard reference suspension.

Approved methods for turbidity are listed at 40 CFR 141.74(a)(1). The performance characteristics of the Yokogawa Method 820 were compared to the performance characteristics of the approved EPA Method 180.1 (USEPA 1993). The validation study report (Yokogawa 2022b) summarizes the results obtained from the turbidimeters tested at three different utilities. Method resolution, linearity, limits of detection, and precision and accuracy were determined at the first site, with subsequent sites evaluating precision and accuracy performance.

EPA has determined that the Yokogawa Method 820 is equally effective relative to EPA Method 180.1. The basis for this determination is discussed in Adams 2023b. Therefore, EPA is approving the Yokogawa Method 820 for determining turbidity in drinking water. A copy of the method is available from Yokogawa Electric Corporation, 2–9–32 Nakamachi, Musashino-shi, Tokyo, Japan 180–8750.

IV. Statutory and Executive Order Reviews

As noted in section II of this preamble, under the terms of SDWA section 1401(1), this streamlined method approval action is not a rule. Accordingly, the Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3). Similarly, this action is not subject to the Regulatory Flexibility Act because it is not subject to notice and comment requirements under the Administrative Procedure Act or any other statute. In addition, because this approval action is not a rule, but simply makes alternative testing methods available as options for monitoring under SDWA, EPA has concluded that other statutes and executive orders generally applicable to rulemaking do not apply to this approval action.

V. References

Adams, W. 2023a. Memo to the record describing basis for expedited approval of Hach Method 10312. May 9, 2023. (Available at *https://www.regulations.gov;* docket ID No. EPA–HQ–OW–2023–0541.)

Adams, W. 2023b. Memo to the record describing basis for expedited approval of Yokogawa Method 820. May 9, 2023. (Available at *https://www.regulations.gov;* docket ID No. EPA–HQ–OW–2023–0541.)

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List of Subjects in 40 CFR Part 141

Environmental protection, Chemicals, Indians—lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water supply.

Jennifer L. McLain,

Director, Office of Ground Water and Drinking Water.

For the reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR part 141 as follows:

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

■ 1. The authority citation for part 141 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

■ 2. Amend Appendix A to subpart C of part 141 by:

■ a. Revising the table entitled ''Alternative Testing Methods for Contaminants Listed at 40 CFR 141.23(k)(1)'';

■ b. Revising the table entitled ''Alternative Testing Methods for Contaminants Listed at 40 CFR 141.24(e)(1)'';

■ c. Revising the table entitled ''Alternative Testing Methods for Contaminants Listed at 40 CFR 141.25(a)'';

■ d. Revising the table entitled ''Alternative Testing Methods for Contaminants Listed at 40 CFR 141.74(a)(1)'';

■ e. Revising the table entitled ''Alternative Testing Methods for Disinfectant Residuals Listed at 40 CFR 141.74(a)(2)'';

■ f. Revising the table entitled ''Alternative Testing Methods for Contaminants Listed at 40 CFR 141.131(b)(1)'';

■ g. Revising the table entitled ''Alternative Testing Methods for Disinfectant Residuals Listed at 40 CFR 141.131(c)(1)'';

■ h. Revising the table entitled ''Alternative Testing Methods for Parameters Listed at 40 CFR 141.131(d)'';

■ i. Revising the table entitled ''Alternative Testing Methods for Contaminants Listed at 40 CFR 141.402(c)(2)'';

■ j. Revising the table entitled ''Alternative Testing Methods for Contaminants Listed at 40 CFR 141.852(a)(5)'';
■ k. Revising the table entitled ''Alternative Testing Methods for Contaminants Listed at 40 CFR 143.4(b)'';

The revisions and additions read as follows:

Appendix A to Subpart C of Part 141—Alternative Testing Methods Approved for Analyses Under the Safe Drinking Water Act

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ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.23(k)(1)

Contaminant	Methodology	EPA method	SM 21st edition [1]	SM 22nd edition [28]	SM 23rd edition,[49] SM 24th edition [66]	SM online [3]	ASTM [4]	Other
Alkalinity	Titrimetric		2320 B	2320 B	2320 B		D1067–06 B, 11 B, 16 B.	
Antimony	Hydride—Atomic Absorption.						D 3697–07, –12, –17.	
	Atomic Absorption; Furnace.		3113 B	3113 B	3113 B	3113 B–04, B–10.		
	Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).	200.5, Revision 4.2 [2].						
Arsenic	Atomic Absorption; Furnace.		3113 B	3113 B	3113 B	3113 B–04, B–10.	D 2972–08 C, –15 C.	
	Hydride Atomic Absorption.		3114 B	3114 B	3114 B	3114 B–09	D 2972–08 B, –15 B.	
	Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).	200.5, Revision 4.2 [2].						
Barium	Inductively Coupled Plasma.		3120 B	3120 B	3120 B.			
	Atomic Absorption; Direct.		3111 D	3111 D	3111 D.			
	Atomic Absorption; Furnace.		3113 B	3113 B	3113 B	3113 B–04, B–10.		
	Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).	200.5, Revision 4.2 [2].						
Beryllium	Inductively Coupled Plasma.		3120 B	3120 B	3120 B.			
	Atomic Absorption; Furnace.		3113 B	3113 B	3113 B	3113 B–04, B–10.	D 3645–08 B, –15 B.	
	Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).	200.5, Revision 4.2 [2].						
Cadmium	Atomic Absorption; Furnace.		3113 B	3113 B	3113 B	3113 B–04, B–10.		
	Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).	200.5, Revision 4.2 [2].						
Calcium	EDTA titrimetric		3500-Ca B	3500-Ca B	3500-Ca B		D 511–09, –14 A.	
	Atomic Absorption; Direct Aspiration.		3111 B	3111 B	3111 B		D 511–09, –14 B.	

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.23(k)(1)—Continued

Contaminant	Methodology	EPA method	SM 21st edition [1]	SM 22nd edition [28]	SM 23rd edition,[49] SM 24th edition [66]	SM online [3]	ASTM [4]	Other
	Inductively Coupled Plasma.	.....	3120 B	3120 B	3120 B.			
	Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).	200.5, Revision 4.2 [2].						
	Ion Chromatography.	.....	.....	.....	.....	.....	D 6919–09, –17.	
Chromium	Inductively Coupled Plasma.	.....	3120 B	3120 B	3120 B.			
	Atomic Absorption; Furnace.	.....	3113 B	3113 B	3113 B	3113 B–04, B–10.		
	Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).	200.5, Revision 4.2 [2].						
Copper	Atomic Absorption; Furnace.	.....	3113 B	3113 B	3113 B	3113 B–04, B–10.	D 1688–07, –12 C, 17 C.	
	Atomic Absorption; Direct Aspiration.	.....	3111 B	3111 B	3111 B	.....	D 1688–07, –12 A, 17 A.	
	Inductively Coupled Plasma.	.....	3120 B	3120 B	3120 B.			
	Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).	200.5, Revision 4.2 [2].						
	Colorimetry	.....	.....	.....	.....	.....	.....	Hach Method 8026,[35] Hach Method 10272.[36]
Conductivity	Conductance ...	.....	2510 B	2510 B	2510 B	.....	D 1125–14 A.	
Cyanide	Manual Distillation with $MgCl_2$ followed by:.	.....	4500–CN$^-$C	4500–CN$^-$C	4500–CN$^-$C	4500–CN$^-$C–99.	D 2036–06 A.	
	Spectrophotometric, Amenable.	.....	4500–CN$^-$G ...	4500–CN$^-$G ...	4500–CN$^-$G ...	.....	D 2036–06 B.	
	Spectrophotometric Manual.	.....	4500–CN$^-$E	4500–CN$^-$E	4500–CN$^-$E	.....	D2036–06 A.	
	Selective Electrode.	.....	4500–CN$^-$F	4500–CN$^-$F	4500–CN$^-$F.			
	Gas Chromatography/ Mass Spectrometry Headspace.	.....	.....	.....	.....	.....	.....	ME355.01.[7]
Fluoride	Ion Chromatography.	.....	4110 B	4110 B	4110 B	.....	D 4327–11, –17.	
	Manual Distillation; Colorimetric SPADNS.	.....	4500–F$^-$B, D ..	4500–F$^-$B, D ..	4500–F$^-$B, D.			
	Manual Electrode.	.....	4500–F$^-$C	4500–F$^-$C	4500–F$^-$C	.....	D 1179–04, 10 B, 16 B.	
	Automated Alizarin.	.....	4500–F$^-$E	4500–F$^-$E	4500–F$^-$E.			
	Arsenite-Free Colorimetric SPADNS.	.....	.....	.....	.....	.....	.....	Hach SPADNS 2 Method 10225,[22] Hach Method 10312.[67]

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.23(k)(1)—Continued

Contaminant	Methodology	EPA method	SM 21st edition [1]	SM 22nd edition [28]	SM 23rd edition,[49] SM 24th edition [66]	SM online [3]	ASTM [4]	Other
Lead	Atomic Absorption; Furnace.		3113 B	3113 B	3113 B	3113 B–04, B–10.	D 3559–08 D, 15 D.	
	Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).	200.5, Revision 4.2 [2].						
	Differential Pulse Anodic Stripping Voltametry.							Method 1001, Rev. 1.1.[57]
Magnesium	Atomic Absorption.		3111 B	3111 B	3111 B		D 511–09, –14 B.	
	Inductively Coupled Plasma.		3120 B	3120 B	3120 B.			
	Complexation Titrimetric Methods.		3500-Mg B	3500-Mg B	3500-Mg B		D 511–09, –14 A.	
	Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).	200.5, Revision 4.2 [2].						
	Ion Chromatography.						D 6919–09, –17.	
Mercury	Manual, Cold Vapor.		3112 B	3112 B	3112 B	3112 B–09	D 3223–12, –17.	
Nickel	Inductively Coupled Plasma.		3120 B	3120 B	3120 B.			
	Atomic Absorption; Direct.		3111 B	3111 B	3111 B.			
	Atomic Absorption; Furnace.		3113 B	3113 B	3113 B	3113 B–04, B–10.		
	Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).	200.5, Revision 4.2 [2].						
Nitrate	Ion Chromatography.		4110 B	4110 B	4110 B		D 4327–11, –17.	
	Automated Cadmium Reduction.		4500–NO_3^- F	4500–NO_3^- F	4500–NO_3^- F.			
	Manual Cadmium Reduction.		4500–NO_3^- E	4500–NO_3^- E	4500–NO_3^- E.			
	Ion Selective Electrode.		4500–NO_3^- D	4500–NO_3^- D	4500–NO_3^- D.			
	Reduction/Colorimetric.							Systea Easy (1-Reagent),[8] NECi Nitrate-Reductase.[40]
	Colorimetric; Direct.							Hach TNTplus™ 835/836 Method 10206.[23]
	Capillary Ion Electrophoresis.						D 6508–15.	
Nitrite	Ion Chromatography.		4110 B	4110 B	4110 B		D 4327–11, –17.	
	Automated Cadmium Reduction.		4500–NO_3^- F	4500–NO_3^- F	4500–NO_3^- F.			
	Manual Cadmium Reduction.		4500–NO_3^- E	4500–NO_3^- E	4500–NO_3^- E.			

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.23(k)(1)—Continued

Contaminant	Methodology	EPA method	SM 21st edition [1]	SM 22nd edition [28]	SM 23rd edition,[49] SM 24th edition [66]	SM online [3]	ASTM [4]	Other
	Spectrophotometric.	.....	4500–NO_2^- B ..	4500–NO_2^- B ..	4500–NO_2^- B.			
	Reduction/Colorimetric.	.....	.....	.....	.....	.....	.....	Systea Easy (1-Reagent),[8] NECi Nitrate-Reductase.[40]
	Capillary Ion Electrophoresis.	.....	.....	.....	.....	.....	D 6508–15.	
Ortho-phosphate ..	Ion Chromatography.	.....	4110 B	4110 B	4110 B	.....	D 4327–11, –17.	
	Colorimetric, ascorbic acid, single reagent.	.....	4500–P E	4500–P E	4500–P E	4500–P E–99.		
	Colorimetric, Automated, Ascorbic Acid.	.....	4500–P F	4500–P F	4500–P F	4500–P F–99 ..	Thermo Fisher Discrete Analyzer.[41].	
	Capillary Ion Electrophoresis.	.....	.....	.....	.....	.....	D 6508–15.	
pH	Electrometric ...	[48] 150.3	4500–H^+ B	4500–H^+ B	4500–H^+ B	.....	D 1293–12, –18.	
Selenium	Hydride-Atomic Absorption.	.....	3114 B	3114 B	3114 B	3114 B–09	D 3859–08 A, –15 A.	
	Atomic Absorption; Furnace.	.....	3113 B	3113 B	3113 B	3113 B–04, B–10.	D 3859–08 B, –15 B.	
	Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).	200.5, Revision 4.2 [2].						
Silica	Colorimetric	.....	.....	.....	.....	.....	D859–05, 10, 16.	
	Molybdosilicate	.....	4500-SiO_2 C	4500-SiO_2 C	4500-SiO_2 C.			
	Heteropoly blue	.....	4500-SiO_2 D	4500-SiO_2 D	4500-SiO_2 D.			
	Automated for Molybdate-reactive Silica.	.....	4500-SiO_2 E	4500-SiO_2 E	4500-SiO_2 E.			
	Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).	200.5, Revision 4.2 [2].						
	Inductively Coupled Plasma.	.....	3120 B	3120 B	3120 B.			
Sodium	Atomic Absorption; Direct Aspiration.	.....	3111 B	3111 B	3111 B.			
	Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).	200.5, Revision 4.2 [2].						
	Ion Chromatography.	.....	.....	.....	.....	.....	D 6919–09, –17.	
Temperature	Thermometric ..	.....	2550	2550	2550	2550–10.		

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.24(e)(1)

Contaminant	Methodology	EPA method	SM 21st edition [1]	SM 22nd edition,[28] SM 23rd edition,[49] SM 24th edition [66]	SM online [3]	ASTM [4]	Other
Benzene	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					
Carbon tetrachloride.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					
Chlorobenzene	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					
1,2-Dichlorobenzene.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					
1,4-Dichlorobenzene.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					
1,2-Dichloroethane	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					
cis-Dichloroethylene.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					
trans-Dichloroethylene.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					
Dichloromethane	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					
1,2-Dichloropropane.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					
Ethylbenzene	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					
Styrene	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4 [29].					
Tetrachloroethylene.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					
1,1,1-Trichloroethane.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					
Trichloroethylene	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					
Toluene	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					
1,2,4-Trichlorobenzene.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					
1,1-Dichloroethylene.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4 [29].					
1,1,2-Trichlorethane.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.24(e)(1)—Continued

Contaminant	Methodology	EPA method	SM 21st edition [1]	SM 22nd edition,[28] SM 23rd edition,[49] SM 24th edition [66]	SM online [3]	ASTM [4]	Other
Vinyl chloride	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					
Xylenes (total)	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					
2,4-D	Gas Chromatography/Electron Capture Detection (GC/ECD).		6640 B	6640 B	6640 B–01, B–06	D 5317–20.	
2,4,5-TP (Silvex)	Gas Chromatography/Electron Capture Detection (GC/ECD).		6640 B	6640 B	6640 B–01, B–06	D 5317–20.	
Alachlor	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	525.3.[24]					
Atrazine	Liquid Chromatography Electrospray Ionization Tandem Mass Spectrometry (LC/ESI–MS/MS).	536.[25]					
	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	525.3,[24] 523.[26]					
Benzo(a)pyrene	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	525.3.[24]					
Carbofuran	High-performance liquid chromatography (HPLC) with post-column derivatization and fluorescence detection.		6610 B	6610 B	6610 B–04.		
	Liquid Chromatography/Mass Spectrometry.						ME 531.[58]
Chlordane	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	525.3.[24]					
Dalapon	Ion Chromatography Electrospray Ionization Tandem Mass Spectrometry (IC–ESI–MS/MS).	557.[14]					
	Gas Chromatography/Electron Capture Detection (GC/ECD).		6640 B	6640 B	6640 B–01, B–06.		

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.24(e)(1)—Continued

Contaminant	Methodology	EPA method	SM 21st edition [1]	SM 22nd edition,[28] SM 23rd edition,[49] SM 24th edition [66]	SM online [3]	ASTM [4]	Other
Di(2-ethylhexyl)adipate.	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	525.3.[24]					
Di(2-ethylhexyl)phthalate.	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	525.3.[24]					
Dibromochloropropane (DBCP).	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3.[9]					
Dinoseb	Gas Chromatography/Electron Capture Detection (GC/ECD).		6640 B	6640 B	6640 B–01, B–06.		
Endrin	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	525.3.[24]					
Ethyl dibromide (EDB).	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3.[9]					
Glyphosate	High-Performance Liquid Chromatography (HPLC) with Post-Column Derivatization and Fluorescence Detection.		6651 B	6651 B	6651 B–00, B–05.		
Heptachlor	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	525.3.[24]					
Heptachlor Epoxide.	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	525.3.[24]					
Hexachlorobenzene.	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	525.3.[24]					
Hexachlorocyclopentadiene.	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	525.3.[24]					
Lindane	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	525.3.[24]					
Methoxychlor	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	525.3.[24]					

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.24(e)(1)—Continued

Contaminant	Methodology	EPA method	SM 21st edition [1]	SM 22nd edition,[28] SM 23rd edition,[49] SM 24th edition [66]	SM online [3]	ASTM [4]	Other
Oxamyl	High-performance liquid chromatography (HPLC) with post-column derivatization and fluorescence detection.		6610 B	6610 B	6610 B–04.		
Liquid Chromatography/Mass Spectrometry.						ME 531.[58].	
PCBs (as Aroclors)	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	525.3.[24]					
Pentachlorophenol	Gas Chromatography/Electron Capture Detection (GC/ECD).		6640 B	6640 B	6640 B–01, B–06	D 5317–20.	
	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	525.3.[24]					
Picloram	Gas Chromatography/Electron Capture Detection (GC/ECD).		6640 B	6640 B	6640 B–01, B–06	D 5317–20.	
Simazine	Liquid Chromatography Electrospray Ionization Tandem Mass Spectrometry (LC/ESI–MS/MS).	536.[25]					
	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	525.3,[24] 523.[26]					
Toxaphene	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	525.3.[24]					
Total Trihalomethanes.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	524.3,[9] 524.4.[29]					

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.25(a)

Contaminant	Methodology	EPA method	SM 21st edition [1]	SM 22nd edition,[28] SM 23rd edition,[49] SM 24th edition [66]	ASTM [4]	SM online [3]
Naturally Occurring:						
Gross alpha and beta.	Evaporation	900.0, Rev. 1.0 [50]	7110 B	7110 B.		
	Liquid Scintillation			7110 D	D 7283–17	7110 D–17.
Gross alpha	Coprecipitation		7110 C	7110 C.		
Radium 226	Radon emanation	903.1, Rev. 1.0 [53]	7500-Ra C	7500-Ra C	D 3454–05, –18, D 3454–21.	
	Radiochemical	903.0, Rev. 1.0 [54]	7500-Ra B	7500-Ra B	D 2460–07.	
	Gamma Spectrometry.			7500-Ra E		7500-Ra E–07.
Radium 228	Radiochemical	904.0, Rev. 1.0 [62]	7500-Ra D	7500-Ra D.		
	Gamma Spectrometry.			7500-Ra E		7500-Ra E–07.
Uranium	Radiochemical		7500–U B	7500–U B.		
	ICP–MS		3125		D 5673–05, 10, 16.	

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.25(a)—Continued

Contaminant	Methodology	EPA method	SM 21st edition [1]	SM 22nd edition,[28] SM 23rd edition,[49] SM 24th edition [66]	ASTM [4]	SM online [3]
	Alpha spectrometry ..	.....	7500–U C	7500–U C	D 3972–09.	
	Laser Phosphorimetry.	.....	.....	.....	D 5174–07.	
	Alpha Liquid Scintillation Spectrometry.	.....	.....	.....	D 6239–09.	
Man-Made:						
Radioactive Cesium.	Radiochemical	.....	7500-Cs B	7500-Cs B.		
	Gamma Ray Spectrometry.	.....	7120	7120	D 3649–06.	
Radioactive Iodine	Radiochemical	.....	7500–I B, 7500–I C, 7500–I D.	7500–I B, 7500–I C, 7500–I D.	D 3649–06.	
	Gamma Ray Spectrometry.	.....	7120	7120	D 4785–08, –20.	
Radioactive Strontium 89, 90.	Radiochemical	.....	7500-Sr B	7500-Sr B.		
Tritium	Liquid Scintillation	.....	7500-^{3}H B	7500-^{3}H B	D 4107–08, –20.	
Gamma Emitters	Gamma Ray Spectrometry.	.....	7120, 7500-Cs B, 7500–I B.	7120, 7500-Cs B, 7500–I B.	D 3649–06, D 4785–08, –20.	

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.74(a)(1)

Organism	Methodology	SM 21st edition [1]	SM 22nd edition [28]	SM 23rd edition [49]	SM 24th edition [66]	SM online [3]	Other
Total Coliform	Total Coliform Fermentation Technique.	9221 A, B, C	9221 A, B, C	9221 A, B, C	9221 A, B, C	9221 A, B, C–06.	
	Total Coliform Membrane Filter Technique.	9222 A, B, C	.....	9222 A, B, C	9222 A, B, C.		
	ONPG–MUG Test	9223	9223 B	9223 B	9223 B	9223 B–04.	
Fecal Coliforms	Fecal Coliform Procedure.	9221 E	9221 E	9221 E	9221 E	9221 E–06.	
	Fecal Coliform Filter Procedure.	9222 D	9222 D	9222 D	9222 D	9222 D–06.	
Heterotrophic bacteria.	Pour Plate Method.	9215 B	9215 B	9215 B	.....	9215 B–04.	
Turbidity	Nephelometric Method.	2130 B	2130 B	2130 B	2130 B	.....	Hach Method 8195, Rev. 3.0.[52]
	Laser Nephelometry (on-line).	.....	.....	.....	.....	.....	Mitchell M5271,[10] Mitchell M5331, Rev. 1.2,[42] Lovibond PTV 6000.[46]
	LED Nephelometry (on-line).	.....	.....	.....	.....	.....	Mitchell M5331,[11] Mitchell M5331, Rev. 1.2,[42] Lovibond PTV 2000,[45] Yokogawa 820.[68]
	LED Nephelometry (on-line).	.....	.....	.....	.....	.....	AMI Turbiwell,[15] Lovibond PTV 1000.[44]
	LED Nephelometry (portable).	.....	.....	.....	.....	.....	Orion AQ4500,[12] Lovibond TB 3500,[64] Lovibond TB 5000.[65]
	Laser Nephelometry (portable).	.....	.....	.....	.....	.....	Lovibond TB 6000.[63]
	360° Nephelometry.	.....	.....	.....	.....	.....	Hach Method 10258, Rev. 1.0,[39] Hach Method 10258, Rev. 2.0.[51]

ALTERNATIVE TESTING METHODS FOR DISINFECTANT RESIDUALS LISTED AT 40 CFR 141.74(a)(2)

Residual	Methodology	EPA methods	SM 21st edition [1]	SM 22nd edition,[28] SM 23rd edition,[49] SM 24th edition [66]	ASTM [4]	Other
Free Chlorine	Amperometric Titration.		4500-Cl D	4500-Cl D	D 1253–08, –14.	
	DPD Ferrous Titrimetric.		4500-Cl F	4500-Cl F.		
	DPD Colorimetric		4500-Cl G	4500-Cl G		Hach Method 10260.[31]
	Indophenol Colorimetric.					Hach Method 10241.[34]
	Syringaldazine (FACTS).		4500-Cl H	4500-Cl H.		
	On-line Chlorine Analyzer.	EPA 334.0.[16]				
	Amperometric Sensor.					ChloroSense,[17] ChloroSense, Rev. 1.1.[59]
Total Chlorine	Amperometric Titration.		4500-Cl D	4500-Cl D	D 1253–08, –14.	
	Amperometric Titration (Low level measurement).		4500-Cl E	4500-Cl E.		
	DPD Ferrous Titrimetric.		4500-Cl F	4500-Cl F.		
	DPD Colorimetric		4500-Cl G	4500-Cl G		Hach Method 10260.[31]
	Indophenol Colorimetric.	127.[55]				
	Iodometric Electrode		4500-Cl I	4500-Cl I.		
	On-line Chlorine Analyzer.	EPA 334.0.[16]				
	Amperometric Sensor.					ChloroSense,[17] ChloroSense, Rev. 1.1.[59]
Chlorine Dioxide	Amperometric Titration.		4500–ClO_2 C	4500–ClO_2 C.		
	Amperometric Titration.		4500–ClO_2 E	4500–ClO_2 E.		
	Amperometric Sensor.					ChlordioX Plus,[32] ChlordioX Plus, Rev. 1.1.[60]
Ozone	Indigo Method		4500–O_3 B	4500–O_3 B.		

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.131(b)(1)

Contaminant	Methodology	EPA method	ASTM [4]	SM online [3]	SM 21st edition [1]	SM 22nd edition,[28] SM 23rd edition,[49] SM 24th Edition [66]	Other
TTHM	P&T/GC/MS	524.3,[9] 524.4.[29]					
HAA5	LLE (diazomethane)/GC/ECD.			6251 B–07	6251 B	6251 B.	
	Ion Chromatography Electrospray Ionization Tandem Mass Spectrometry (IC–ESI–MS/MS).	557.[14]					
	Two-Dimensional Ion Chromatography (IC) with Suppressed Conductivity Detection.						Thermo Fisher 557.1.[47]
Bromate	Two-Dimensional Ion Chromatography (IC).	302.0[18]					
	Ion Chromatography Electrospray Ionization Tandem Mass Spectrometry (IC–ESI–MS/MS).	557.[14]					

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.131(b)(1)—Continued

Contaminant	Methodology	EPA method	ASTM [4]	SM online [3]	SM 21st edition [1]	SM 22nd edition,[28] SM 23rd edition,[49] SM 24th Edition [66]	Other
	Chemically Suppressed Ion Chromatography.	.....	D 6581–08 A.				
	Electrolytically Suppressed Ion Chromatography.	.....	D 6581–08 B.				
Chlorite	Chemically Suppressed Ion Chromatography.	.....	D 6581–08 A.				
	Electrolytically Suppressed Ion Chromatography.	.....	D 6581–08 B.				
Chlorite—daily monitoring as prescribed in 40 CFR 141.132(b)(2)(i)(A).	Amperometric Titration.	.....	.....	.....	4500-ClO_2 E	4500-ClO_2 E.	
	Amperometric Sensor.	.....	.....	.....	.....	.....	ChlordioX Plus,[32] ChlordioX Plus, Rev. 1.1.[60]

ALTERNATIVE TESTING METHODS FOR DISINFECTANT RESIDUALS LISTED AT 40 CFR 141.131(c)(1)

Free Chlorine	Amperometric Titration ...	4500-Cl D	4500-Cl D	D 1253–08, –14.		
	DPD Ferrous Titrimetric ..	4500-Cl F	4500-Cl F.			
	DPD Colorimetric	4500-Cl G	4500-Cl G	.....		Hach Method 10260.[31]
	Indophenol Colorimetric	.....	.....	.....		Hach Method 10241.[34]
	Syringaldazine (FACTS)	4500-Cl H	4500-Cl H.			
	Amperometric Sensor	.....	.....	.....		ChloroSense,[17] ChloroSense, Rev. 1.1.[59]
	On-line Chlorine Analyzer	.....	.....	.....		EPA 334.0.[16]
Combined Chlorine	Amperometric Titration ...	4500-Cl D	4500-Cl D	D 1253–08, –14..		
	DPD Ferrous Titrimetric ..	4500-Cl F	4500-Cl F.			
	DPD Colorimetric	4500-Cl G	4500-Cl G	.....		Hach Method 10260.[31]
Total Chlorine	Amperometric Titration ...	4500-Cl D	4500-Cl D	D 1253–08, –14.		
	≤Low level Amperometric Titration.	4500-Cl E	4500-Cl E.			
	DPD Ferrous Titrimetric ..	4500-Cl F	4500-Cl F.			
	DPD Colorimetric	4500-Cl G	4500-Cl G	.....		Hach Method 10260.[31]
	Iodometric Electrode	4500-Cl I	4500-Cl I.			
	Amperometric Sensor	.....	.....	.....		ChloroSense,[17] ChloroSense, Rev. 1.1.[59]
	On-line Chlorine Analyzer	.....	.....	.....		EPA 334.0.[16]
Chlorine Dioxide	Amperometric Method II	4500–ClO_2 E	4500–ClO_2 E.			
	Amperometric Sensor	.....	.....	.....		ChlordioX Plus,[32] ChlordioX Plus, Rev. 1.1.[60]

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ALTERNATIVE TESTING METHODS FOR PARAMETERS LISTED AT 40 CFR 141.131(d)

Total Organic Carbon (TOC).	High Temperature Combustion.	5310 B	5310 B	5310 B	.....	415.3, Rev 1.2 [19].	
	Persulfate-Ultraviolet or Heated Persulfate Oxidation.	5310 C	5310 C	5310 C	.....	415.3, Rev 1.2 [19]	Hach Method 10267 [38].
	Wet Oxidation	5310 D	5310 D	.....	.....	415.3, Rev 1.2 [19].	
	Ozone Oxidation	.....	.....	.....	.....	.....	Hach Method 10261 [37].
Specific Ultraviolet Absorbance (SUVA).	Calculation using DOC and UV_{254} data.	.....	.....	.....	.....	415.3, Rev 1.2 [19].	
Dissolved Organic Carbon (DOC).	High Temperature Combustion.	5310 B	5310 B	5310 B	.....	415.3, Rev 1.2 [19].	

ALTERNATIVE TESTING METHODS FOR PARAMETERS LISTED AT 40 CFR 141.131(d)—Continued

	Persulfate-Ultraviolet or Heated Persulfate Oxidation.	5310 C	5310 C	5310 C		415.3, Rev 1.2 [19].	
	Wet Oxidation	5310 D	5310 D			415.3, Rev 1.2 [19].	
Ultraviolet absorption at 254 nm (UV_{254}).	Spectrophotometry.	5910 B	5910 B	5910 B	5910 B–11	415.3, Rev 1.2 [19]	

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ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.402(c)(2)

E. coli	Colilert		9223 B	9223 B	9223 B	9223 B–97, B–04.	
	Colisure		9223 B	9223 B	9223 B	9223 B–97, B–04.	
	Colilert-18	9223 B	9223 B	9223 B	9223 B	9223 B–97, B–04.	
	Readycult®						Readycult®.[20]
	Colitag						Modified Colitag™ [13], Modified Colitag™, Version 2.0.[61]
	Chromocult®						Chromocult®.[21]
	EC–MUG			9221 F	9221 F	9221 F–06.	
	NA–MUG				9222 I.		
	mColiBlue24 Test				9222 J.		
	Tecta EC/TC [33 43].						
	RAPID'E.coli 2 [56].						
Enterococci	Multiple-Tube Technique.				9230 B	9230 B–04.	
	Membrane Filter Techniques.				9230 C.		
	Fluorogenic Substrate Enterococcus Test (using Enterolert).				9230 D.		
Coliphage	Two-Step Enrichment Presence-Absence Procedure.						Fast Phage.[30]

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ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.852(a)(5)

Total Coliforms	Lactose Fermentation Methods.	Standard Total Coliform Fermentation Technique.		9221 B.1, B.2	9221 B.1, B.2, B.3, B.4.	9221 B.1, B.2–06.
		Presence-Absence (P–A) Coliform Test.			9221 D.1, D.2, D.3.	
	Membrane Filtration Methods.	Standard Total Coliform Membrane Filter Procedure using Endo Media.			9222 B, C.	
		Simultaneous Detection of Total Coliforms and *E. coli* by Dual Chromogen Membrane Filter Procedure (using mColiBlue24 medium).			9222 J.	
		Simultaneous Detection of Total Coliform Bacteria and *Escherichia coli* Using RAPID'*E.coli* (REC2) in Drinking Water [56].				
	Enzyme Substrate Methods.	Colilert®		9223 B	9223 B	9223 B–04.
		Colisure®		9223 B	9223 B	9223 B–04.
		Colilert-18	9223 B	9223 B	9223 B	9223 B–04.
		Tecta EC/TC [33 43].				

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.852(a)(5)—Continued

		Modified Colitag™, Version 2.0[61].				
Escherichia coli	*Escherichia coli* Procedure (following Lactose Fermentation Methods).	EC–MUG medium		9221 F.1	9221 F.1	9221 F.1–06.
	Escherichia coli Partitioning Methods (following Membrane Filtration Methods).	EC broth with MUG (EC–MUG).			9222 H.	
		NA–MUG medium			9222 I.	
	Simultaneous Detection of Total Coliforms and *E. coli* by Dual Chromogen Membrane Filter Procedure.	mColiBlue24 medium			9222 J.	
	Membrane Filtration Method.	Simultaneous Detection of Total Coliform Bacteria and *Escherichia coli* Using RAPID'*E.coli* (REC2) in Drinking Water[56].				
	Enzyme Substrate Methods.	Colilert®		9223 B	9223 B	9223 B–04.
		Colisure®		9223 B	9223 B	9223 B–04.
		Colilert-18	9223 B	9223 B	9223 B	9223 B–04.
		Tecta EC/TC[33 43].				
		Modified Colitag™, Version 2.0[61].				

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 143.4(b)

Contaminant	Methodology	EPA method	ASTM[4]	SM 21st edition[1]	SM 22nd edition,[28] SM 23rd edition,[49] SM 24th edition[66]	SM online[3]
Aluminum	Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).	200.5, Revision 4.2[2].				
	Atomic Absorption; Direct.			3111 D	3111 D.	
	Atomic Absorption; Furnace.			3113 B	3113 B	3113 B–04, B–10.
	Inductively Coupled Plasma.			3120 B	3120 B.	
Chloride	Silver Nitrate Titration.		D 512–04 B, 12 B	4500-Cl minus;B	4500-Cl minus;B.	
	Ion Chromatography		D 4327–11, –17	4110 B	4110 B.	
	Potentiometric Titration.			4500-Cl minus;D	4500-Cl minus;D.	
Color	Visual Comparison			2120 B	2120 B.	
Foaming Agents	Methylene Blue Active Substances (MBAS).			5540 C	5540 C.	
Iron	Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).	200.5, Revision 4.2[2].				
	Atomic Absorption; Direct.			3111 B	3111 B.	
	Atomic Absorption; Furnace.			3113 B	3113 B	3113 B–04, B–10
	Inductively Coupled Plasma.			3120 B	3120 B.	
Manganese	Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).	200.5, Revision 4.2[2].				
	Atomic Absorption; Direct.			3111 B	3111 B.	
	Atomic Absorption; Furnace.			3113 B	3113 B	3113 B–04, B–10.
	Inductively Coupled Plasma.			3120 B	3120 B.	

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 143.4(b)—Continued

Contaminant	Methodology	EPA method	ASTM[4]	SM 21st edition[1]	SM 22nd edition,[28] SM 23rd edition,[49] SM 24th edition[66]	SM online[3]
Odor	Threshold Odor Test			2150 B	2150 B.	
Silver	Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).	200.5, Revision 4.2[2].				
	Atomic Absorption; Direct.			3111 B	3111 B.	
	Atomic Absorption; Furnace.			3113 B	3113 B	3113 B–04, B–10.
	Inductively Coupled Plasma.			3120 B	3120 B.	
Sulfate	Ion Chromatography		D 4327–11, –17	4110 B	4110 B.	
	Gravimetric with ignition of residue.			4500–SO_4 $^{2\ minus;}$C.	4500–SO_4 $^{2\ minus;}$C.	4500–SO_4 $^{2\ minus;}$C–97.
	Gravimetric with drying of residue.			4500–SO_4 $^{2\ minus;}$D.	4500–SO_4 $^{2\ minus;}$D.	4500–SO_4 $^{2\ minus;}$D–97.
	Turbidimetric method		D 516–07, 11, 16	4500–SO_4 $^{2\ minus;}$E.	4500–SO_4 $^{2\ minus;}$E.	4500–SO_4 $^{2\ minus;}$E–97.
	Automated methylthymol blue method.			4500–SO_4 $^{2\ minus;}$F.	4500–SO_4 $^{2\ minus;}$F.	4500–SO_4 $^{2\ minus;}$F–97.
Total Dissolved Solids	Total Dissolved Solids Dried at 180 deg C.			2540 C	2540 C.	
Zinc	Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES).	200.5, Revision 4.2[2].				
	Atomic Absorption; Direct Aspiration.			3111 B	3111 B.	
	Inductively Coupled Plasma.			3120 B	3120 B.	

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Proposed Rules

Federal Register
Vol. 89, No. 20
Tuesday, January 30, 2024

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 331

9 CFR Part 121

[Docket No. APHIS–2019–0018]

RIN 0579–AE52

Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: In accordance with the Agricultural Bioterrorism Protection Act of 2002, we are proposing to amend and republish the list of select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products. This Act requires the biennial review and republication of the list of select agents and toxins and the revision of the list as necessary. This action would implement findings from the biennial review for the list. The biennial review was initiated within 2 years of the completion of the previous biennial review. In addition, we are proposing to add definitions for several terms; codify policies regarding the role of responsible officials and alternate responsible officials, conclusion of patient care, and annual internal inspections; and revise or clarify provisions related to validated inactivation procedures and viable select agent removal methods, recordkeeping, non-possession of select agents and toxins, electronic Federal Select Agent Programs, registration, Tier 1 enhancements, and exclusion of naturally infected animals. We are also proposing to add requirements for reporting discoveries of select agents and toxins, provisions regarding effluent decontamination system, biosafety provisions for facility verification requirements for registered biosafety level 3 and animal biosafety level 3 laboratories, a new requirement related to restricted experiments, and to correct editorial errors. These proposed changes would economically benefit producers, research and reference laboratories, and State and Federal oversight agencies, while also maintaining adequate program oversight of select agents and toxins.

DATES: We will consider all comments that we receive on or before April 1, 2024.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov.* Enter APHIS–2019–0018 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2019–0018, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Commenters should not include any information in their comments or supporting materials that they consider confidential or inappropriate for public disclosure. APHIS will carefully consider all comments submitted in preparation of a final rule.

Supporting documents and any comments we receive on this docket may be viewed at *www.regulations.gov* or in our reading room, which is located in Room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 7997039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Jacek Taniewski, DVM, Director, Division of Agricultural Select Agents and Toxins, ERCS, APHIS, 4700 River Road, Riverdale, MD 20737; (301) 851–3352; *jacek.taniewski@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (referred to below as the Bioterrorism Response Act) provides for the regulation of certain biological agents and toxins that have the potential to pose a severe threat to human, animal, and plant health, or to animal and plant products. The Animal and Plant Health Inspection Service (APHIS) has the responsibility for implementing the provisions of the Bioterrorism Response Act within the U.S. Department of Agriculture (USDA). Veterinary Services (VS) select agents and toxins, listed in 9 CFR 121.3, are those that have been determined to have the potential to pose a severe threat to animal health or animal products. Plant Protection and Quarantine (PPQ) select agents and toxins, listed in 7 CFR 331.3, are those that have been determined to have the potential to pose a severe threat to plant health or plant products. Overlap select agents and toxins, listed in 9 CFR 121.4, are those that have been determined to pose a severe threat to public health and safety, to animal health, or to animal products. Overlap select agents are subject to regulation by both APHIS and the Centers for Disease Control and Prevention (CDC), which has the primary responsibility for implementing the provisions of the Act for the U.S. Department of Health and Human Services (HHS). Together, APHIS and CDC comprise the Federal Select Agent Program (FSAP).

Title II, Subtitle B of the Bioterrorism Response Act (which is cited as the ''Agricultural Bioterrorism Protection Act of 2002'' and referred to below as the Act), section 212(a)(1)(A) (7 U.S.C. 8401(a)(1)(A)), provides, in part, that the Secretary of Agriculture (the Secretary) must establish by regulation a list of each biological agent and each toxin that the Secretary determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products.

In determining whether to include an agent or toxin in the list, the Act (7 U.S.C. 8401(a)(1)(B)) requires that the following criteria be considered:

- The effect of exposure to the agent or toxin on animal or plant health, and on the production and marketability of animal or plant products;
- The pathogenicity of the agent or the toxicity of the toxin and the methods by which the agent or toxin is transferred to animals or plants;

• The availability and effectiveness of pharmacotherapies and prophylaxis to treat and prevent any illness caused by the agent or toxin;

• Whether such inclusion would have a substantial negative impact on the research and development of solutions for the animal and plant disease caused by the agent or toxin and whether the negative impact on research and development would substantially outweigh the risk posed by the agent or toxin to animal or plant health if it is not included on the list (added by the 2018 Farm Bill); and

• Any other criteria that the Secretary considers appropriate to protect animal or plant health, or animal or plant products.

Paragraph (a)(2) of section 212 of the Act (7 U.S.C. 8401(a)(2)) requires the Secretary to review and republish the list of select agents and toxins every 2 years and to otherwise revise the list as necessary. To fulfill this statutory mandate, APHIS convenes separate interagency working groups in order to review the lists of PPQ and VS select agents and toxins, as well as any overlap select agents and toxins, and develop recommendations regarding possible changes to the list using the five criteria for listing found in the Act.

Advance Notice of Proposed Rulemaking

Pursuant to this same paragraph of the Act, on March 17, 2020, we issued an advance notice of proposed rulemaking (ANPR) in the **Federal Register** (85 FR 15078–15079, Docket No. APHIS–2019–0018) in which we solicited public comment on the possible delisting of one PPQ select agent, *Peronosclerospora philippinensis,* formerly known as *Peronosclerospora sacchari,* one VS select agent, African horse sickness virus, and five overlap select agents, *Bacillus anthracis* (Pasteur strain), *Brucella abortus, B. suis,* and *B. melitensis,* and Venezuelan equine encephalitis virus. We took comment on the ANPR for 60 days, ending May 18, 2020. We received 224 comments by that time. They were from private citizens and stakeholders. We discuss the comments on the ANPR below.

Commenters overwhelmingly supported delisting of *B. abortus, B. suis,* and *B. melitensis.* We did not receive any comments relative to delisting *P. philippinensis* or African horse sickness virus. Additionally, we did receive adverse comments regarding our proposed possible removal of Venezuelan equine encephalitis virus (VEEV) and *Bacillus anthracis* (Pasteur strain).

Finally, we received two comments suggesting the delisting of *Ralstonia solanacearum* Race 3 biovar 2 and several comments suggesting delisting of other agents from the list of select agents and toxins. We acknowledge these requests but before we propose to delist or list an agent, it is reviewed by the Agricultural Interagency Select Agents and Toxins Technical Advisory Committee, or Ag-ISATTAC. In that regard, it is beneficial to clarify how those reviews take place. On a biannual basis, the Ag-ISATTAC, a Federal interagency committee of subject matter experts in domestic and transboundary animal diseases and toxins, reviews existing USDA select agents and toxins and makes recommendations regarding their continued listing, possible delisting, or addition of new agents/toxins, according to several risk categories. Until such time as the Ag-ISATTAC has recommended listing or delisting, we do not propose to do so. In the case of the additional changes to the list recommended by commenters, we have not received recommendations from the Ag-ISATTAC in support of the changes.

Based upon the subject matter expert scientific assessment conducted during the biennial review, the conclusions of which were referenced in the ANPR, along with consideration of the accompanying public comments received on the ANPR, we are proposing to delist *P. philippinensis,* African horse sickness virus, *B. abortus, B. suis,* and *B. melitensis* as select agents. As we discussed in the ANPR, the technical justification for the agents we are proposing to delist is the following:

• *Peronosclerospora philippinensis:* This agent is only able to survive and reproduce in the host plant and requires specific environmental conditions to become infectious, for which mitigations exist. (Food and Agriculture Organization of the United Nations, cited October 19, 2017; Murray, G.M. 2009; Purdue University Extension, cited October 20, 2017; USDA, 2013.)

• *African horse sickness virus:* This virus is difficult to successfully disseminate and effectively transmit. An effective vaccine exists. (Alberca, B, et al., 2014; Braverman, Y, 1996; Lulla, V., et al., 2017; Sanchez-Vizcaino, J.M., 2004; Spickler, 2015.)

• *Brucella abortus:* This agent presents little economic or animal health risk as it is unlikely to result in large-scale population introduction due to the high concentration of the agent necessary to produce disease as well as modern cattle production processes that limit animal-to-animal transmission routes. There is an efficacious vaccine, moderate immunity status within vulnerable populations, limited farm-to-farm transmission risk, and effective quarantine procedures. (Center for Food Security and Public Health, 2009; Moreno, E., 2014; Olsen, S.C., 2011.)

• *Brucella melitensis:* This agent, which primarily affects goats and sheep, is of lesser concern because the low farm-to-farm transmission risk due to modern production practices limits the chance of introduction on a scale large enough to impact domestic production. (The Center for Food Security and Public Health, 2009; Moreno, E., 2014; Olsen, S.C., 2011.)

• *Brucella suis:* This agent presents a low to moderate animal health risk due to limited farm-to-farm transmission risk as a result of modern production practices which reduce the risk of a large-scale introduction. (The Center for Food Security and Public Health, 2009; Stoffregen, W.C., 2006; World Organizsation for Animal Health (OIE), 2017; Zhu, L., et al., 2016.)

In addition, we are proposing to retain Venezuelan equine encephalitis virus and *Bacillus anthracis* (Pasteur strain) as select agents.

We appreciate all comments received from the ANPR and will consider these comments in future deliberations.

We are also proposing additional changes to the regulations beyond those discussed in the ANPR. Certain of these would be codifications of existing operational policy. These include provisions related to: Discovery of a select agent or toxin, disposal of select agent waste after conclusion of patient care, the exclusion of animals naturally infected with select agents from the requirements of the regulations, allowing individuals other than the responsible official (*e.g.,* principal investigators) to revise inactivation procedure documentation, removal procedures, and the content of annual internal inspections.

Many of the proposed revisions are intended to clarify existing provisions of the regulations. These include proposed definitions of *loss, release,* and *theft;* clarifying reporting requirements for ''discovered'' select agents or toxins, a clarification regarding what constitutes an acceptable ''validated inactivation procedure,'' clarifications related to the existing reporting requirements, clarifying that certificates must accompany transfers of a select agent or toxin, including intra-entity transfers, clarifying that the documentation in the IT system for the FSAP program serves as official records required by the regulations, clarifying the documentation that may be needed for the issuance of a certificate of

registration, clarifying that a responsible official cannot be approved as the responsible official at more than one registered entity and cannot be the sole alternate responsible official at another registered entity, clarifying requirements related to restricted experiments, clarifying the notification requirements for changes to the application for registration, and clarifying the scope of pre-access suitability assessments.

Lastly, there are certain provisions that would be new. They include: Provisions regarding effluent decontamination system, biosafety provisions for facility verification requirements for registered biosafety level 3 and animal biosafety level 3 laboratories, and a new requirement related to restricted experiments.

We discuss the codifications of existing policy, the proposed clarifications, and the new provisions immediately below, by topic.

Discovery of Select Agents or Toxins

Since 2003, the FSAP has received at least 100 instances of reports from entities that ''discovered'' a select agent or toxin in their possession for which the entity was not registered to possess and neither an exemption nor an exclusion to compliance with the select agent and toxins regulations applied. Many of the select agents and toxins ''discovered'' were from studies associated with personnel who had left their entity, such as a research institution, and the custodianship of samples was not reassigned. Some of the materials were labeled with obsolete pathogen names, where other ''discovered'' materials were found in laboratories where their active use had ceased, in some cases, decades prior to the establishment of the select agent and toxin regulations. Discovery of a select agent in situations when there is an unexpected finding of the select agent as described above, is mutually exclusive from regulatory applications when instances of a theft, loss, or release of a select agent occur.

Since 2003, unless an exemption applied or the select agent was excluded from the requirements of the select agent and toxin regulations, unregistered possession of a select agent or toxin on the HHS or USDA select agent and toxin list is a regulatory violation that could subject an individual or entity to civil and/or criminal penalties.

APHIS continues to receive reports from registered and non-registered entities who find themselves in possession of select agents and toxins that they are not registered to possess and to which neither an exemption nor exclusion applies. We are proposing to revise 9 CFR 121.2 and 7 CFR 331.2 of the regulations to codify this longstanding operational policy by clarifying that any individual or entity in possession of a select agent or toxin, for which an exclusion or exemption listed in 9 CFR part 121 or 7 CFR part 331 does not apply, and that is not included on a certificate of registration issued by the HHS Secretary or APHIS Administrator for that individual or entity, must immediately report such possession to either the APHIS Administrator or the HHS Secretary.

To date, when registered and non-registered entities have reported such ''discoveries,'' they have often done so on an APHIS/CDC Form 3. However, the APHIS/CDC Form 3 is for reporting of thefts, losses, and releases, and not for discoveries. To facilitate such reporting for discoveries, HHS and USDA plan to create, in compliance with the Paperwork Reduction Act, a new APHIS/CDC Form 6 that will require submission of information regarding the discovery of a select agent or toxin. Establishing a standard form for reporting will enable HHS and USDA to better understand the circumstances and assess regulatory violations related to the possession of a ''discovered'' select agent and/or toxin. We would also add reference to this form in the regulations.

We are also proposing to add a definition for the term *Discovery* to 7 CFR 331.1 and 9 CFR 121.1 of the regulations to distinguish a ''discovery'' from a ''theft,'' ''loss,'' and ''release'' and to clarify the scope of the reporting requirement for discoveries. We would define *Discovery* to mean the finding of a select agent or toxin by an individual or entity that is not aware of the select agent or toxin's existence. Examples would include, but would not be limited to, the following:

- A registered individual or entity finds a select agent or toxin not accounted for in their inventory; or
- A non-registered individual or entity finds a select agent or toxin.

Disposal of Select Agent Waste After Conclusion of Patient Care

In 7 CFR 331.3(d)(8), 9 CFR 121.3(d)(8) and 9 CFR 121.4(d)(8), the regulations provide that waste generated during the delivery of patient care by health care professionals from a patient diagnosed with an illness or condition associated with a select agent is excluded from the requirements of the regulations, provided that the waste is decontaminated or transferred for destruction by complying with State and Federal regulations within 7 calendar days of the conclusion of patient care. Additionally, 9 CFR 121.5(a)(3) and 9 CFR 121.6(a)(3) exempt from the regulations diagnostic laboratories and other entities that collect clinical or diagnostic specimens from a patient infected with a select agent provided that, among other requirements, the specimens are transferred in accordance with § 121.16 or destroyed on-site within 7 calendar days after delivery of patient care by health care professionals has concluded.

In this rulemaking, APHIS is proposing to codify in regulation a current operational policy that, for an individual who has been admitted to a medical facility, that individual's ''conclusion of patient care,'' and the point when ''delivery of patient care by health care professionals has concluded,'' is when an individual is released from the medical facility where treatment was being provided by the medical facility or physician. If the patient is seen by the physician or medical facility for follow-up care (*e.g.,* 6 month follow-up visit), such follow-up care would be considered a new delivery of patient care. The policy that we are codifying further clarifies that the exclusion is intended for select agent waste generated during the treatment of humans and is not intended to apply to animals receiving veterinary care, or plants or plant products submitted for diagnostic purposes.

Exclusion of Animals Naturally Infected With Select Agents

In this rulemaking, we are proposing to codify in regulation the current policy regarding when animals naturally infected with select agents are excluded from the requirements of the regulations. Sections 121.3(d)(1) and 121.4(d)(1) in 9 CFR of the regulations provide for exclusion of select agents occurring in their natural environment. Mere possession of an animal that is naturally infected with a select agent, either within its natural environment or having been transported to an artificially established environment, meets the criteria of this exclusion. However, the removal of an animal that is infected with a select agent from its natural environment to an artificially established environment for the purpose of the intentional exposure or introduction of a select agent to a naïve or experimental animal, or the introduction of a naïve animal to a natural environment where there is an animal that is naturally infected with a select agent for the purpose of the intentional exposure or introduction of a select agent to the naïve or

experimental animal, does not meet the exclusion criteria. To provide an example, avian influenza virus is listed in § 121.3(b) as a VS select agent. When animals within a poultry flock are confirmed to be naturally infected with highly pathogenic avian influenza, the individual infected animals are not subject to the select agent requirements based on possession of the animals. However, if animals from the same flock were sold to a research facility for the purpose of intentionally exposing naïve animals to these naturally infected animals during a disease transmissibility study, that study and the associated animals would be subject to the select agent requirements.

We are proposing to revise the two sections to clarify the scope of the exclusion.

Finally, please note that when such infected animals are involved there may be existing USDA disease control programs and requirements regarding the management, movement, and disposition of infected animals. Additionally, even if an animal is confirmed to be naturally infected with a select agent and is excluded from the select agent and toxin regulations, there may still be transfer and/or transport restrictions placed upon its movement based upon specific Federal and/or State requirements.

Inactivation

The regulations in 7 CFR 331.3(d)(4), 9 CFR 121.3(d)(4), and 9 CFR 121.4(d)(4) provide an exclusion from the requirements of the regulations for a select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. The exclusion further specifies that surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactivation procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.

We are proposing several revisions (discussed in detail below) related to the inactivation exclusion discussed above.

We are clarifying what constitutes an acceptable ''validated inactivation procedure.'' Specifically, we are proposing to revise the exclusion discussed above so that a select agent or regulated nucleic acids that can produce infectious forms of any select agent virus would be excluded from the requirements of the regulations if subjected to a validated inactivation procedure, provided that:

- In-house validation of the inactivation procedure is completed prior to use;
- A certificate of inactivation (discussed below) has been generated in accordance with the regulations;
- For use of a select agent surrogate to validate an inactivation procedure, the select agent surrogate chosen is known to possess equivalent properties with respect to inactivation, and, if there are known variations in the resistance of a select agent to an inactivation procedure, including strain to strain, then the inactivation procedure must also be validated using the most resistant select agent surrogate; and
- For use of a whole tissue or homogenized tissue surrogate to validate a chemical inactivation procedure for other tissues, including those in other animal or plant models, all standardized conditions must be held constant such as the select agent used, the tissue volume, and the ratio of tissue to volume of inactivating material; a safety margin must be incorporated into the final inactivation procedure to ensure the effective inactivation of the select agent; and the tissue surrogate is either expected to have the highest concentration of the specific select agent to be inactivated, or the concentration of the select agent in the tissue is determined and this select agent concentration is not exceeded when applying the validated inactivation procedure on subsequent tissue samples.

The purpose of these revisions is to indicate that the inactivation procedure must have been validated in-house and must have been validated in a manner that provides assurances regarding its general suitability and use within that facility. The regulations in 9 CFR 121.5(a) and 9 CFR 121.6(a) currently also exempt diagnostic laboratories and other entities that possess, use, or transfer a select agent or toxin that is contained in a specimen presented for diagnosis or verification from the requirements of the regulations, if, among other requirements, the select agent or toxin is destroyed on-site within 7 calendar days using an approved inactivation process. We are proposing to revise this exemption so that if an inactivation process is used, it meets the parameters in the above exclusion, as revised. We are also clarifying that such an inactivation process may not necessarily entail physical destruction of the select agent or toxin.

We are also proposing a new exclusion related to inactivation in 7 CFR 331.3(d), 9 CFR 121.3(d), and 9 CFR 121.4(d). Specifically, we propose to exclude from the requirements of the regulations any select agent or regulated nucleic acid that can produce infectious forms of any select agent virus if the material is contained in a formalin-fixed paraffin-embedded tissue that has been effectively inactivated by a recognized method for that particular agent or regulated nucleic acid. This would exclude from the requirements of the regulations, as an example, appropriately prepared histopathology samples that have undergone satisfactory formalin fixation and further paraffin embedding processes that result in a quality sample. In this example, such properly prepared samples that will yield a usable histopathology sample provide assurances that the additional processing steps required to prepare an acceptable formalin-fixed, paraffin-embedded tissue sample will result in agent inactivation.

The regulations in 7 CFR 331.9(a) and 9 CFR 121.9(a) require individuals or entities required to register under the regulations to designate an individual to be the responsible official for the individual or entity. One of the current responsibilities of the responsible official is to review, and revise as necessary, each of the entity's validated inactivation procedures or viable select agent removal methods (7 CFR 331.9(a)(9); 9 CFR 121.9(a)(9)).

We are proposing to codify a policy that allows individuals besides the responsible official (*e.g.,* principal investigators) to revise the inactivation procedures, if necessary. Responsible officials would still be responsible for ensuring the revision occurs but would not necessarily have to revise the procedure themselves. This revision is being proposed because, often, the principal investigators are the subject matter experts when it comes to the procedures and are the most qualified to enact revisions to the inactivation procedures.

Finally, we are proposing to revise the existing definition of *validated inactivation procedure* in 7 CFR 331.1 and 9 CFR 121.1. Currently, we define the term as ''[a] procedure, whose efficacy is confirmed by data generated from a viability testing protocol, to render a select agent non-viable but allows the select agent to retain characteristics of interest for future use; or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.'' As revised, to be consistent with

its use in our proposed revisions to the exclusion and exemption noted above, we would specify that the validated inactivation procedure must be conducted in-house and must have its efficacy confirmed by an in-house viability test, and would clarify that, if used on nucleic acids of a select agent virus, it must render the nucleic acids incapable of producing infectious virus.

Removal

In addition to inactivation, the regulations in 7 CFR 331.3(d)(5), 9 CFR 121.3(d)(5), and 9 CFR 121.4(d)(5) also provide for an exclusion from the requirements of the regulations for material containing a select agent that is subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is subjected to a viability testing protocol to ensure that the removal method has rendered the material free of all viable select agent. We are proposing to revise this exclusion to reflect current operational practices and policies. As revised, it would exclude from the requirements of the regulations material containing a select agent that is subjected to a validated viable select agent removal procedure, provided that all of the following conditions are met:

- In-house validation of the viable select agent removal procedure is completed prior to use;
- A certificate of viable select agent removal (discussed below) has been generated in accordance with § 121.17(a)(8) or § 331.17(a)(8);
- For use of a surrogate to validate a viable select agent removal procedure, only surrogates known to possess equivalent properties with respect to removal are used; and
- A portion of each subsequent sample has been subjected to a verification viability testing protocol to ensure that the validated viable select agent removal procedure has rendered the material free of all viable select agent.

In a similar manner to our proposed revisions to the exclusion based on inactivation in 7 CFR 331.3(d)(4), 9 CFR 121.3(d)(4), and 9 CFR 121.4(d)(4), the intent of these revisions is to indicate that the removal procedure must be validated in-house as appropriate and effective for the facility's particular circumstances. We are also proposing to add to the definitions in 7 CFR 331.1 and 9 CFR 121.1 the term *Validated removal procedure,* which we propose to define as ''a procedure, whose efficacy has been confirmed by data generated in-house from a viability testing protocol, to confirm removal of all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.''

Currently, the definition of *Viability testing protocol* in 7 CFR 331.1 and 9 CFR 121.1 does not include reference to removal procedures. However, given that we are proposing to include viability testing protocols in our proposed revision to the removal procedures, it is correspondingly necessary to revise the definition of *Viability testing protocol* to include such reference. We would also specify that it must be conducted in-house. We would also add to the definitions in 7 CFR 331.1 and 9 CFR 121.1 a definition of the term *Verification viability testing protocol.* We would define this term as ''a protocol, used on samples that have been subjected to a validated inactivation or removal procedure, to confirm the material is free of all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.''

Finally, wherever the exclusion related to removal is currently discussed in other provisions of the regulations, we are proposing harmonizing changes to ensure the terminology remains consistent with our proposed revisions to that exclusion.

Loss, Release, and Theft

The terms *loss, release,* and *theft* are used in several instances in the existing regulations. For example, 7 CFR 331.19 and 9 CFR 121.19 discuss the notification requirements for loss, release, and theft. Additionally, 7 CFR 331.3(f) and 9 CFR 121.3(f) also contain an exclusion from the requirements of the regulations for any select agent or toxin seized by a Federal law enforcement agency during the period between seizure of the agent or toxin and the transfer or destruction of such agent or toxin provided that, among other requirements, the Federal law enforcement agency safeguards and secures the seized agent or toxin against theft, loss, or release, and reports any theft, loss, or release of such agent or toxin. However, the terms *loss, release,* and *theft* are not currently defined within the regulations. We are proposing definitions for each of these terms in 7 CFR 331.1 and 9 CFR 121.1 to clarify their meaning.

We are proposing to define *loss* as ''the inability to account for a select agent or toxin known to be in the individual or entity's possession.''

We are proposing to define *release* as any of the following:

- An incident resulting in occupational exposure to a select agent or toxin;
- An incident resulting in animal/plant exposure to a select agent or toxin;
- The failure of equipment used to contain a select agent or toxin such that it is reasonably anticipated that a select agent or toxin was released;
- The failure of or breach in personal protective equipment in the presence of a select agent or toxin; or
- The failure of biosafety procedures such that it is reasonably anticipated that a select agent or toxin was outside of containment.

Finally, we are proposing to define *theft* as the unauthorized taking and removing of a select agent or toxin from the possession of an entity or individual.

Recordkeeping

The regulations in 7 CFR 331.17 and 9 CFR 121.17 contain recordkeeping requirements for individuals and entities required to register pursuant to the regulations. We are proposing amendments to these sections to ensure an accurate, current inventory is maintained for all select agents and toxins held in long-term storage. Specifically, the section is being modified to add more specific language regarding from whom material is acquired and the date the agent was removed and returned from the storage locations to more specifically define required recordkeeping information.

We are proposing to require that records contain:

- The quantity acquired and the name of the individual by whom it was acquired. The quantity acquired is currently one of the recordkeeping requirements; the name of the individual by whom it was acquired would be new.
- The location where the select agent or toxin is stored (*e.g.,* building, room number or name, and freezer identification or other storage container). This is an existing requirement, but we are clarifying that the salient information is not the manner in which it is stored (*e.g.,* freezer versus non-refrigerated unit) but where in the facility it is stored.
- The date the agent was removed and returned, the purpose for using the agent, the name of the individual who removed and returned the agent, and when applicable, date of final disposition of the agent and by whom. This would clarify the existing recordkeeping requirement to keep records of when an agent is removed or returned; we require a record of the calendar date, but not specific times within that day.
- For intra-entity transfers (sender and the recipient are covered by the

same certificate of registration), name of the select agent or toxin, the date of the transfer, the number of items transferred or number of vials or quantity of toxin transferred, the name of the sender, and the name of the recipient. The current recordkeeping requirement is substantially similar but only specifically refers to select agents, whereas the intent is that it applies both to select agents and toxins.

The regulations in 7 CFR 331.17(a)(8)(vii) and 9 CFR 121.17(a)(8)(vii) also currently require individuals and entities to maintain, for select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent, a certificate, signed by the principal investigator, that includes the date of inactivation or viable select agent removal, the validated inactivation or viable select agent removal method used, and the name of the principal investigator. The regulations further specify that a copy of the certificate must accompany any transfer of inactivated or select agent removed material.

We are proposing several revisions to the records needed for inactivated or select agent-free material created by an entity. We are proposing to allow a designee to sign the certificate of inactivation on behalf of a principal investigator, so that certificates may be signed during the principal investigator's absence. We are further proposing that certificates must be signed within 7 days after completion of the validated inactivation or validated viable select agent removal, so that a significant amount of time does not elapse between when the inactivation or removal occurs and when the certificate is issued. We are also proposing that records must be maintained for as long as the material is in the possession of the registered individual or entity plus an additional 3 years, and clarifying the requirement that certificates must accompany any transfers, and that such transfers include intra-entity transfers. Principal investigator is defined in the regulations as the one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program. When a principal investigator is unavailable (such as out of the office) to review the results of a select agent that has been subjected to a validated inactivation or removal procedure, a temporary designee (appointed by the principal investigator and approved of by the responsible official) may sign the inactivation certificate to allow for work to continue. The temporary designee must be listed on the entity's registration and have the knowledge and expertise to provide scientific and technical direction regarding the validated inactivation procedure or the procedure for removal of viable select agent to which the certificate refers. The appointment of a designee to sign certificates is not for regular substitution of the principal investigator, such as the principal investigator relinquishing this requirement to other individuals in the laboratory due to normal work demands or general unavailability.

Non-Possession of Select Agent or Toxin

When an individual or entity registers to possess a select agent or toxin, they agree to comply with the standards in the regulations regardless of whether they currently possess or plan on possessing the agent or toxin. Registration is a choice, and indicates readiness to possess, use, or transfer select agents or toxins; the specific select agents or toxins for which the facility is registered are listed on its registration certificate. Although an entity does not need to have intent to possess a select agent or toxin to be registered, in most cases, registered entities for a select agent or toxin possess or are in the process of acquiring the select agent or toxin.

Should these plans change, prior to registration, an individual or entity may ask FSAP to hold review and processing of their registration application at any point. They may, also, choose to terminate their registration certificate at any time, if they no longer possess a select agent or toxin and no longer wish to be registered. Lastly, prior to required annual inspections and triannual renewal of registration, FSAP will ask a non-possessing entity if they desire to continue to be registered since there are agency and entity-related regulatory compliance costs associated with maintaining registration.

Despite the foregoing considerations, there are a few registered entities, primarily academic institutions, who have never possessed the select agent or toxin for which they are registered and have no current plans to obtain it, yet still wish to remain registered. We propose to revise the regulations in order to clarify that these entities must meet all regulatory requirements for registered entities should they continue to desire to maintain registration.

Electronic Federal Select Agent Program (eFSAP) Information System

As discussed previously in this document, the regulations sometimes require individuals and entities to submit reports and maintain records pursuant to the terms of the regulations. The regulations currently do not provide, however, how such reports may be submitted or how such records are to be maintained.

APHIS currently utilizes a highly secure information system, the eFSAP information system, to conduct all select agent program activities. The eFSAP information system is a two-way communication portal, which is accessible by both CDC and APHIS staff and the regulated community. For users at registered entities, benefits of the system include reduced paperwork, increased ease of validating and submitting information, and reduced processing time for requests (as real-time information exchange allows for increased responsiveness). Based on the implementation of the eFSAP information system, APHIS is proposing to update the regulations to indicate that reports (*e.g.,* APHIS/CDC Forms 2, 3, and 4) and requests (*e.g.,* amendments to registration) can be submitted via the eFSAP information system (or successor IT system as specified by APHIS in guidance). In addition, APHIS is proposing to update the regulations to clarify that the electronic documentation in the eFSAP information system serves as official records required by the select agent and toxin regulations, and once submitted in the eFSAP information system, there is no requirement for entities to retain a separate copy.

Registration

Unless exempted by the regulations, individuals and entities are required to have a certificate of registration issued by the APHIS Administrator to possess, use, or transfer select agents or toxins (7 CFR 331.7(a); 9 CFR 121.7(a)). This certificate of registration denotes approval for the select agents and/or toxins that an individual or entity is authorized to possess, use, and/or transfer; the specific activities the individual or entity is approved to conduct related to the registered select agents and/or toxins; the persons authorized to access the select agents and/or toxins; and the locations (buildings, rooms, suites of rooms, storage facilities, etc.) where select agents and/or toxins are authorized to be present as described in the entity's APHIS/CDC Form 1.

The regulations currently indicate that issuance of a certificate of registration may be contingent upon inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared to meet the requirements of the select agent and toxin regulations (7 CFR 331.7(g) and 9 CFR 121.7(g)). This provision could be construed to suggest that the security plan, biosafety plan, and incident response plan are each mutually exclusive, illustrative examples of additional information that APHIS may request, but that we would not request more than one of the examples. This is, however, not the case. Depending on the circumstances of the facility, we may request any or all of the documents listed in this provision. We are proposing to clarify that this may be the case.

Additionally, currently, the regulations in 7 CFR 331.7(i) and 9 CFR 121.7(i) state that a certificate of registration may be amended to reflect changes in circumstances (*e.g.,* replacement of the responsible official or other personnel changes, changes in ownership or control of the entity, changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins). However, this amendment is not discretionary. Each of the illustrative examples currently provided in the regulations could have a direct, material adverse impact on the possession and use of the select agents and toxins at the entity, and the entity's certificate of registration must be amended to reflect those changes. We are proposing to clarify that such an amendment is not discretionary.

Responsible Official and Alternate Responsible Official

As we mentioned previously in this document, the regulations in 7 CFR 331.9(a) and 9 CFR 121.9(a) require individuals or entities required to register under the regulations to designate an individual to be the responsible official for the individual or entity. The regulations require the responsible official to have a physical, and not merely telephonic or audio/visual, presence at the registered entity to ensure compliance with the regulations and respond in a timely manner to onsite incidents (7 CFR 331.9(a)(5); 9 CFR 121.9(a)(5)). This requirement effectively precludes a responsible official from serving as the primary responsible official for two separate registered entities, because the responsible official cannot be physically present at both entities simultaneously. Likewise, although the regulations allow the responsible official for one registered entity to serve as an alternate responsible official for another registered entity, the regulations do not currently provide that the official cannot be the sole alternate responsible official at the other entity; such an allowance would, again, run the risk of requiring the official to be physically present at two entities simultaneously. Accordingly, we are proposing to amend the regulations to clarify that a responsible official cannot be approved as the responsible official at more than one registered entity and cannot be the sole alternate responsible official at another registered entity. We are, however, proposing to allow an individual who has been approved as an alternate responsible official at one entity to also be able to be approved to be an alternate responsible official at another registered entity.

Annual Internal Inspections

The regulations at 7 CFR 331.9(a)(6) and 9 CFR 121.9(a)(6) currently require responsible officials to ensure that annual inspections are conducted of each registered space where select agents or toxins are stored or used to ensure compliance with the requirements of the regulations. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected and the corrections documented. However, the content of the inspections themselves is not specified. We are therefore proposing to codify the current policy that an entity's annual internal inspections must address whether:

- The entity's biosafety/biocontainment plan is being effectively implemented as outlined in the regulations (7 CFR 331.12 and 9 CFR 121.12, respectively).
- The entity's security plan is being effectively implemented as outlined in the regulations (7 CFR 333.11 and 9 CFR 121.11, respectively).
- The entity's incident response plan is implemented to ensure whether the entity is able to respond, as outlined in the regulations (7 CFR 331.14 and 9 CFR 121.14, respectively).
- Each individual with access approval from the Administrator or HHS Secretary has received the appropriate training as outlined in the regulations (7 CFR 331.15 and 9 CFR 121.15, respectively).

Tier 1 Security Enhancements

Currently, the regulations in 9 CFR 121.3 specify that certain VS select agents and toxins are Tier 1; the current VS Tier 1 select agents are foot-and-mouth disease virus and rinderpest virus. The regulations further specify that Tier 1 select agents are subject to additional requirements relative to other VS select agents and toxins. Currently, among these additional requirements is a requirement that registered entities with Tier 1 select agents must have procedures for screening visitors, including their property, and vehicles, at the entry and exit points to the registered space or at other designated points of entry to the building, facility, or compound that are based on the entity's site-specific risk assessment (9 CFR 121.11(f)(4)(iii)).

This requirement could be construed to suggest that the facility must authorize visitors to enter the facility, whereas the intent is to specify that, if the facility does allow visitors, they must be screened at an appropriate checkpoint. Accordingly, we propose to revise the provision to require procedures for screening any visitors, their property, and, where appropriate, vehicles at entry points to registered space based on the entity's site-specific risk assessment.

Biosafety—Facility Verification

The CDC has established guidelines for four biosafety levels for laboratories engaged in microbiological and biomedical laboratories (Biosafety in Microbiological & Biomedical Laboratories (BMBL), current edition). Biosafety level 3 facilities are facilities that possess an agent with a known potential for aerosol transmission and that may cause serious or potentially lethal disease in humans. The CDC has also established parallel animal biosafety level 3 biosafety guidelines for facilities that possess an agent with a known potential for aerosol transmission and that may cause lethal disease in animals.

Because of the unique and significant biosafety risks at such facilities, we are proposing to amend 7 CFR 331.12 and 9 CFR 121.12 to require facility verification every 12 months for registered entities that maintain biosafety level 3 and animal biosafety level 3 laboratories. The verifications would also have to be documented to confirm that systems are in place to monitor, maintain, and validate performance of the facility's containment functions, such as inward directional airflow, decontamination systems, as well as preventative maintenance conducted to ensure all systems are functioning appropriately to maintain containment during normal operations. Therefore, we also are proposing to amend 7 CFR 331.12 and

9 CFR 121.12 to require the entity to document facility verification and require the entity to verify the facility's containment functions.

APHIS does not believe that the new provisions will create an additional burden to entities that maintain biosafety level 3 and animal biosafety level 3 laboratories because we believe these entities are already performing such annual facility verifications. However, if a registered entity has not been performing annual facility verifications for biosafety level 3 and animal biosafety level 3 laboratories, we would be interested in comments concerning the cost and burden of annual facility verifications, especially if the entity is considered a small business.

Biosafety—Effluent Decontamination Systems

Biosafety level 3 and biosafety level 4 facilities are highly sophisticated facilities built to contain biological agents and toxins with the highest potential to threaten agricultural, plant, and public health and safety. Any defect, such as a crack or leaky pipe, could have severe consequences. For example, in August 2007, foot-and-mouth disease virus was discovered at farms in the United Kingdom. The source of the contamination was determined to be long-term damage and leakage of a drainage system used by a high-containment laboratory working with the foot-and-mouth disease virus. As such, APHIS is proposing to amend the security (7 CFR 331.11 and 9 CFR 121.11), biosafety (7 CFR 331.12 and 9 CFR 121.12), and incident response (7 CFR 331.14 and 9 CFR 121.14) sections of the select agent and toxin regulations to address risks posed by the effluent decontamination systems used by biosafety level 3 and biosafety level 4 facilities.

If an effluent decontamination system is used by an entity possessing and using select agents and toxins, to comply with the regulations, the entity would have to include in its plans how it will address security, biosafety, and incident response as it relates to the system. Specifically, the biosafety plan, to ensure it contains adequate biosafety and containment procedures, would have to provide for verification that the liquid waste generated from registered space is sufficiently treated to prevent the release of a select agent or toxin prior to discharge of the waste from the facility. The security plan, to ensure it contains adequate safeguards for select agents and toxins for any space not listed on the entity's registration that contains a portion of an effluent decontamination system, would have to describe procedures to prevent the theft, loss, release, or unauthorized access to a select agent or toxin. The incident response plan, to ensure it contains adequate response procedures, would have to fully describe the entity's response procedures for the theft, loss, or release of a select agent or toxin; the failure of an effluent decontamination system resulting in a release of a select agent or toxin; and how personnel will access an area potentially containing a select agent or toxin due to the failure of an effluent decontamination system.

Restricted Experiments

The regulations in 7 CFR 331.13 and 9 CFR 121.13 place restrictions on the experiments that registered entities or individuals may conduct and on their possession of products resulting from such experiments. Under the regulations, restricted experiments are experiments that involve the deliberate transfer of, or selection for, a drug or chemical resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, and experiments that involve the deliberate formation of synthetic or recombinant nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an $LD_{50} < 100$ ng/kg body weight.

Due to heightened biosafety concerns of research involving potential pandemic pathogens and emerging diseases, increased emphasis on oversight of products of restricted experiments is being proposed. To ensure that an entity has the appropriate safeguards to work with the product of a select agent or toxin resulting from a restricted experiment, APHIS is proposing to clarify the provision that the receiving entity of a transfer must amend their certificate of registration and receive approval by CDC or APHIS to possess the products of a restricted experiment. Entities are currently required to obtain approval to conduct restricted experiments and possess the product of a select agent or toxin resulting from a restricted experiment.

Training

The regulations in 9 CFR 121.15 require individuals or entities registered to possess, use or transfer select agents or toxins to provide information and training on biocontainement, biosafety, security, and incident response to individuals with access to select agents or toxins. APHIS is proposing revisions to the training requirements in accordance with the new mandate in the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (42 U.S.C. 262a(k)(1); Pub. L. 117–328) amendment of subsection (b)(1). These revisions have been made in an effort to comply with the statutory amendment that states training requirements for (1) unapproved individuals whose responsibilities routinely place them in close proximity to laboratory facilities and (2) those individuals who perform administrative or oversight functions. Trainings must be completed within 6 months after publication of a final rule for this proposed rulemaking.

Miscellaneous

We are proposing to remove the definition of the term *permit* from 7 CFR 331.1. We currently define the term as ''a written authorization by the Administrator to import or move interstate select agents or toxins, under conditions prescribed by the Administrator.'' However, the term is only used once in 7 CFR part 331, specifically in 7 CFR 331.11(c)(9)(i) and is used as a verb. Additionally, it is used in that one instance with the dictionary definition of allowing or authorizing an action to occur. For these reasons, the definition of the term *permit* serves no function and its removal is appropriate.

In 7 CFR 331.3(b), *Ralstonia solanacearum* is listed as a select agent. However, only *Ralstonia solanacearum* Race 3 biovar 2 poses a severe threat to plant health or plant products and merits inclusion on the list of select agents; other races and biovars are less pathogenic. We propose to amend this section accordingly.

The regulations in 7 CFR 331.3(e)(1), 9 CFR 121.3(e)(1), and 9 CFR 121.4(e)(1) currently refer to exclusions being posted to ''the National Select Agent Registry website.'' However, the name of the website has changed to ''the Federal Select Agent Program website.'' We propose to update the regulations accordingly.

Multiple regulations currently indicate that APHIS can receive reports received via facsimile. Due to the implementation of the eFSAP information system for official recordkeeping, this is no longer the case. We are proposing to amend the regulations accordingly.

Prior to issuance of a certificate of registration, we currently require that the responsible official must provide notification of any changes to the application for registration by submitting the relevant pages of the registration application (7 CFR 331.7(f); 9 CFR 121.7(f)). We propose to clarify that the submission should be the

relevant information that needs to be updated, rather than a particular page citation.

The regulations in 7 CFR 331.11(d)(4) and 9 CFR 121(d)(4) currently require registered individuals and entities to inspect all suspicious packages before they are brought into or removed from an area where select agents or toxins are used or stored. However, the presence of a suspicious package in any registered space, and not just the area where the select agents or toxins are used or stored, could represent a significant biosecurity and personal safety risk, and therefore, the presence of a suspicious package in any registered space should be inspected. We propose to amend the regulations accordingly.

In § 121.3, we are proposing revisions to footnotes 1, 4, and 5 to reflect the current understanding of the genomic structure and advancements in molecular characterization of infectious Newcastle disease virus and pigeon paramyxovirus in columbid birds.

Currently, § 121.11(f) requires pre-access suitability assessments and ongoing assessments of suitability for persons who will have access to a Tier 1 select agent or toxin at a registered entity. We are proposing to clarify that such assessments are needed for all employees authorized to have access to the Tier 1 select agent or toxin, whether or not they ever actually access the select agent or toxin. The current language can be interpreted that an ongoing assessment is only required for those who do access a Tier 1 select agent or toxin and not necessarily applicable to those individuals authorized for access but not currently accessing the Tier 1 agent space. This updated language will ensure all those authorized to have access will have ongoing assessments. The section is also updated to more clearly define requirements for visitor screening for security enhancements.

In that same section of the regulations (9 CFR 121.11(f)(5)(iii)), we currently require entities that possess foot-and-mouth disease virus and rinderpest virus to have closed circuit television, or CCTV. We are proposing to revise this to video surveillance, which may or may not be by CCTV. With the advances in video surveillance and options available, a broader video surveillance provision is being proposed.

Although we previously updated paragraph (b) of 9 CFR 121.3 to list avian influenza virus as a select agent, without reference to particular strains or pathogenicity, two references later in the regulations, in paragraph (f)(3)(i) of that same section and paragraph (c)(1) of 9 CFR 121.9, were not updated at that time to conform with that revised listing. We are proposing to update them accordingly.

Finally, although Newcastle disease virus is listed as a select agent regardless of virulence, in certain instances within part 121, requirements are stated to pertain to ''virulent'' Newcastle disease virus. To clarify that the requirements pertain to Newcastle disease virus in the broad sense, we are proposing to delete the word ''virulent'' in those instances.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

This proposed rule has been determined to be significant for the purposes of Executive Order 12866 as amended by Executive Order 14094, ''Modernizing Regulatory Review,'' and, therefore, has been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this proposed rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also examines the potential economic effects of this rulemaking on small entities, as required by the Regulatory Flexibility Act.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188) provides for the regulation of certain biological agents and toxins that have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products. The Animal and Plant Health Inspection Service (APHIS), Division of Agricultural Select Agents and Toxins (DASAT) has the primary responsibility for implementing the provisions of the Act with the United States Department of Agriculture (USDA). Within APHIS, Veterinary Services (VS) select agents and toxins, listed in 9 CFR 121.3, are those that have been determined to have the potential to pose a severe threat to animal health or animal products, and Plant Protection and Quarantine (PPQ) select agents and toxins, listed in 7 CFR 331.3, are those that have been determined to have the potential to pose a severe threat to plant health or plant products. Overlap select agents and toxins, listed in 9 CFR 121.4, are those that have been determined to pose a severe threat to public health and safety, to animal health, or to animal products. Overlap select agents and toxins are subject to regulation by both APHIS DASAT and the Centers for Disease Control and Prevention (CDC), Division of Regulatory Science and Compliance (DRSC), which has the primary responsibility for implementing the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 for the Department of Health and Human Services (HHS). Together, APHIS' DASAT and CDC's DRSC comprise the Federal Select Agent Program (FSAP).

Title II, Subtitle B of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (which is cited as the ''Agricultural Bioterrorism Protection Act of 2002'' and referred to below as the Act), section 212(a) (7 U.S.C. 8401(a)(1)), provides, in part, that the Secretary of Agriculture (the Secretary) must establish by regulation a list of each biological agent and each toxin that the Secretary determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products. Paragraph (a)(2) of section 212 of the Act (7 U.S.C. 8401(a)(2)) requires the Secretary to review and republish the list of select agents and toxins every two years and to otherwise revise the list as necessary. To fulfill this statutory mandate, APHIS convenes separate interagency working groups to review the list of PPQ and VS select agents and toxins, as well as any overlap select agents and toxins, and develop recommendations regarding possible changes to the list using the five criteria for listing found in the Act. APHIS and CDC coordinate on the biennial review for overlap select agents and toxins that have been determined to pose a severe threat to human and animal health or animal products.

Description of Proposed Rule

Pursuant to the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401(a)(2)), APHIS has completed its required biennial review of the current list of select agents and toxins in 7 CFR 331.3 (PPQ select agents), 9 CFR 121.3 (VS select agents), and 9 CFR 121.4 (overlap select agents overseen jointly with CDC). This proposed rule would implement the recommendations of the interagency working groups with respect to the list of select agents and toxins. APHIS, in conjunction with CDC, proposes removing the following overlap select

agents: *Brucella abortus, Brucella suis,* and *Brucella melitensis.* APHIS proposes removing one VS select agent, African horse sickness virus. APHIS also proposes removing one PPQ select agent, *Peronosclerospora philippinensis,* also known as *Peronosclerospora sacchari.*

Public response showed overwhelming support for the proposed delisting, particularly for the Brucella agents. Therefore, for reasons set forth in the ANPR and further articulated in the proposed rule that this economic analysis accompanies, we consider it appropriate to propose to delist the agents.

In addition to the delisting of some select agents, APHIS is also proposing several amendments to the select agent and toxin regulations and several corrections to fix editorial errors. The amendments are summarized as follows:

- *Discovery of Select Agents and Toxins:* We are proposing a definition for the term *Discovery,* clarifying that an individual or entity in possession of a select agent or toxin for which an exclusion or exemption listed in 9 CFR part 121 or 7 CFR part 331 does not apply, and that is not included on a certificate of registration, must immediately report such possession to either the APHIS Administrator or HHS Secretary, and creating a new APHIS/CDC Form 6 to facilitate reporting of discoveries.
- *Disposal of Select Agent Waste After Conclusion of Patient Care:* This proposes to codify a current operational policy that, for an individual who has been admitted to a medical facility, that individual's ''conclusion of patient care'' and the point when ''delivery of patient care by health care professionals has concluded'' is when an individual is released from the medical facility where treatment was being provided by the medical facility or physician.
- *Exclusion of Animals Naturally Infected with Select Agents:* We are proposing to codify the current operational policy regarding when animals naturally infected with select agents are excluded from the requirements of the regulations.
- *Inactivation:* We are proposing to clarify what constitutes an acceptable ''validated inactivation procedure,'' including revising the existing definition of the term; add a new exclusion 7 CFR 331.3(d), 9 CFR 121.3(d), and 9 CFR 121.4(d) that would exclude any select agent or regulated nucleic acid that can produce infectious forms of any select agent virus if the material is contained in a formalin-fixed paraffin-embedded tissue or fixed to slides (*e.g.,* Gram stain) that has been effectively inactivated by a recognized method; and codify a policy that allows individuals besides the responsible official to revise the inactivation procedures.
- *Removal:* We are proposing to codify an operational exclusion in 7 CFR 331.3(d)(5), 9 CFR 121.3(d)(5), and 9 CFR 121.4(d)(5) regarding material containing a select agent that is subjected to a validated viable select agent removal procedure, revise the definition of *Viability testing protocol,* and add a definition for the term *Verification viability testing protocol.*
- *Loss, Release, and Theft:* APHIS proposes to add definitions for the terms *Loss, Release,* and *Theft.*
- *Recordkeeping:* We are proposing amendments to the recordkeeping requirements in 7 CFR 331.17 and 9 CFR 121.17 to ensure an accurate, current inventory is maintained for all select agents and toxins held in long-term storage and address intra-agency transfer. APHIS is also proposing several revisions to the records needed for inactivated or select agent-free material created by an entity and to clarify throughout the regulations that whenever an entity is registered to possess, use, or transfer a select agent or toxin, the entity is required to meet all of the regulatory requirements for those select agents and toxins listed on the entity's certificate of registration regardless of whether the select agent or toxin is in the actual possession of the entity and without regard to the amount of toxin in possession.
- *Electronic Federal Select Agent Program (eFSAP) Information System:* We are proposing to add references to eFSAP's electronic data submission and management procedures throughout the regulations.
- *Registration:* We are clarifying the conditions under which issuance of a certificate of registration may be contingent and that amendment of a certification of registration to reflect changes in circumstances is mandatory.
- *Responsible Official and Alternate Responsible Official:* We are proposing to clarify that a responsible official is precluded from serving as the primary responsible official for two separate registered entities. We are also clarifying that a responsible official cannot be the sole alternate responsible official at another registered entity, but that an alternate responsible official at one entity may be approved to be an alternate responsible official at another registered entity.
- *Annual Internal Inspections:* We are proposing to codify current policy on what an entity's annual internal inspections must address.
- *Tier 1 Security Enhancements:* We are proposing to clarify that registered entities that possess Tier 1 select agents must have procedures for screening any visitors, their property, and, where appropriate, vehicles at entry points to registered space based on the entity's site-specific risk assessment.
- *Biosafety—Facility Verification:* We are proposing to amend 7 CFR 331.12 and 9 CFR 121.12 to require facility verification every 12 months for registered entities that maintain biosafety level 3 and animal biosafety level 3 laboratories.
- *Biosafety—Effluent Decontamination System:* We are proposing to amend the security (7 CFR 331.11 and 9 CFR 121.11), biosafety (7 CFR 331.12 and 9 CFR 121.12), and incident response (7 CFR 331.14 and 9 CFR 121.14) sections of the select agent and toxin regulations to address risks posed by the effluent decontamination systems used by high and maximum-containment laboratories.
- *Restricted Experiments:* We are proposing to add a provision that an individual or entity must submit a written request to CDC or APHIS prior to the transfer or possession of the products of restricted experiments.

Overview of the Action and Affected Entities

There are 236 entities registered with APHIS and CDC. Of these entities, there are 13 Private entities, 30 Federal entities, 42 Commercial entities, 84 Academic entities, and 67 State entities. Of these, less than 4 percent of all entities within these NAICS categories are considered to be small entities. The delisting of several select agents and the proposed amendments to the select agent and toxins regulations are anticipated to economically benefit producers, research and reference laboratories, and State and Federal oversight agencies, while also maintaining adequate program oversight of select agents and toxins, while minimizing additional costs to adherence. Below we provide a benefit-cost analysis, as required by Executive Orders 12866, 13563, and 14094, to examine the potential economic effects of the rule on small entities.

Expected Benefits and Costs of the Proposed Rule

Costs for regulated entities to implement the changes contemplated in this proposed rule are expected to be very modest. For example, APHIS is proposing to add a provision that an individual or entity must submit a written request to CDC or APHIS prior to the transfer or possession of the

products of restricted experiments. (Restricted experiments are experiments that involve the deliberate transfer of, or selection for, a drug or chemical resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, and experiments that involve the deliberate formation of synthetic or recombinant nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight.)

This request is likely to take minimal time, less than a few minutes per request for these entities to provide, but could inform and result in a rapid mitigation if the products are accidently exposed to the natural environment. The written request is simply checking a box on a form that has already been readily available to them.

Additionally, there are benefits of reducing the risks of the unintended release of select of select agents and toxins. For example, Kaufman et. al., 1997 estimated the economic impacts of a bioterrorist attack at approximately $26.2 billion per 100,000 people exposed to the release of the anthrax select agent. Additionally, many regulated entities have been requesting some of the amendments, particularly the delisting of *Brucella* species. State Veterinarians have expressed concern regarding the limitation on *brucellosis* research because of the designation of *Brucella* as a select agent.

Livestock producer organizations and the United States Animal Health Association (USAHA) have emphasized the need for continued research on an improved *B. abortus* vaccine and development of a *B. suis* vaccine, as well as improved diagnostics for both agents. Regulatory restrictions prohibit vaccine trials using natural transmission models, limit the opportunity for large animal studies, inhibit available surveillance, and prohibit studies that would evaluate vaccine or diagnostic product efficacy through comingling vaccinated and naturally infected animals. These limitations increase disease management costs for State and Federal governments as well as livestock producers.

One previous example of the public requesting delisting of a select agent for research purposes was Valley Fever or *Coccidiodes spp.* Until October 2012, Valley Fever or *Coccidiodes spp.* had been listed as a select agent by both USDA and HHS as a level 3 pathogen, but due to financial difficulties for researchers to provide a biosafety three laboratory to conduct desperately needed clinical and environmental research, research was limited. Now research is taking place, and doctors and medical personnel are more familiar with it and understand that climate change is contributing to this disease in California, and research is ongoing along with outreach to inform potential infected citizens. Again, due to the high cost of laboratory requirements for select agents as mentioned above for Valley fever and other select agents, the appropriate research and field studies could not take place, thus hampering new information and research to limit or stop the spread of the disease or at least inform the public of its method of infection. Very few laboratories have the resources or ability to do research on select agents due to costs of containment and facility needs required by the regulations.

There is currently limited courier availability for these five select agent shipments, which has resulted in prohibitive shipment costs for many laboratories. The increased shipment costs have inhibited isolate sharing between reference and research laboratories, thus leading to decreased advancements from researchers and laboratories involved in diagnostic improvements and disease eradication efforts. Removing the three Brucella agents (*B. abortus, B. suis,* and *B. melitensis*), as overlap select agents and one VS agent, African horse sickness virus, along with one plant agent, *Peronosclerospora philippinensis,* from the list of select agents and toxins would thus economically benefit producers, research and reference laboratories, and State and Federal oversight agencies. We welcome comments from the public if there are any reasons we should not be delisting these select agents.

APHIS' proposed amendment to require facility verification every 12 months for registered entities that maintain biosafety level 3 and animal biosafety level 3 laboratories is not anticipated to create an additional burden to entities that maintain biosafety level 3 and animal biosafety level 3 laboratories. APHIS reached this conclusion as we understand that these entities are already performing such annual facility verifications. Level 3 facilities are a highly regulated industry (at the Federal, State, and local level) with significant start-up and maintenance costs. It is highly likely that these are being monitored multiple times a week, if only for safety reasons. Also, many of the facilities operate, at least in part, on grants that are conditioned on demonstrating routine maintenance checks. However, APHIS has specifically requested comments concerning the cost and burden of annual facility verifications, especially if the entity is considered a small business, and will reevaluate as appropriate.

APHIS has proposed several amendments to the select agent and toxin regulations related to security, biosafety, and incident response to address risks posed by the effluent decontamination systems used by Level 3 and level 4-containment laboratories. Level 3 and level 4-containment laboratories are highly sophisticated facilities built to contain biological agents and toxins with the highest potential to threaten agricultural, plant, and public health and safety. Any defect, such as a crack or leaky pipe, could have severe consequences. For example, in August 2007, foot-and-mouth disease virus was discovered at farms in the United Kingdom. The source of the contamination was determined to be long-term damage and leakage of a drainage system used by a high-containment laboratory working with the foot-and-mouth disease virus. APHIS does not believe this proposal will cause an undue burden to regulated entities. The regulations already require that entities prepare a security plan that is sufficient to safeguard the select agent or toxin against theft, loss, or release and unauthorized access, a biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use, and an incident response plan based upon a site-specific risk assessment. These facilities are well versed in the security, biocontainment, and incident response measures that are necessary.

Therefore, making changes to their current security, biocontainment, and incident response plans, as applicable, is not expected to cause a burden to these facilities other than the time it takes to develop the plans—if not previously done—and clearly describe the procedures to address the risks posed by the effluent decontamination systems. We have estimated that adherence to future security, biocontainment, and incident response plans could take as little as a few hours to no longer than a day. Additionally, the procedures needed are, in most cases, well-known and currently being implemented by entities with these effluent decontamination systems because lack of such procedures could potentially result in millions/billions of dollars in damages if a select agent or toxin was accidentally released into the natural environment. Once again, APHIS would be interested in comments concerning the cost and

burden of annual security plans, especially if the entity is considered a small business.

APHIS is also proposing that an entity must submit a written request to APHIS or CDC prior to the transfer or possession of products of restricted experiments. Restricted experiments are experiments that involve the deliberate transfer of, or selection for, a drug or chemical resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, and experiments that involve the deliberate formation of synthetic or recombinant nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight. Again, we do not believe this proposed requirement will negatively impact these highly sophisticated entities other than the time requirement it takes to send a written request for the transfer or possession of products of restricted experiments. APHIS would once again welcome feedback regarding the burden of providing written requests prior to the transfer of restricted items, especially if the entity is considered a small business.

Lastly, as described above, this proposed rule will codify several current policies that entities have already implemented, specifically, policies related to the disposal of select agent waste after conclusion of patient care, the exclusion appliable to animals naturally infected with a select agent, who can revise inactivation procedures, and matters that an entity's annual internal inspection must address. APHIS has no reason to believe that continued adherence to these polices would negatively impact regulated entities going forward. In contrast, APHIS believes codification of the current policies adds clarity and consistency across facilities, which benefits the security of select agents and toxins.

As described, any impacts of the proposed changes to the list of select agents and toxins are expected to be beneficial for the affected industries.

Small-Entity Prevalence

Entities that possess, use, or transfer certain plant, animal, or human select agents or toxins would either benefit or be unaffected by this rulemaking. Potentially affected entities include laboratories, other research institutions, and related entities in possession of select agents or toxins. Affected entities (other than Federal and State governmental entities) are likely found within the following North American Industry Classification System (NAICS) categories:

541714, Research and Development in Biotechnology.

541715, Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology);

325412, Pharmaceutical Preparation Manufacturing;

325413, In-Vitro Diagnostic Substance Manufacturing;

325414, Biological Product (except Diagnostic) Manufacturing;

541940, Veterinary Services;

611310, Colleges, Universities and Professional Schools;

621511, Medical Laboratories;

622110, General Medical and Surgical Hospitals.

The Small Business Administration (SBA) has established small-entity size standards based on the NAICS categories. An entity classified within NAICS 541714 or NAICS 541715 is considered small with 1,000 or fewer employees, and one within NAICS 325412, 325413, or 325414 is considered small with 1,250 or fewer employees. An entity in NAICS 541940 is considered small with annual receipts of $8 million or less, and an entity in NAICS 611310 is considered small with annual receipts of not more than $30 million. Entities classified within NAICS 621511 are considered to be small if they have annual receipts of not more than $35 million. An entity classified within NAICS 622110 is considered to be small with annual receipts of not more than $41.5 million.

While the breakdown of the size of the establishments, as reported by the 2017 Economic Census, does not precisely fit the SBA guidelines, the data indicate that the vast majority of the entities in industries potentially affected by this proposed rule, other than post-secondary institutions, can be considered large entities. In other words, over 96 percent of all firms included in the above mentioned NAICS codes are large entities meaning only approximately 4 percent of these firms are small entities. According to the 2017 Economic Census, the most recent census data available for all entities, 96 percent of entities in NAICS 541714 and 541715, 49 percent of entities in NAICS 325412, 19 percent of entities in NAICS 325413, 25 percent of entities in NAICS 325414, 100 percent of entities in NAICS 541940, 87 percent of entities in NAICS 621511, 93 percent of entities in NAICS 611310, and 97 percent of entities in NAICS 622110 and can be classified as large.

TABLE 1—PREVALENCE OF SMALL/LARGE ENTITIES WITHIN AFFECTED INDUSTRIES

NAICS code	Number of firms		Annual revenue, receipts, or value of shipments	
SBA Small-entity Standard based on Employment.	<1,000 Employees small entities.	1,000+ Employees large entities.	<1,000 Employees small entities.	1,000+ Employees large entities.
541714 R&D in Biotechnology (commercial and non-profit) 3,109 firms.	438	2,671	$20.6 m	$24.5b.
541715 R&D in the Life Sciences (commercial and non-profit) 8,019 firms.	0	8,019	$0	$96.8.
	<1,250 Employees	1,250+ Employees	<1,250 Employees	1,250+ Employees.
325412 Pharmaceutical Preparation	494	513	$1.9b	$152.7b.
325413 In-vitro Diagnostic Substance.	153	35	$1b	$12.6b.
325414 Biological Product (except Diagnostic).	197	67	$1.4b	$29.2b.
SBA Small-entity Standard based on Annual Receipts.	<$8 million in Receipts employees.	$8 million+ in Receipts employees.	<$8 million in Receipts	$8 million+ in Receipts.
541940 Veterinary Services 42 b receipts.	0	28,291	$0	$42.1 b.
SBA Small-entity Standard based on Annual Receipts.	<$35 million in Receipts employees.	$35 million+ in Receipts employees.	<$35 million in Receipts	$35 million+ in Receipts.
621511 Medical Laboratories 35.6b	438	2,927	$22.m	$35.6b.
SBA Small-entity Standard based on Annual Receipts.	<$30 million in Receipts employees.	$30 million+ in Receipts employees.	<$30 million in Receipts	$30 million+ in Receipts.
611310 Colleges, Universities, and Professional Schools.	168	2,265	7.9 m	255.6 b.
SBA Small-entity Standard based on Annual Receipts.	<$41.5 million in Receipts employees.	$41.5 million+ in Receipts employees.	<$41.5 million in Receipts	$41.5 million+ in Receipts.
622110 General Medical and Surgical Hospitals.	65	2,495	$35.5 m	$997.3 b.

The analysis above shows the potential costs of the proposed rule to be slight. The benefits will of the proposed rule will accrue to all firms, most of which (96 percent) included in the above mentioned NAICS codes are large entities meaning only approximately 4 percent of these firms are small entities. Very few entities registered for select agents and toxins are considered small and because there are so few small entities, the proposed rule is not expected to have a significant economic impact on small entities.

Alternatives to the Rule

Status Quo—Not Delisting

APHIS convenes separate interagency working groups in order to review the list of PPQ and VS select agents and toxins, as well as any overlap select agents and toxins, and develop recommendations regarding possible changes to the list using the five criteria for listing found in the Act. APHIS and CDC coordinate on the biennial review for overlap select agents and toxins that have been determined to pose a severe threat to human and animal health or animal products. The proposed changes are based on the recommendations of the interagency working groups.

Maintaining the status quo would mean foregoing continued research on an improved *B. abortus* vaccine and development of a *B. suis* vaccine, as well as improved diagnostics for both agents. Regulatory restrictions prohibit vaccine trials using natural transmission models, limit the opportunity for large animal studies, inhibit available surveillance, and prohibit studies that would evaluate vaccine or diagnostic product efficacy through comingling vaccinated and naturally infected animals. These limitations increase disease management costs for State and Federal governments as well as livestock producers.

Not Codifying Policies

One alternative to the proposed rule considered by APHIS was not to propose to codify the current operational policies listed above and just delist the proposed select agents. However, we decided to propose codification for the sake of consistency with CDC and transparency with our stakeholders. The proposed changes are currently operationalized, and codification of the policies has been recommended by various governmental entities.

Without codification we would not have transparency and consistency throughout agencies which is important when requiring strict adherence to our proposed regulatory policies for select agents; thus we have rejected the alternative to not codify our operational policies that are closely coordinated between APHIS and CDC.

APHIS convenes separate interagency working groups in order to review the list of PPQ and VS select agents and toxins, as well as any overlap select agents and toxins, and develop recommendations regarding possible changes to the list using the five criteria for listing found in the Act. APHIS and CDC coordinate on the biennial review for overlap select agents and toxins that have been determined to pose a severe threat to human and animal health or animal products. The proposed changes are based on the recommendations of the interagency working groups.

Maintaining the status quo would mean foregoing continued research on an improved *B. abortus* vaccine and development of a *B. suis* vaccine, as well as improved diagnostics for both agents. Regulatory restrictions prohibit vaccine trials using natural transmission models, limit the opportunity for large animal studies, inhibit available surveillance, and prohibit studies that would evaluate vaccine or diagnostic product efficacy through comingling vaccinated and naturally infected animals. These limitations increase disease management costs for State and Federal governments as well as livestock producers.

The analysis above shows the potential costs of the proposed rule to

be slight. The benefits of the proposed rule will accrue to all firms, most of which (96 percent) included in the above mentioned NAICS codes are large entities, meaning only approximately 4 percent of these firms are small entities. Very few entities registered for select agents and toxins are considered small and because there are so few small entities, the proposed rule is not expected to have a significant economic impact on small entities.

Objectives of and Legal Basis for the Rule

Pursuant to the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401(a)(2)), APHIS has completed its required biennial review of the current list of select agents and toxins in 7 CFR 331.3 (PPQ select agents), 9 CFR 121.3 (VS select agents), and 9 CFR 121.4 (overlap select agents overseen jointly with CDC). This proposed rule will implement the recommendations of the interagency working groups with respect to the list of select agents and toxins. APHIS, in conjunction with CDC, proposes removing the following overlap select agents: *Brucella abortus, Brucella suis, and Brucella melitensis.* APHIS proposes removing one VS select agent, African horse sickness virus. APHIS also proposes removing one PPQ select agent, *Peronosclerospora philippinensis,* also known as *Peronosclerospora sacchari.*

Projected Reporting, Recordkeeping, and Other Compliance Requirements

New regulatory compliance, reporting and recordkeeping requirements associated with the information collection in this proposed rule are discussed above in the section on expected benefits and costs of the proposed rule. Those requirements are also discussed in the rule under the heading ''Paperwork Reduction Act.''

Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments.'' Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. What follows is a summary of such coordination to date.

The Animal and Plant Health Inspection Service (APHIS) has assessed the impact of this proposed rule on Indian Tribes by soliciting tribal feedback on its provisions. On April 8, 2022, APHIS sent tribal nations a letter outlining the provisions of the proposed rule and soliciting their feedback. On May 5, 2022, the Sac and Fox Tribe of the Mississippi in Iowa submitted a response expressing concerns regarding whether possible *Brucella abortus* delisting would materially adversely impact APHIS' domestic quarantine program for the control and eradication of brucellosis in cattle and bison. In response, APHIS clarified that the two issues were distinct, and no adverse operational impacts were anticipated. On June 6, 2022, the Tribe indicated that they have no further comments or concerns. To date, no other Tribes have expressed concerns regarding the proposed rule. Therefore, the Agency has determined that this proposed rule does not, to our knowledge, have Tribal implications that require formal Tribal consultation under Executive Order 13175. If a Tribe requests consultation, the Animal and Plant Health Inspection Service will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR Chapter IV.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule (1) preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

FSAP is the collaboration of the CDC's Division of Regulatory Science and Compliance (DRSC) and the APHIS Division of Agricultural Select Agents and Toxins (DASAT) to administer the select agent and toxin regulations in a manner to minimize the administrative burden on persons subject to the select agent and toxin regulations. The Federal select agent activities managed by APHIS are described in 7 CFR part 331 and 9 CFR part 121; otherwise, they are managed by the CDC in 42 CFR part 73.

Both agencies are concurrently publishing proposed rules in this issue of the **Federal Register** [1] with changes to the select agent and toxin regulations, and the changes are uniform, as applicable, across all three sets of regulations. In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the CDC is reporting, as the sponsoring agency, information collection requirements to the Office of Management and Budget under OMB control number 0920–0576, Possession, Use, and Transfer of Select Agents and Toxins. Reportable activities include requests for exclusions, reports of identification of a select agent or toxin, requests of exemption, applications for registration, amendments to a certificate of registration, documentation of self-inspection, requests for expedited review, security plans, biosafety plans, requests regarding restricted experiments, incident response plans, training, requests to transfer select agents and toxins, recordkeeping, notifications of theft, loss, or release; and administrative reviews. There are no new activities in this proposed rule. There are an estimated 3,656 hours of burden associated with this program.

Information about information collection 0920–0576 may be obtained from the *www.reginfo.gov* website or from Ms. Lori Bane, Deputy Director, Division of Select Agents and Toxins, Center for Preparedness and Response, Centers for Disease Control and Prevention, at (404) 718–2006. APHIS and CDC will respond to any ICR-related comments in the final rule. All comments will also become a matter of public record.

E-Government Act Compliance

APHIS is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. FSAP utilizes a highly secure eFSAP information system to conduct select agent and toxin program activities and the information system is a two-way communication portal accessible by both CDC and APHIS staff and the regulated community. APHIS estimates 100 percent of the total responses can be

[1] Go to *www.regulations.gov* and enter CDC–2020–0024 in the Search field.

processed electronically. For users at registered entities, benefits of the system include reduced paperwork, increased ease of validating and submitting information, and reduced processing time for requests (as real-time information exchange allows for increased responsiveness). Both APHIS and CDC collect information from reports (*e.g.,* APHIS/CDC Forms 2, 3, and 4) and requests (*e.g.,* amendments to registration) submitted via the eFSAP information system.

For assistance with E-Government Act compliance related to this proposed rule, please contact Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851–2483, or the individual listed under **FOR FURTHER INFORMATION CONTACT**.

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List of Subjects

7 CFR Part 331

Agricultural research, Laboratories, Plant diseases and pests, Reporting and recordkeeping requirements.

9 CFR Part 121

Agricultural research, Animal diseases, Laboratories, Medical research, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 7 CFR part 331 and 9 CFR part 121 as follows:

TITLE 7—AGRICULTURE

PART 331—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

■ 1. The authority citation for part 331 continues to read as follows:

Authority: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, and 371.3.

■ 2. Amend § 331.1 by:
■ a. Adding in alphabetical order definitions for ''Discovery'' and ''Loss'';
■ b. Removing the definition for ''Permit'';
■ c. Adding in alphabetical order definitions for ''Release'' and ''Theft'';
■ d. Revising the definition for ''Validated inactivation procedure'';
■ e. Adding in alphabetical order definitions for ''Validated removal procedure'' and ''Verification viability testing protocol''; and
■ f. Revising the definition for ''Viability testing protocol''.

The additions and revisions read as follows:

§ 331.1 Definitions.

* * * * *

Discovery. The finding of a select agent or toxin by an individual or entity that is not aware of the select agent or toxin's existence. Examples include, but are not limited to the following:

(1) A registered individual or entity finds a select agent or toxin not accounted for in their purpose inventory; or

(2) A non-registered individual or entity finds a select agent or toxin.

* * * * *

Loss. The inability to account for a select agent or toxin known to be in the individual or entity's possession.

* * * * *

Release means any of the following:

(1) An incident resulting in occupational exposure to a select agent or toxin;

(2) An incident resulting in animal/plant exposure to a select agent or toxin;

(3) The failure of equipment used to contain a select agent or toxin such that it is reasonably anticipated that a select agent of toxin was released;

(4) The failure of or breach in personal protective equipment in the presence of a select agent or toxin; or

(5) The failure of biosafety procedures such that it is reasonably anticipated that a select agent or toxin was outside of containment.

* * * * *

Theft. The unauthorized taking and removing of a select agent or toxin from the possession of an entity or individual.

* * * * *

Validated inactivation procedure. A procedure, whose efficacy has been confirmed by data generated from an in-house viability testing protocol, to render a select agent non-viable but allows the select agent to retain characteristics of interest for future use;

or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.

Validated removal procedure. A procedure, whose efficacy has been confirmed by data generated in-house from a viability testing protocol, to confirm removal of all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.

* * * * *

Verification viability testing protocol. A protocol, used on samples that have been subjected to a validated inactivation or removal procedure, to confirm the material is free of all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.

Viability testing protocol. A protocol, used on samples that have been subjected to a validated inactivation or removal procedure, to confirm the material is free of all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.

■ 3. Revise § 331.2 to read as follows:

§ 331.2 Purpose and scope.

(a) This part implements the provisions of the Agricultural Bioterrorism Protection Act of 2002 setting forth the requirements for possession, use, and transfer of select agents and toxins. The biological agents and toxins listed in this part have the potential to pose a severe threat to plant health or plant products.

(b) Any individual or entity in possession of a select agent or toxin, for which an exclusion or exemption listed in this part does not apply, and that is not included on a certificate of registration issued by the Administrator for that individual or entity, must immediately report such possession to the Administrator by the submission of an APHIS/CDC Form 6.

■ 4. Amend § 331.3 by:

■ a. Revising paragraphs (b) and (d)(4) through (6);

■ b. Redesignating paragraphs (d)(7) through (9) as paragraphs as (d)(8) through (10) and adding a new paragraph (d)(7);

■ c. In newly redesignated paragraph (d)(9), removing the words ''of the conclusion of patient care'' and adding the words ''from when the individual has been released from the medical facility where treatment was being provided'' in their place;

■ d. Revising newly redesignated paragraph (d)(10);

■ e. In paragraph (e)(1), removing the words ''National Select Agent Registry website'' and adding the words ''Federal Select Agent Program website'' in their place; and

■ f. In paragraph (f)(3), removing the words ''telephone, facsimile, or email'' and adding the words ''eFSAP information system, telephone, or email'' in their place in the second sentence.

The revisions and addition read as follows:

§ 331.3 PPQ select agents and toxins.

* * * * *

(b) PPQ select agents and toxins:

Coniothyrium glycines, (formerly *Phoma glycinicola, Pyrenochaeta glycines*);

Ralstonia solanacearum Race 3 biovar 2;

Rathayibacter toxicus;

Sclerophthora rayssiae;

Synchytrium endobioticum; and

Xanthomonas oryzae.

* * * * *

(d) * * *

(4) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure, provided that:

(i) In-house validation of the inactivation procedure is completed prior to use;

(ii) A certificate of inactivation has been generated in accordance with § 331.17(a)(8);

(iii) For use of a select agent surrogate is used to validate an inactivation procedure:

(A) Select agent surrogates must be known to possess equivalent properties with respect to inactivation;

(B) If there are known variations in the resistance of a select agent to an inactivation procedure, including strain to strain, then an inactivation procedure must also be validated using the most resistant select agent surrogate;

(iv) For use of whole plant tissue or homogenized plant tissue surrogate to validate a chemical inactivation procedure for other tissues including those in other plant models:

(A) All standardized conditions must be held constant such as the select agent used, plant tissue volume, and ratio of plant tissue to volume of inactivating chemical;

(B) A safety margin must be incorporated into the final chemical inactivation procedure to ensure the effective inactivation of the select agent;

(C) The tissue surrogate must meet the following criteria:

(*1*) The plant tissue is expected to have the highest concentration of the specific select agent to be inactivated; or

(*2*) The concentration of the select agent in the plant tissue must be determined and this select agent concentration must not be exceeded when applying the validated inactivation procedure on subsequent plant tissue samples.

(5) Material containing a select agent that is subjected to a validated viable select agent removal procedure that has rendered the material free of all viable select agent provided that:

(i) In-house validation of the viable select agent removal procedure is completed prior to use;

(ii) A certificate of viable select agent removal has been generated in accordance with § 331.17(a)(8);

(iii) For use of a surrogate to validate a viable select agent removal procedure, only surrogates known to possess equivalent properties with respect to removal are used;

(iv) A portion of each subsequent sample has been subjected to a verification viability testing protocol to ensure that the validated viable select agent removal procedure has rendered the material free of all viable select agent.

(6) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus not subjected to a validated inactivation procedure or material containing a select agent not subjected to a validated viable select agent removal procedure that removes all viable select agent cells, spores, or virus particles if the material is determined by the Administrator or HHS Secretary to be effectively inactivated or effectively removed. To apply for a determination, an individual or entity must submit a written request and supporting scientific information to APHIS. A written decision granting or denying the request will be issued.

(7) Any select agent or regulated nucleic acids that can produce infectious forms of any select agent virus contained in a formalin-fixed paraffin-embedded (FFPE) tissue if the FFPE process used is a recognized procedure for that particular select agent or regulated nucleic acids.

* * * * *

(10) All subspecies of *Sclerophthora rayssiae* except var. *zeae,* provided that the individual or entity can identify that the agent is within the exclusion category.

* * * * *

■ 5. Amend § 331.5 by:

■ a. Revising paragraphs (a) introductory text and (a)(1); and

■ b. In paragraph (a)(3), removing the words ''by telephone, facsimile, or email'' and adding the words ''through the eFSAP information system, telephone, or email'' in their place in the first sentence.

The revisions read as follows:

§ 331.5 Exemptions.

(a) Clinical or diagnostic laboratories and other entities that possess, use, or transfer a PPQ select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the Administrator, within 7 calendar days after identification of the select agent or toxin, the select agent or toxin is transferred in accordance with § 331.16 or destroyed on-site by a recognized sterilization process or inactivated for future use in accordance with § 331.3(d)(4).

* * * * *

■ 6. Amend § 331.7 by:

■ a. In paragraph (f), removing the words ''the relevant page(s) of'' and adding the words ''information related to'' in their place;

■ b. Revising paragraph (g);

■ c. In paragraph (i) introductory text, removing the word ''may'' and adding the word ''must'' in its place, and removing the word ''circumstances'' and adding the words ''the possession and use of the select agents and toxins'' in its place;

■ d. In paragraph (i)(1), removing the words ''the relevant page(s) of'' and adding the words ''information related to'' in their place and removing footnote 2.

The revision reads as follows:

§ 331.7 Registration and related security risk assessments.

* * * * *

(g) The issuance of a certificate of registration may be contingent upon inspection and submission of additional information to include any or all of the following: The security plan, biosafety plan, incident response plan, or any other documents related to the requirements of this part.

* * * * *

§ 331.8 [Amended]

■ 7. Amend § 331.8, in paragraph (a)(3), by redesignating footnote 3 as footnote 1.

■ 8. Amend § 331.9 by:

■ a. Redesignating paragraphs (a)(5) through (9) as paragraphs (a)(6) through (10) and adding a new paragraph (a)(5);

■ b. Revising newly redesignated paragraphs (a)(7), (9), and (10);

■ c. Adding a new second sentence to paragraph (b); and

■ d. Revising paragraph (c)(1).

The addition and revisions read as follows:

§ 331.9 Responsible official.

(a) * * *

(5) Not be approved as Responsible Official or alternate Responsible Official at another registered entity.

* * * * *

(7) Ensure that annual inspections are conducted for each registered space to determine compliance with the requirements in accordance with the regulations of this part. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected and the corrections documented. The annual inspection must address whether:

(A) The entity's biosafety/biocontainment plan is being effectively implemented as outlined in § 331.12.

(B) The entity's security plan is being effectively implemented as outlined in § 331.11.

(C) The entity's incident response plan is implemented to ensure whether the entity is able to respond, as outlined in § 331.14.

(D) Each individual with access approval from the Administrator or HHS Secretary has received the appropriate training as outlined in § 331.15.

* * * * *

(9) Investigate to determine the reason for any failure of a validated inactivation or validated viable select agent removal procedure to render material free from viable select agent. If the responsible official is unable to determine the cause of the failure from a validated inactivation or validated viable select agent removal procedure or receives a report of any inactivation failure after the movement of material to another location, the responsible official must report immediately through the eFSAP information system, telephone, or email the inactivation or viable select agent removal procedure failure to APHIS or CDC.

(10) Review each of the entity's validated select agent inactivation procedure or validated viable select agent removal procedure and ensure they are revised as necessary. The review must be conducted annually or after any change in principal investigator, change in the validated inactivation or validated viable select agent removal procedure, or failure of the validated inactivation or validated viable select agent removal procedure. The review must be documented, and training must be conducted if there are any changes to the validated select agent inactivation or validated viable select agent removal procedure, or viability testing protocol.

(b) * * * An alternate responsible official can serve at multiple registered entities. * * *

* * * * *

(c) * * *

(1) The identification of the select agent or toxin must be immediately reported through the eFSAP information system, telephone, or email. The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within 7 calendar days after identification. A copy of the completed form not submitted through eFSAP information system must be maintained for 3 years.

* * * * *

§ 331.10 [Amended]

■ 9. Amend § 331.10, in paragraph (c), by removing the words ''access to select agents or toxins'' and adding the words ''approval from the Administrator or HHS Secretary'' in their place.

■ 10. Amend § 331.11 by:

■ a. Redesignating paragraphs (c)(9) and (10) as (c)(10) and (11) and adding a new paragraph (c)(9);

■ b. In paragraph (d)(4), removing the words ''an area where select agents or toxins are used or stored'' and adding the words ''registered space'' in their place; and

■ c. Removing paragraph (g) and redesignating paragraph (h) as paragraph (g).

The addition reads as follows:

§ 331.11 Security.

* * * * *

(c) * * *

(9) Describe procedures to prevent the theft, loss, release, or unauthorized access to a select agent or toxin from an effluent decontamination system originating from a registered laboratory.

* * * * *

■ 11. Amend § 331.12 by:

■ a. In paragraph (a) introductory text, redesignating footnote 4 as footnote 1.

■ b. Removing paragraph (c)(1) and redesignating paragraph (c)(2) as paragraph (c)(1);

■ c. Adding a new reserved paragraph (c)(2); and

■ d. Adding paragraphs (f), (g), and (h).

The additions read as follows:

§ 331.12 Biocontainment.

* * * * *

(c) * * *

(2) [Reserved]

* * * * *

(f) When an effluent decontamination system is used, the plan must provide for verification that the liquid waste generated from registered space is sufficiently treated to prevent the

release of a select agent or toxin prior to discharge of the waste from the facility.

(1) For a new effluent decontamination system, verification is required before initial use.

(2) For an effluent decontamination system in place, verification is required at least once every 12 months and following any major change to the effluent decontamination system.

(3) The verification must be documented.

(g) When an effluent decontamination system is used, the plan must provide that monthly routine maintenance is conducted of the effluent decontamination system, including at a minimum verification that:

(1) Alarms are functioning according to established specifications;

(2) Piping, pumps, valves, and tanks are not leaking; and

(3) Methods used to monitor and record performance measurements are functioning according to established specifications.

(h) An individual or entity must document every 12 months the following facility verification requirements for registered biosafety level 3 and animal biosafety level 3 laboratories.

(1) Accuracy of devices that monitor directional air-flow;

(2) Confirmation that decontamination systems (*e.g.,* autoclave, room decontamination systems, digesters, liquid effluent decontamination systems) are operating to ensure the containment of the select agent and toxin;

(3) Confirmation that systems are in place to monitor, maintain, and validate performance of mechanical systems to ensure that airflows and differential pressures are appropriate to maintain containment during normal/operational conditions;

(4) Verification that the facility mechanical, electrical, and drain waste and ventilation systems responsible for containment are inspected, maintained, and function as designed by the manufacturer specifications;

(5) Verification that the facility systems perform as intended in response to failure conditions as defined and tested during commissioning to prevent the release of a select agent or toxin and verification of secondary containment:

(i) Evaluate using work objectives, use of space, and facility infrastructure systems against the verified original design and standards (*e.g.,* Biosafety in Microbiological and Biomedical Laboratories, NIH Design Requirements Manual).

(ii) Implement controls and alarms to identify and alert personnel when systems fail, malfunction, or are unable to maintain containment during such an event.

(6) Certification of laboratory ventilation system HEPA filters, if present;

(7) Confirmation that room integrity has been evaluated and repairs are addressed (*e.g.,* sealed penetrations);

(8) Primary containment equipment is certified based on manufacturer's specifications (or recommendations) (*e.g.,* biological safety cabinets, flexible film isolators, animal caging);

(9) Seals on centrifuges not used in primary containment have been checked and replaced if needed; and

(10) Showers, eye wash stations, and hands-free sinks are operating properly.

§ 331.13 [Amended]

■ 12. Amend § 331.13, in paragraph (a) introductory text, by adding the words ''or transfer'' after the word ''possess''.

■ 13. Amend § 331.14 by:

■ a. In the section heading, redesignating footnote 5 as footnote 1;

■ b. In paragraph (a), redesignating footnote 6 as footnote 2;

■ c. In paragraph (b), adding the words ''the failure of an effluent decontamination system resulting in a release of a select agent or toxin;'' after the words ''a select agent or toxin;''; and

■ d. Revising paragraph (c).

The revision reads as follows:

§ 331.14 Incident response [1].

* * * * *

(c) The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such select agent or toxin in registered space including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent, or an effluent decontamination system originating from registered space.

* * * * *

[1] Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

■ 14. Amend § 331.15 by:

■ a. In paragraph (d), revising the last sentence; and

■ b. In paragraph (e), removing the words ''and document.''

The addition reads as follows:

§ 331.15 Training.

* * * * *

(d) * * * The record must include the name of the individual who received the training, the date of the training, a description of the training provided, and the means used to verify that the individual understood the training.

* * * * *

§ 331.16 [Amended]

■ 15. Amend § 331.16, in paragraph (a), by redesignating footnote 7 as footnote 1.

■ 16. Amend § 331.17 by:

■ a. Revising paragraphs (a)(1), (3), and (8);

■ b. Removing the last sentence in paragraph (c); and

■ c. Adding paragraph (d).

The revisions and addition read as follows:

§ 331.17 Records.

(a) * * *

(1) An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including:

(i) The name and characteristics (*e.g.,* strain designation, GenBank Accession number);

(ii) The quantity acquired from another individual or entity (*e.g.,* containers, vials, tubes), date of acquisition, by whom, and the source;

(iii) Location where it is stored (*e.g.,* building, room number or name, and freezer identification or other storage container);

(iv) The date the agent was removed and returned, the purpose for using the agent, the name of the individual who removed and returned the agent, and when applicable, date of final disposition of the agent and by whom;

(v) Records created under § 331.16;

(vi) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), name of the select agent, the date of the transfer, the number of items transferred, the name of the sender, and the name of the recipient; and

(vii) Records created under § 331.19.

* * * * *

(3) Accurate, current inventory for each toxin held, including:

(i) The name and characteristics;

(ii) The quantity acquired from another individual or entity (*e.g.,* containers, vials, tubes, volume including concentration), date of acquisition, by whom, and the source;

(iii) The initial and current amount (*e.g.,* milligrams, milliliters, grams);

(iv) Location where the toxin is stored (*e.g.,* building, room number or name, and freezer identification or other storage container);

(v) When the toxin was accessed, the name of the toxin, the location where the toxin was accessed, the date the toxin was accessed, the purpose for accessing the toxin, the name of the individual accessing the toxin, the date the toxin was returned back to storage, the name of the individual returning the toxin back to storage, and date of final disposition of the toxin and by whom;

(vi) Records created under § 331.16;

(vii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), name of the toxin, the date of the transfer, the number of vials or quantity of toxin transferred, the name of the sender, and the name of the recipient; and

(viii) Records created under § 331.19.

* * * * *

(8) For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a validated viable select agent removal procedure:

(i) A written description of the validated inactivation procedure or validated viable select agent removal procedure used, including validation data;

(ii) A written description of the viability testing protocol used;

(iii) A written description of the investigation conducted by the entity's responsible official involving a validated inactivation or validated viable select agent removal failure and the corrective actions taken;

(iv) The name of each individual performing the validated select agent inactivation or validated viable select agent removal;

(v) The date(s) the validated inactivation or validated viable select agent removal was completed;

(vi) The location where the validated inactivation or validated viable select agent removal was performed; and

(vii) A signed certificate that must:

(A) Include the date(s) the validated inactivation or validated viable select agent removal was completed.

(B) Include the validated inactivation procedure or validated viable select agent removal procedure used.

(C) Include the name of the principal investigator.

(D) Include an attestation statement certifying that the information on the certificate is true, complete, and accurate, and that the validated inactivation or validated viable select agent removal was performed as described in paragraph (a)(8)(i) of this section.

(E) Be signed by the principal investigator or designee within 7 days after completion of the validated inactivation or validated viable select agent removal. Such designee must be listed on the entity's registration and have the knowledge and expertise to provide scientific and technical direction regarding the validated inactivation procedure or the validated viable select agent removal procedure to which the certificate refers.

(F) Be maintained for as long as the material is in the possession of the registered individual or entity plus an additional 3 years.

(G) A copy of the certificate must accompany all transfers of inactivated or select agent removed material including intra-entity transfers.

* * * * *

(d) All records created in accordance with the regulations of this part must be maintained for 3 years unless otherwise stated.

§ 331.19 [Amended]

■ 17. Amend § 331.19, in paragraphs (a)(1) introductory text and (b)(1) introductory text, by removing the words ''telephone, facsimile, or e-mail'' and adding the words ''eFSAP information system, telephone, or email'' in their place.

TITLE 9—ANIMALS AND ANIMAL PRODUCTS

PART 121—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

■ 18. The authority citation for part 121 continues to read as follows:

Authority: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, and 371.4.

■ 19. Amend § 121.1 by:

■ a. Adding in alphabetical order definitions for ''Discovery'', ''Loss'', ''Release'', and ''Theft'';

■ b. Revising the definition of ''Validated inactivation procedure'';

■ c. Adding in alphabetical order definitions for ''Validated removal procedure'' and ''Verification viability testing protocol''; and

■ d. Revising the definition of ''Viability testing protocol''.

The additions and revisions read as follows:

§ 121.1 Definitions.

* * * * *

Discovery. The finding of a select agent or toxin by an individual or entity that is not aware of the select agent or toxin's existence. Examples include, but are not limited to the following:

(1) A registered individual or entity finds a select agent or toxin not accounted for in their inventory; or

(2) A non-registered individual or entity finds a select agent or toxin.

* * * * *

Loss. The inability to account for a select agent or toxin known to be in the individual or entity's possession.

* * * * *

Release means any of the following:

(1) An incident resulting in occupational exposure to a select agent or toxin;

(2) An incident resulting in animal/plant exposure to a select agent or toxin;

(3) The failure of equipment used to contain a select agent or toxin such that it is reasonably anticipated that a select agent of toxin was released;

(4) The failure of or breach in personal protective equipment in the presence of a select agent or toxin; or

(5) The failure of biosafety procedures such that it is reasonably anticipated that a select agent or toxin was outside of containment.

* * * * *

Theft. The unauthorized taking and removing of a select agent or toxin from the possession of an entity or individual.

* * * * *

Validated inactivation procedure. A procedure, whose efficacy has been confirmed by data generated from an in-house viability testing protocol, to render a select agent non-viable but allows the select agent to retain characteristics of interest for future use; or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.

Validated removal procedure. A procedure, whose efficacy has been confirmed by data generated in-house from a viability testing protocol, to confirm removal of all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.

* * * * *

Verification viability testing protocol. A protocol, used on samples that have been subjected to a validated inactivation or removal procedure, to confirm the material is free of all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.

Viability testing protocol. A protocol to confirm the efficacy of the inactivation or removal procedure by demonstrating the material is free of all viable select agent.

* * * * *

■ 20. Revise § 121.2 to read as follows:

§ 121.2 Purpose and scope.

(a) This part implements the provisions of the Agricultural Bioterrorism Protection Act of 2002 setting forth the requirements for possession, use, and transfer of select agents and toxins. The biological agents and toxins listed in this part have the potential to pose a severe threat to public health and safety, to animal health, or to animal products. Overlap select agents and toxins are subject to regulation by both APHIS and CDC.

(b) Any individual or entity in possession of a select agent or toxin, for which an exclusion or exemption listed in this part does not apply, and that is not included on a certificate of registration issued by the Administrator or HHS Secretary for that individual or entity, must immediately report such possession to the either the Administrator or HHS Secretary by the submission of an APHIS/CDC Form 6.

■ 21. Amend § 121.3 by:

■ a. Revising paragraphs (b) and (d)(1), (4), (5), and (6);

■ b. Redesignating paragraphs (d)(7) through (9) as paragraphs as (d)(8) through (10) and adding a new paragraph (d)(7);

■ c. In newly redesignated paragraph (d)(9), removing the words ''of the conclusion of patient care'' and adding the words ''from when the individual has been released from the medical facility where treatment was being provided'' in their place;

■ d. In newly redesignated paragraph (d)(10), revising footnotes 4 and 5;

■ e. In paragraph (e)(1), removing the words ''National Select Agent Registry website'' and adding the words ''Federal Select Agent Program website'' in their place; and

■ f. In paragraph (f)(3)(i), removing the words ''telephone, facsimile, or email'' and adding the words ''eFSAP information system, telephone, or email'' in their place, and removing the words ''(highly pathogenic)'' and ''virulent''.

The revisions and addition read as follows:

§ 121.3 VS select agents and toxins.

* * * * *

(b) VS select agents and toxins: African swine fever virus; Avian influenza virus; Classical swine fever virus; * Foot-and-mouth disease virus; Goat pox virus; Lumpy skin disease virus; *Mycoplasma capricolum; Mycoplasma mycoides;* Newcastle disease virus; [1] Peste des petits ruminants virus; * Rinderpest virus; Sheep pox virus; Swine vesicular disease virus.

* * * * *

(d) * * *

(1) Any VS select agent or toxin that is in its naturally occurring environment, provided that the agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source. Except for,

(i) Removal of an animal which is naturally infected with a select agent from its natural environment to an artificially established environment for the purpose of the intentional exposure or introduction of a select agent to a naïve or experimental animal; or

(ii) the introduction of a naïve animal to a natural environment where there is an animal which is naturally infected with a select agent for the purpose of the intentional exposure or introduction of a select agent to the naïve or experimental animal.

* * * * *

(4) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure, provided that:

(i) In-house validation of the inactivation procedure is completed prior to use;

(ii) A certificate of inactivation has been generated in accordance with § 121.17(a)(8).

(iii) For use of a select agent surrogate to validate an inactivation procedure:

(A) Select agent surrogates must be known to possess equivalent properties with respect to inactivation;

(B) If there are known variations in the resistance of a select agent to an inactivation procedure, including strain to strain, then an inactivation procedure must also be validated using the most resistant select agent surrogate.

(iv) For use of whole tissue or homogenized tissue surrogate to validate a chemical inactivation procedure for other tissues including those in other animal models:

(A) All standardized conditions must be held constant such as the select agent used, tissue volume, and ratio of tissue to volume of inactivating chemical;

(B) A safety margin must be incorporated into the final chemical inactivation procedure to ensure the effective inactivation of the select agent;

(C) The tissue surrogate must meet one of the following criteria:

(*1*) The tissue is expected to have the highest concentration of the specific select agent to be inactivated; or

(*2*) The concentration of the select agent in the tissue must be determined and this select agent concentration must not be exceeded when applying the validated inactivation procedure on subsequent tissue samples.

(5) Material containing a select agent that is subjected to a validated viable select agent removal procedure that has rendered the material free of all viable select agent provided that:

(i) In-house validation of the viable select agent removal procedure is completed prior to use;

(ii) A certificate of viable select agent removal has been generated in accordance with § 121.17(a)(8);

(iii) For use of a surrogate to validate a viable select agent removal procedure, only surrogates known to possess equivalent properties with respect to removal are used;

(iv) A portion of each subsequent sample has been subjected to a verification viability testing protocol to ensure that the validated viable select agent removal procedure has rendered the material free of all viable select agent.

(6) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus not subjected to a validated inactivation procedure or material containing a select agent not subjected to a validated viable select agent removal procedure that removes all viable select agent cells, spores, or virus particles if the material is determined by the Administrator to be effectively inactivated or effectively free of select agents. To apply for a determination, an individual or entity must submit a written request and supporting scientific information to APHIS. A written decision granting or denying the request will be issued.

(*7*) Any select agent or regulated nucleic acids that can produce infectious forms of any select agent virus contained in a formalin-fixed paraffin-embedded (FFPE) tissue if the FFPE process used is a recognized procedure for that particular select agent or regulated nucleic acids.

* * * * *

[1] A virulent Newcastle disease virus (avian paramyxovirus type 1) has an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater, or has an amino acid sequence at the fusion (F) protein cleavage that is consistent with virulent strains of Newcastle disease virus and phenylalanine at residue 117 of the F1 protein N-terminus, except for genotype VI viruses from columbid birds.

* * * * *

[4] An avian paramyxovirus type 1 virus (APMV–1) isolated from poultry which has an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage that is consistent with

virulent strains of Newcastle disease virus and phenylalanine at residue 117 of the F1 protein N-terminus, except for genotype VI viruses from columbid birds.

[5] Pigeon paramyxovirus (PPMV–1) is a species-adapted APMV–1 virus which is endemic in pigeons and doves in the United States and can be identified through demonstration of the characteristic amino acid signature at the fusion gene cleavage site along with accompanying phylogenetic analysis confirming classification as a PPMV–1.

■ 22. Amend § 121.4 by:
■ a. Revising paragraph (b);
■ b. In paragraph (c)(1), redesignating footnote 6 as footnote 1;
■ c. Revising paragraph (d)(1);
■ d. In paragraph (d)(2), redesignating footnote 7 as footnote 2;
■ e. Revising paragraphs (d)(4) through (6);
■ f. Redesignating paragraphs (d)(7) through (9) as paragraphs as (d)(8) through (10) and adding a new paragraph (d)(7);
■ g. In newly redesignated paragraph (d)(9), removing the words ''of the conclusion of patient care'' and adding the words ''from when the individual has been released from the medical facility where treatment was being provided'' in their place;
■ h. In paragraph (e)(1), removing the words ''National Select Agent Registry website'' and adding the words ''Federal Select Agent Program website'' in their place in the last sentence;
■ i. Revising paragraph (f)(3)(i);
■ j. In paragraph (f)(3)(iii), adding the words ''not submitted through eFSAP Information System'' between the words ''APHIS/CDC Form 4'' and ''must''; and
■ k. In paragraph (f)(4), adding the words ''not submitted through eFSAP information system'' between the words ''form'' and ''must'' in the last sentence.

The revisions and addition read as follows:

§ 121.4 Overlap select agents and toxins.

* * * * *

(b) Overlap select agents and toxins: ** Bacillus anthracis; Bacillus anthracis* (Pasteur strain); ** Burkholderia mallei; * Burkholderia pseudomallei;* Hendra virus; * Nipah virus; and Rift Valley fever virus; and Venezuelan equine encephalitis virus.

* * * * *

(d) * * *

(1) Any overlap select agent or toxin that is in its naturally occurring environment, provided that the agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source. Except for,

(i) Removal of an animal which is naturally infected with a select agent from its natural environment to an artificially established environment for the purpose of the intentional exposure or introduction of a select agent to a naïve or experimental animal; or

(ii) The introduction of a naïve animal to a natural environment where there is an animal which is naturally infected with a select agent for the purpose of the intentional exposure or introduction of a select agent to the naïve or experimental animal.

* * * * *

(4) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure, provided that:

(i) In-house validation of the inactivation procedure is completed prior to use;

(ii) A certificate of inactivation has been generated in accordance with § 121.17(a)(8);

(iii) For use of a select agent surrogate to validate an inactivation procedure:

(A) Select agent surrogates must be known to possess equivalent properties with respect to inactivation;

(B) If there are known variations in the resistance of a select agent to an inactivation procedure, including strain to strain, then an inactivation procedure must also be validated using the most resistant select agent surrogate.

(iv) For use of a whole tissue or homogenized tissue surrogate to validate a chemical inactivation procedure for other tissues, including those in other animal models:

(A) All standardized conditions must be held constant, such as the select agent used, tissue volume, and ratio of tissue to volume of inactivating chemical;

(B) A safety margin must be incorporated into the final chemical inactivation procedure to ensure the effective inactivation of the select agent;

(C) The tissue surrogate must meet the following criteria:

(*1*) The tissue is expected to have the highest concentration of the specific select agent to be inactivated; or

(*2*) The concentration of the select agent in the tissue must be determined and this select agent concentration must not be exceeded when applying the validated inactivation procedure on subsequent tissue samples.

(5) Material containing a select agent that is subjected to a validated viable select agent removal procedure that has rendered the material free of all viable select agent provided that:

(i) In-house validation of the viable select agent removal procedure is completed prior to use;

(ii) A certificate of viable select agent removal has been generated in accordance with § 121.17(a)(8);

(iii) For use of a surrogate to validate a viable select agent removal procedure, only surrogates known to possess equivalent properties with respect to removal are used;

(iv) A portion of each subsequent sample has been subjected to a verification viability testing protocol to ensure that the validated viable select agent removal procedure has rendered the material free of all viable select agent.

(6) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus not subjected to a validated inactivation procedure or material containing a select agent not subjected to a validated viable select agent removal procedure that removes all viable select agent cells, spores, or virus particles if the material is determined by the Administrator or HHS Secretary to be effectively inactivated or effectively removed. To apply for a determination, an individual or entity must submit a written request and supporting scientific information to APHIS or CDC. A written decision granting or denying the request will be issued.

(7) Any select agent or regulated nucleic acids that can produce infectious forms of any select agent virus contained in a formalin-fixed paraffin-embedded (FFPE) tissue if the FFPE process used is a recognized procedure for that particular select agent or regulated nucleic acids.

* * * * *

(f) * * *

(3) * * *

(i) The seizure of any Tier 1 overlap select agents and toxins must be reported within 24 hours by eFSAP information system, telephone, or email, or email. This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after seizure of the overlap select agent or toxin.

* * * * *

■ 23. Amend § 121.5 by:
■ a. Revising paragraphs (a) introductory text and (a)(1);
■ b. In paragraph (a)(3), removing the words ''delivery of patient care by health care professionals has concluded'' and adding the words ''the individual has been released from the medical facility where treatment was being provided'' in their place;
■ c. In paragraph (a)(4), removing the words ''by telephone, facsimile, or email'' and adding the words ''through the eFSAP information system, telephone, or email'' in their place in the first sentence;

■ d. Adding paragraphs (a)(4)(i) and (ii);
■ e. Revising paragraph (b)(1); and
■ f. In paragraph (b)(3), adding the words ''not submitted through eFSAP information system'' between the words ''form'' and ''must'' in the last sentence.

The revisions and additions read as follows:

§ 121.5 Exemptions for VS select agents and toxins.

(a) Clinical or diagnostic laboratories and other entities that possess, use, or transfer a VS select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the Administrator, within 7 calendar days after identification of the select agent or toxin, the select agent or toxin is transferred in accordance with § 121.16 or destroyed on-site by a recognized sterilization process or inactivated for future use in accordance with § 121.3(d)(4).

* * * * *

(4) * * *

(i) The identification of VS Tier 1 select agents or toxins must be immediately reported through the eFSAP information system, telephone, or email. This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after identification.

(ii) [Reserved]

(b) * * *

(1) Unless directed otherwise by the Administrator, within 90 calendar days of receipt, the select agent or toxin is transferred in accordance with § 121.16 or destroyed on-site by a recognized sterilization process or inactivated for future use in accordance with § 121.3(d)(4).

* * * * *

■ 24. Amend § 121.6 by:
■ a. Revising paragraph (a)(1);
■ b. In paragraph (a)(3), removing the words ''delivery of patient care by health care professionals has concluded'' and adding the words ''the individual has been released from the medical facility where treatment was being provided'' in their place;
■ c. In paragraph (a)(4), removing the words ''by telephone, facsimile, or email'' and adding the words ''through the eFSAP information system, telephone, or email'' in their place in the first sentence;
■ d. Adding paragraphs (a)(4)(i) through (iv);
■ e. Revising paragraph (b)(1); and
■ f. In paragraph (b)(3), adding the words ''not submitted through eFSAP information system'' between the words ''form'' and ''must'' in the last sentence.

The revisions and additions read as follows:

§ 121.6 Exemptions for overlap select agents and toxins.

(a) * * *

(1) Unless directed otherwise by the Administrator or HHS Secretary, within 7 calendar days after identification, the select agent or toxin is transferred in accordance with § 121.16 or 42 CFR 73.16 or destroyed on-site by a recognized sterilization process, or inactivated for future use in accordance with § 121.4(d)(4);

* * * * *

(4) * * *

(i) The identification of any of the following overlap select agents or toxins must be immediately reported by telephone or email: *Bacillus anthracis, Burkholderia mallei* and *Burkholderia pseudomallei.* This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after identification.

(ii) For all other overlap select agents or toxins, APHIS/CDC Form 4 must be submitted within 7 calendar days after identification.

(iii) Less stringent reporting may be required during agricultural emergencies or outbreaks, or in endemic areas.

(iv) A copy of APHIS/CDC Form 4 must be maintained for 3 years.

(b) * * *

(1) Unless directed otherwise by the Administrator or HHS Secretary, within 90 calendar days of receipt, the select agent or toxin is transferred in accordance with § 121.16 or 42 CFR 73.16 or destroyed on-site by a recognized sterilization process or inactivated for future use in accordance with § 121.4(d)(4);

* * * * *

■ 25. Amend § 121.7 by:
■ a. In paragraph (d)(3) introductory text, redesignating footnote 8 as footnote 1;
■ b. In paragraph (f), removing the words ''the relevant page(s) of'' and adding the words ''information related to'' in their place;
■ c. Revising paragraph (g);
■ d. In paragraph (i) introductory text, removing the word ''may'' and adding the word ''must'' in its place, and removing the word ''circumstances'' and adding the words ''the possession and use of the select agents and toxins'' in its place; and
■ e. In paragraph (i)(1), removing the words ''the relevant page(s) of'' and adding the words ''information related to'' in their place and removing footnote 9.

The revision reads as follows:

§ 121.7 Registration and related security risk assessments.

* * * * *

(g) The issuance of a certificate of registration may be contingent upon inspection and submission of additional information to include any or all of the following: the security plan, biosafety plan, incident response plan, or any other documents related to the requirements of this part.

* * * * *

§ 121.8 [Amended]

■ 26. Amend § 121.8, in paragraph (a)(3), by redesignating footnote 10 as footnote 1.
■ 27. Amend § 121.9 by:
■ a. Redesignating paragraphs (a)(5) through (9) as paragraphs (a)(6) through (10) and adding a new paragraph (a)(5);
■ b. Revising newly redesignated paragraphs (a)(7), (9), and (10);
■ c. Adding a new second sentence to paragraph (b);
■ d. Revising paragraph (c)(1); and
■ e. In paragraphs (c)(2) and (d), adding the words ''not submitted through eFSAP information system'' between the words ''form'' and ''must'' in the last sentence.

The addition and revisions read as follows:

§ 121.9 Responsible official.

(a) * * *

(5) Not be approved as responsible official or alternate responsible official at another registered entity.

* * * * *

(7) Ensure that annual inspections are conducted for each registered space to determine compliance with the requirements in accordance with the regulations of this part. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected and the corrections documented. The annual inspection must address whether:

(A) The entity's biosafety/biocontainment plan is being effectively implemented as outlined in § 121.12.

(B) The entity's security plan is being effectively implemented as outlined in § 121.11.

(C) The entity's incident response plan is implemented to ensure whether the entity is able to respond, as outlined in § 121.14.

(D) Each individual with access approval from the Administrator or HHS Secretary has received the appropriate training as outlined in § 121.15.

* * * * *

(9) Investigate to determine the reason for any failure of a validated inactivation or validated viable select agent removal procedure to render material free from viable select agent. If the responsible official is unable to determine the cause of the failure from a validated inactivation or validated viable select agent removal procedure or receives a report of any inactivation failure after the movement of material to another location, the responsible official must report immediately through the eFSAP information system, telephone, or email the inactivation or viable select agent removal procedure failure to APHIS or CDC.

(10) Review each of the entity's validated select agent inactivation procedure or validated viable select agent removal procedure and ensure they are revised as necessary. The review must be conducted annually or after any change in principal investigator, change in the validated inactivation or validated viable select agent removal procedure, or failure of the validated inactivation or validated viable select agent removal procedure. The review must be documented, and training must be conducted if there are any changes to the validated select agent inactivation or validated viable select agent removal procedure, or viability testing protocol.

(b) * * * An alternate responsible official can serve at multiple registered entities. * * *

* * * * *

(c) * * *

(1) The identification of any of the following select agents or toxins must be immediately reported through the eFSAP information system, telephone, or email: African swine fever virus, avian influenza virus, *Bacillus anthracis, Burkholderia mallei, Burkholderia pseudomallei,* classical swine fever virus, foot-and-mouth disease virus, Newcastle disease virus, rinderpest virus, or swine vesicular disease virus. The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within 7 calendar days after identification. A copy of the completed form must be maintained for 3 years.

* * * * *

§ 121.10 [Amended]

■ 28. Amend § 121.10 by:

■ a. In paragraph (c), removing the words ''to select agents or toxins'' and adding the words ''approval from the Administrator or HHS Secretary'' in their place; and

■ b. In paragraph (h), removing the text ''(f)(2) through (f)(3)'' and adding the text ''(g)(2) through (3)'' in its place.

■ 29. Amend § 121.11 by:

■ a. Redesignating paragraphs (c)(9) and (10) as paragraphs (c)(11) and (12) and adding new paragraphs (c)(9) and (10);

■ b. In paragraph (d)(4), removing the words ''an area where select agents or toxins are used or stored'' and adding the words ''registered space'' in their place;

■ c. In paragraph (f) introductory text, removing the word ''possessing'' and adding the words ''registered for'' in their place;

■ d. Revising paragraph (f)(4)(iii);

■ e. In paragraph (f)(5)(iii), removing the ''CCTV'' and adding the word ''Video'' in its place; and

■ f. Removing paragraph (g) and redesignating paragraph (h) as paragraph (g).

The additions and revision read as follows:

§ 121.11 Security.

* * * * *

(c) * * *

(9) Describe procedures for conducting a pre-access suitability assessment of persons prior to seeking access approval for a Tier 1 select agent or toxin;

(10) Describe procedures to prevent the theft, loss, release, or unauthorized access to a select agent or toxin from an effluent decontamination system originating from a registered laboratory.

* * * * *

(f) * * *

(4) * * *

(iii) Procedures for screening any visitors, their property, and, where appropriate, vehicles at entry points to registered space based on the entity's site-specific risk assessment;

* * * * *

■ 30. Amend § 121.12 by:

■ a. In paragraph (a) introductory text, redesignating footnote 11 as footnote 1;

■ b. In paragraph (c)(1), removing the words ''National Select Agent Registry'' and adding the words ''Federal Select Agent Program website'' in their place;

■ c. In paragraph (c)(2), removing the words ''the internet'' and adding the words ''the Federal Select Agent Program website'';

■ d. Revising paragraph (d); and

■ e. Adding paragraphs (f), (g), and (h).

The revision and additions read as follows:

§ 121.12 Biosafety.

* * * * *

(d) The biosafety plan must include an occupational health plan for individuals listed on the entity's registration for access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health plan.

* * * * *

(f) When an effluent decontamination system is used, the plan must provide for verification that the liquid waste generated from registered space is sufficiently treated to prevent the release of a select agent or toxin prior to discharge of the waste from the facility.

(1) For a new effluent decontamination system, verification is required before initial use.

(2) For an effluent decontamination system in place, verification is required at least once every 12 months and following any major change to the effluent decontamination system.

(3) The verification must be documented.

(g) When an effluent decontamination system is used, the plan must provide that monthly routine maintenance is conducted of the effluent decontamination system, including at a minimum verification that:

(1) Alarms are functioning according to established specifications;

(2) Piping, pumps, valves, and tanks are not leaking; and

(3) Methods used to monitor and record performance measurements are functioning according to established specifications.

(h) An individual or entity must document every 12 months the following facility verification requirements for registered biosafety level 3 and animal biosafety level 3 laboratories.

(1) Accuracy of devices that monitor directional air-flow;

(2) Confirmation that decontamination systems (*e.g.,* autoclave, room decontamination systems, digesters, liquid effluent decontamination systems) are operating to ensure the containment of the select agent and toxin;

(3) Confirmation that systems are in place to monitor, maintain, and validate performance of mechanical systems to ensure that airflows and differential pressures are appropriate to maintain containment during normal/operational conditions;

(4) Verification that the facility mechanical, electrical, and drain waste and ventilation systems responsible for containment are inspected, maintained, and function as designed by the manufacturer specifications;

(5) Verification that the facility systems perform as intended in response to failure conditions as defined and tested during commissioning to prevent the release of a select agent or

toxin and verification of secondary containment:

(i) Evaluate using work objectives, use of space, and facility infrastructure systems against the verified original design and standards (*e.g.,* Biosafety in Microbiological and Biomedical Laboratories, NIH Design Requirements Manual).

(ii) Implement controls and alarms to identify and alert personnel when systems fail, malfunction, or are unable to maintain containment during such an event.

(6) Certification of laboratory ventilation system HEPA filters, if present;

(7) Confirmation that room integrity has been evaluated and repairs are addressed (*e.g.,* sealed penetrations);

(8) Primary containment equipment is certified based on manufacturer's specifications (or recommendations) (*e.g.,* biological safety cabinets, flexible film isolators, animal caging);

(9) Seals on centrifuges not used in primary containment have been checked and replaced if needed; and

(10) Showers, eye wash stations, and hands-free sinks are operating properly.

§ 121.13 [Amended]

■ 31. Amend § 121.13, in paragraph (a) introductory text, by adding the words ''or transfer'' after the word ''possess''.

■ 32. Amend § 121.14 by:

■ a. In the section heading, redesignating footnote 12 as footnote 1;

■ b. In paragraph (a), redesignating footnote 13 as footnote 2;

■ c. In paragraph (b), adding the words ''the failure of an effluent decontamination system resulting in a release of a select agent or toxin;'' after the words ''a select agent or toxin;'';

■ d. Revising paragraph (c); and

■ e. In paragraph (e) introductory text, removing the words ''Entities with'' and adding the words ''An individual or entity registered for'' in their place.

The revision reads as follows:

§ 121.14 Incident response[1].

* * * * *

(c) The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such select agent or toxin in registered space including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent, or an effluent decontamination system originating from registered space.

* * * * *

[1] Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

■ 33. Amend § 121.15 by:

■ a. Adding paragraphs (a)(3) and (4);

■ b. In paragraph (b), removing the words ''Entities with'' and adding the words ''An individual or entity registered for'' in their place;

■ c. Revising paragraph (d); and

■ d. In paragraph (e), by removing words ''and document''.

The additions and revision read as follows:

§ 121.15 Training.

(a) * * *

(3) Each individual not approved for access to HHS and overlap select agents and toxins by the HHS Secretary or APHIS Administrator whose responsibilities routinely place them in close proximity (*e.g.,* shared laboratory space) to areas where select agents or toxins are transferred, possessed, or used. The training must be based on the particular needs of the individual and risks associated with working near areas where select agents and toxins are handled or stored. The training must also instruct each individual on the notification requirements related to select agents and toxins. Training must be accomplished prior to the individual's close proximity to areas where select agents or toxins are handled or stored and refresher training must be provided annually.

(4) Each individual not approved for access to HHS and overlap select agents and toxins by the HHS Secretary or APHIS Administrator who performs administrative or oversight functions of the facility related to the transfer, possession or use of such agents or toxins on behalf of the entity (*e.g.,* administrative professionals, facility managers, etc.). The training must instruct each individual on the regulatory requirements relevant to their administrative or oversight functions. The training must also instruct each individual on the notification requirements related to select agents and toxins. Training must be accomplished prior to the individual performing these functions and refresher training must be provided annually.

* * * * *

(d) The Responsible Official must ensure a record of the training provided for each individual listed in paragraph (a) of this section is maintained. The record must include the name of the individual who received the training, the date of the training, a description of the training provided, and the means used to verify that the individual understood the training.

* * * * *

§ 121.16 [Amended]

■ 34. Amend § 121.16, in paragraph (a), by redesignating footnote 14 as footnote 1.

■ 35. Amend § 121.17 by:

■ a. Revising paragraphs (a)(1), (3), and (8);

■ b. Removing the last sentence in paragraph (c); and

■ c. Adding paragraph (d).

The revisions and addition read as follows:

§ 121.17 Records.

(a) * * *

(1) An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including:

(i) The name and characteristics (*e.g.,* strain designation, GenBank Accession number);

(ii) The quantity acquired from another individual or entity (*e.g.,* containers, vials, tubes), date of acquisition, by whom, and the source;

(iii) Location where it is stored (*e.g.,* building, room number or name, and freezer identification or other storage container);

(iv) The date the agent was removed and returned, the purpose for using the agent, the name of the individual who removed and returned the agent, and when applicable, date of final disposition of the agent and by whom;

(v) Records created under § 121.16;

(vi) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), name of the select agent, the date of the transfer, the number of items transferred, the name of the sender, and the name of the recipient; and

(vii) Records created under § 121.19.

* * * * *

(3) Accurate, current inventory for each toxin held, including:

(i) The name and characteristics;

(ii) The quantity acquired from another individual or entity (*e.g.,* containers, vials, tubes, volume including concentration), date of acquisition, by whom, and the source;

(iii) The initial and current amount (*e.g.,* milligrams, milliliters, grams);

(iv) Location where the toxin is stored (*e.g.,* building, room number or name, and freezer identification or other storage container);

(v) When the toxin was accessed, the name of the toxin, the location where the toxin was accessed, the date the

toxin was accessed, the purpose for accessing the toxin, the name of the individual accessing the toxin, the date the toxin was returned back to storage, the name of the individual returning the toxin back to storage, and date of final disposition of the toxin and by whom;

(vi) Records created under § 121.16;

(vii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), name of the toxin, the date of the transfer, the number of vials or quantity of the toxin transferred, the name of the sender, and the name of the recipient; and

(viii) Records created under § 121.19.

* * * * *

(8) For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a validated viable select agent removal procedure:

(i) A written description of the validated inactivation procedure or validated viable select agent removal procedure used, including validation data;

(ii) A written description of the viability testing protocol used;

(iii) A written description of the investigation conducted by the entity's responsible official involving a validated inactivation or validated viable select agent removal failure and the corrective actions taken;

(iv) The name of each individual performing the validated select agent inactivation or validated viable select agent removal;

(v) The date(s) the validated inactivation or validated viable select agent removal was completed;

(vi) The location where the validated inactivation or validated viable select agent removal was performed; and

(vii) A signed certificate that must:

(A) Include the date(s) the validated inactivation or validated viable select agent removal was completed.

(B) Include the validated inactivation procedure or validated viable select agent removal procedure used.

(C) Include the name of the principal investigator.

(D) Include an attestation statement certifying that the information on the certificate is true, complete, and accurate, and that the validated inactivation or validated viable select agent removal was performed as described in paragraph (a)(8)(i) of this section.

(E) Be signed by the principal investigator or designee within 7 days after completion of the validated inactivation or validated viable select agent removal. Such designee must be listed on the entity's registration and have the knowledge and expertise to provide scientific and technical direction regarding the validated inactivation procedure or the validated viable select agent removal procedure to which the certificate refers.

(F) Be maintained for as long as the material is in the possession of the registered individual or entity plus an additional 3 years.

(G) A copy of the certificate must accompany all transfers of inactivated or select agent removed material including intra-entity transfers.

* * * * *

(d) All records created in accordance with the regulations of this part must be maintained for 3 years unless otherwise stated.

§ 121.19 [Amended]

■ 36. Amend § 121.19, in paragraphs (a)(1) introductory text and (b)(1) introductory text, by removing the words ''telephone, facsimile, or email'' and adding the words ''eFSAP information system, telephone, or email'' in their place.

Done in Washington, DC, this 19th day of January 2024.

Jennifer Moffitt,

Undersecretary, Marketing and Regulatory Programs, USDA.

[FR Doc. 2024–01501 Filed 1–26–24; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 172

[FHWA Docket No. FHWA–2023–0046]

RIN 2125–AG12

Procurement, Management, and Administration of Engineering and Design Related Services

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: This proposed rule would update the regulations governing the procurement, management, and administration of engineering and design related services directly related to a highway construction project that is funded through a discretionary grant administered by FHWA. The intent of the proposed rule is to clarify how the regulations apply to recipients other than State transportation agencies (STA). This proposed rulemaking would also make technical changes and corrections to improve the administration of these regulations.

DATES: Comments must be received on or before April 1, 2024. Late comments will be considered to the extent practicable.

ADDRESSES: You may submit comments by any of the following methods:

- *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:* U.S. Department of Transportation, Docket Operations, 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; or
- *Electronically through the Federal eRulemaking Portal: www.regulations.gov.* Follow the online instructions for submitting comments.

FOR FURTHER INFORMATION CONTACT: Mr. John McAvoy, Consultant Services Program Manager, FHWA Office of Preconstruction, Construction, and Pavements, (202) 853–5593, or via email at *john.mcavoy@dot.gov,* or Mr. Lev Gabrilovich, Senior Attorney Advisor, FHWA Office of the Chief Counsel, (202) 366–3813, or via email at *lev.gabrilovich@dot.gov.* Office hours for the FHWA are from 8 a.m. to 4:30 p.m., ET, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document and all comments received may be viewed online through the Federal eRulemaking portal at *www.regulations.gov.* The website is available 24 hours each day, 366 days this year. Please follow the instructions. Electronic submission and retrieval help and guidelines are available under the help section of the website.

An electronic copy of this document may also be downloaded by accessing the Office of the Federal Register's home page at *www.FederalRegister.gov,* or the Government Printing Office's website at *www.GovInfo.gov.*

All comments received before the close of business on the comment closing date indicated above will be considered and will be available for examination in the docket at the above address. Comments received after the comment closing date will be filed in the docket and will be considered to the extent practicable. In addition to late

comments, FHWA will also continue to file relevant information in the docket as it becomes available after the comment period closing date and interested persons should continue to examine the docket for new material. A final rule may be published at any time after the close of the comment period and after FHWA has had the opportunity to review the comments submitted.

Background and Legal Authority

Through this NPRM, FHWA proposes to modify existing regulations for the administration of engineering and design related service contracts to clarify how the regulations apply to recipients other than STAs that are awarded FHWA-administered discretionary grants and to make technical amendments to improve the regulations. The FHWA, through the Federal-aid Highway Program (FAHP) and other programs administered under chapter 1 of title 23, United States Code (U.S.C.), provides financial resources and technical assistance to State and local governments and other public authorities for planning, design, constructing, operating, preserving, and improving public roads and other surface transportation infrastructure. The primary authority for the procurement, management, and administration of engineering and design related services funded with a highway construction grant administered under chapter 1 of 23 U.S.C. is codified at 23 U.S.C. 112(b)(2). Generally, each contract for engineering and design related services paid for with Federal funds and leading to a construction project must be awarded in accordance with the qualifications-based selection procedures prescribed in the Brooks Act (40 U.S.C. 1101 *et seq.*) and must accept and apply consultant indirect cost rates established by a cognizant Federal or State agency in accordance with the Federal Acquisition Regulation (FAR) cost principles (48 CFR part 31). The FHWA promulgated 23 CFR part 172 as a means of implementing the Brooks Act. Part 172 defines and illustrates specific responsibilities of an STA and its subrecipients (entities that receive a subaward from their STA).

The Infrastructure Investment and Jobs Act, (Pub. L. 117–58) also known as the ''Bipartisan Infrastructure Law,'' (BIL) provided $550 billion over fiscal years 2022 through 2026 in new Federal investment in roads, bridges, mass transit, water infrastructure, resilience improvements, and broadband. The BIL provides approximately $350 billion for Federal highway programs.

Statement of the Problem

Most of the funding in the BIL for highway projects is distributed to STAs based on formulas specified in Federal law. However, the BIL also provides funding through a wide range of discretionary grant programs, including the ''Rebuilding American Infrastructure with Sustainability and Equity'' (RAISE) program, the ''Nationally Significant Multimodal Freight and Highway Projects'' (INFRA) program, the ''National Infrastructure Project Assistance Program'' (MEGA), the ''Safe Streets and Roads for All'' (SS4A) program, and others. Each of these discretionary grant programs has its own eligibility requirements, but for many programs, entities other than STAs are eligible to apply for and receive grant awards. For example, under the RAISE grant program, in addition to STAs, eligible entities include U.S. territories, Metropolitan Planning Organizations (MPO), federally recognized Indian Tribes, local governments, and other public authorities.[1] The SS4A grants are only available to MPOs, political subdivisions of a State, and federally recognized Indian Tribes.[2]

When a recipient other than an STA is awarded a discretionary grant under the programs described above, the award is made through an executed grant agreement with DOT rather than as a subaward from the STA. This non-STA recipient is responsible for compliance with all Federal regulations pertaining to the grant, including those covering the procurement of professional services. In their current form, the regulations at 23 CFR part 172 could be interpreted as applying to all recipients of discretionary grants administered under chapter 1 of 23 U.S.C., not just STAs. Consequently, non-STA recipients would be responsible for compliance with part 172, including the requirement that recipients prepare and maintain written policies and procedures for the procurement, management, and administration of engineering and design related consultant services. However, the requirements of 23 U.S.C. 112(b)(2), and therefore 23 CFR part 172, apply only to the procurement, management, and administration of engineering and design related consultant services for projects ''under [the] supervision'' of an STA.[3] This includes projects administered by entities other than STAs when these entities are subrecipients of STAs but not when these entities are recipients of an award directly from DOT, and FHWA did not intend for 23 CFR part 172 to apply beyond the scope of 23 U.S.C. 112(b)(2). Non-STA recipients that receive or are eligible to receive discretionary grant funds directly from FHWA do not necessarily have FHWA-approved written policies and procedures in place for the procurement of professional services that comply with 23 CFR part 172, and creating these policies and procedures from scratch would create an undue burden on non-STA recipients and FHWA. By removing any ambiguity regarding the applicability of 23 CFR part 172, this NPRM proposes to clarify the responsibilities of the non-STA recipients to remain compliant with Federal regulations while reducing unnecessary regulatory burden.

Section-by-Section Discussion of the Proposals

The FHWA proposes to revise 23 CFR part 172–Administration of Engineering and Design Related Service Contracts as follows:

Authority Citation

The FHWA proposes to revise the authority citation for 23 CFR part 172 to remove the reference to 23 U.S.C. 402. Part 172 no longer applies to programs and activities authorized under 23 U.S.C. 402, and the remaining authorities cited provide the necessary authority for 23 CFR part 172; therefore, citation to 23 U.S.C. 402 is unnecessary.

Section 172.1—Purpose and Applicability

Section 172.1 would be amended to clarify that the provisions of 23 CFR part 172 apply only to STAs and their subrecipients.

Section 172.3—Definitions

In section 172.3, the definitions for the terms ''Consultant'' and ''Subconsultant'' would be modified to remove outdated citations to 2 CFR part 200 that formerly contained definitions of ''Recipient'' and ''Subrecipient.'' The proposed rule would add definitions for ''Recipient'' and ''Subrecipient'' and give those terms the same meaning as they are defined in 2 CFR 200.1. Finally, the definition of ''Contracting agencies'' would be revised to eliminate reference to ''other recipients.''

Section 172.5—Program Management and Oversight

Section 172.5 would be amended to remove the references to ''recipient'' and ''other recipient'' to clarify that the

[1] 49 U.S.C. 6702(a)(2).

[2] BIL, sec. 24112(a)(2).

[3] 23 U.S.C. 112(a).

regulations apply only to STAs and their subrecipients. Also, a reference to a provision in 2 CFR part 200 would be revised to reflect the current location of that provision in 2 CFR part 200.

Section 172.7—Procurement Methods and Procedures

Section 172.7 would be amended to remove the references to ''recipient'' and ''other recipient'' to clarify the applicability of the regulations only to STAs and their subrecipients. Also, references to a provision in 2 CFR part 200 would be revised to reflect the current location of that provision in 2 CFR part 200.

Section 172.9—Procurement Methods and Procedures

Section 172.9 would be amended to remove a reference to ''recipient'' to clarify the applicability of the regulations only to STAs and their subrecipients. A reference to a provision in 2 CFR part 200 would be revised to reflect the current location of that provision in 2 CFR part 200. Also, a typographical error in an internal cross-reference in § 172.9(a)(3)(iv)(B)(*1*) will be corrected. The regulation in this paragraph currently references § 172.5(a)(1)(ii); the corrected reference would read § 172.7(a)(1)(ii).

Section 172.11—Allowable Costs and Oversight

Section 172.11 would be amended to remove references to ''recipient'' and ''other recipient,'' and where appropriate, substitute ''STA'' to clarify that the regulations apply only to STAs and their subrecipients.

Rulemaking Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

The FHWA has considered the impacts of this rule under Executive Order (E.O.) 12866 (58 FR 51735, Oct. 4, 1993), Regulatory Planning and Review, as amended by E.O. 14094 (''Modernizing Regulatory Review''), and DOT's regulatory policies and procedures. This proposed rule complies with E.O. 12866 and E.O. 13563 to improve regulation. The Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB) has determined that this rulemaking is not a significant regulatory action under section 3(f) of E.O. 12866. Accordingly, OMB has not reviewed it under that E.O.

It is anticipated that the proposed rule would not be economically significant for purposes of E.O. 12866. The proposed rule would not have an annual effect on the economy of $200 million or more. The proposed rule would not adversely affect in a material way the economy, any sector of the economy, productivity, competition, or jobs. In addition, the proposed changes would not interfere with any action taken or planned by another Agency and would not materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612), FHWA has evaluated the effects of this proposed rule on small entities, such as local governments and businesses. Based on the evaluation, FHWA anticipates that this action would not have a significant economic impact on a substantial number of small entities. The proposed rule would clarify the applicability of the requirements for the procurement, management, and administration of engineering and design related services that use FHWA-administered funding and are directly related to a construction project. Specifically, the proposed rule would clarify that the regulations in 23 CFR part 172 do not apply to recipients of FHWA-administered grants that are not STAs. Consequently, the economic impact of this proposed rule on small entities is expected to be minimal. Therefore, FHWA certifies that the proposed action would not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This proposed rule would not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 109 Stat. 48). The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires Federal Agencies to prepare a written statement, which includes estimates of anticipated impacts, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $183 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. This rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $183 million or more in any one year (2 U.S.C. 1532). Further, in compliance with the Unfunded Mandates Reform Act of 1995, FHWA will evaluate any regulatory action that might be proposed in subsequent stages of the proceeding to assess the effects on State, local, and Tribal governments and the private sector. In addition, the definition of ''Federal Mandate'' in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal Government. The FAHP and other FHWA-administered financial assistance impacted by this proposed rule permit this type of flexibility.

Executive Order 13132 (Federalism Assessment)

The E.O. 13132 requires Agencies to ensure meaningful and timely input by State and local officials in the development of regulatory policies that may 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. The FHWA has analyzed this proposed rule in accordance with the principles and criteria contained in E.O. 13132. The FHWA has determined that this proposed rule would not have sufficient federalism implications to warrant the preparation of a federalism assessment. The FHWA has also determined that this proposed rule would not preempt any State law or State regulation or affect the States' ability to discharge traditional State governmental functions.

Paperwork Reduction Act

Federal Agencies must obtain approval from OMB for each collection of information they conduct, sponsor, or require through regulations. This proposed action does not contain a collection of information requirement for the purpose of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*).

National Environmental Policy Act

The FHWA has analyzed this rule pursuant to the National Environmental Policy Act (NEPA) and has determined that it is categorically excluded under 23 CFR 771.117(c)(20), which applies to the promulgation of rules, regulations, and directives. Categorically excluded actions meet the criteria for categorical exclusions under the Council on Environmental Quality regulations and under 23 CFR 771.117(a) and normally do not require any further NEPA approvals by FHWA. This proposed rule

would clarify the applicability of FHWA regulations governing the requirements for the procurement, management, and administration of engineering and design related services that use FHWA-administered grant funding and are directly related to a construction project. The FHWA does not anticipate any adverse environmental impacts from this rule; moreover, no unusual circumstances are present under 23 CFR 771.117(b).

Executive Order 13175 (Tribal Consultation)

The FHWA has analyzed this proposed action under E.O. 13175, dated November 6, 2000, and believes that this proposed action would not have substantial direct effects on one or more Indian Tribes, would not impose substantial direct compliance costs on Indian Tribal governments, and would not preempt Tribal law. This proposed rule would clarify the applicability of FHWA regulations governing the requirements for the procurement, management, and administration of engineering and design related services that use FHWA-administered grant funding and are directly related to a construction project. As such, this proposed rule would not impose any direct compliance requirements on Indian Tribal governments nor would it have any economic or other impacts on the viability of Indian Tribes. Therefore, a Tribal summary impact statement is not required.

Executive Order 12898 (Environmental Justice)

The E.O. 12898 requires that each Federal Agency make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minorities and low-income populations. The FHWA has determined that this proposed rule does not raise any environmental justice issues.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 172

Government procurement, Grant programs—transportation, Highways and roads.

Shailen P. Bhatt,

Administrator, Federal Highway Administration.

For the reasons stated in the preamble, FHWA proposes to amend title 23, Code of Federal Regulations, part 172, as follows:

PART 172—PROCUREMENT, MANAGEMENT, AND ADMINISTRATION OF ENGINEERING AND DESIGN RELATED SERVICES

■ 1. The authority citation for part 172 is revised to read as follows:

Authority: 23 U.S.C. 106, 112, 114(a), 302, and 315; 40 U.S.C. 1101 *et seq.;* 48 CFR part 31; 49 CFR 1.48(b); and 2 CFR part 200.

■ 2. Amend § 172.1 by revising the fourth sentence and adding a sentence at the end of the section. The revision and addition read as follows:

§ 172.1 Purpose and applicability.

* * * State transportation agencies (STA) shall ensure that subrecipients comply with the requirements of this part and the Uniform Administrative Requirements, Cost Principles and Audit Requirements For Federal Awards rule. * * * The provisions of this part shall only apply to State transportation agencies and their subrecipients.

■ 3. Amend § 172.3 as follows:

■ a. Revise the definitions for *Consultant* and *Contracting agencies;*

■ b. Add a definition in alphabetical order for *Recipient;*

■ c. Revise the definition of *Subconsultant;* and

■ b. Add a definition in alphabetical order for *Subrecipient.*

The revisions and additions read as follows:

§ 172.3 Definitions.

* * * * *

Consultant means the individual or firm providing engineering and design related services as a party to a contract with a recipient or subrecipient of Federal assistance.

* * * * *

Contracting agencies means a State transportation agency or a procuring agency of the State acting in conjunction with and at the direction of the State transportation agency and all subrecipients that are responsible for the procurement, management, and administration of engineering and design related services.

* * * * *

Recipient has the same meaning as defined in 2 CFR 200.1.

* * * * *

Subconsultant means the individual or firm contracted by a consultant to provide engineering and design related or other types of services that are part of the services which the consultant is under contract to provide to a recipient or subrecipient (as defined in of Federal assistance.

Subrecipient has the same meaning as defined in 2 CFR 200.1.

■ 4. Amend § 172.5 by revising paragraph (a) introductory text, the third sentence of paragraph (a)(4), paragraph (b)(1) introductory text, the second and third sentences of paragraph (c) introductory text, and paragraph (c)(15) to read as follows:

§ 172.5 Program management and oversight.

(a) *STA responsibilities.* STAs shall develop and sustain organizational capacity and provide the resources necessary for the procurement, management, and administration of engineering and design related consultant services, reimbursed in whole or in part with FAHP funding, as specified in 23 U.S.C. 302(a). Responsibilities shall include the following:

* * * * *

(4) * * * Nothing in this part shall be taken as relieving the STA of its responsibility under laws and regulations applicable to the FAHP for the work performed under any consultant agreement or contract entered into by a subrecipient.

(b) * * *

(1) Adopting written policies and procedures prescribed by the awarding STA for the procurement, management, and administration of engineering and design related consultant services in accordance with applicable Federal and State laws and regulations; or when not prescribed, shall include:

* * * * *

(c) * * * The FHWA shall approve the written policies and procedures, including all revisions to such policies and procedures, of the STA to assess compliance with applicable requirements. The STA shall approve the written policies and procedures, including all revisions to such policies and procedures, of a subrecipient to assess compliance with applicable requirements. * * *

* * * * *

(15) Retaining supporting programmatic and contract records, as

specified in 2 CFR 200.334 and the requirements of this part;

* * * * *

■ 5. Amend § 172.7 by revising paragraph (a)(1)(iv)(F), the first sentence of paragraph (a)(1)(v)(E), paragraph (b)(1)(i), and the first sentence of paragraph (b)(5)(i) to read as follows:

§ 172.7 Procurement methods and procedures.

(a) * * *

(1) * * *

(iv) * * *

(F) The contracting agency shall retain supporting documentation of the solicitation, proposal, evaluation, and selection of the consultant in accordance with this section and the provisions of 2 CFR 200.334.

(v) * * *

(E) The contracting agency shall retain documentation of negotiation activities and resources used in the analysis of costs to establish elements of the contract in accordance with the provisions of 2 CFR 200.334. * * *

* * * * *

(b) * * *

(1) * * *

(i) STAs and their subrecipients shall comply with procurement requirements established in State and local laws, regulations, policies, and procedures that are not addressed by or are not in conflict with applicable Federal laws and regulations, as specified in 2 CFR part 1201.

* * * * *

(5) * * *

(i) When FAHP funds participate in a consultant services contract, the contracting agency shall receive approval from FHWA, or the STA, as appropriate, before utilizing a consultant to act in a management support role for the contracting agency; unless an alternate approval procedure has been approved. * * *

* * * * *

■ 6. Amend § 172.9 by revising paragraph (a)(3)(iv)(B)(*1*), paragraph (c)(1)(iv), and paragraph (d)(1)(vii) to read as follows:

§ 172.9 Contracts and administration.

(a) * * *

(3) * * *

(iv) * * *

(B) * * *

(*1*) Through an additional qualifications-based selection procedure, which may include, but does not require, a formal RFP in accordance with § 172.7(a)(1)(ii); or

* * * * *

(c) * * *

(1) * * *

(iv) Access by the STA, subrecipient, FHWA, the U.S. Department of Transportation's Inspector General, the Comptroller General of the United States, or any of their duly authorized representatives to any books, documents, papers, and records of the consultant which are directly pertinent to that specific contract for the purpose of making audit, examination, excerpts, and transcriptions;

* * * * *

(d) * * *

(1) * * *

(vii) Documenting contract monitoring activities and maintaining supporting contract records, as specified in 2 CFR 200.334.

* * * * *

■ 7. Amend § 172.11 by revising paragraph (b)(1)(iii) introductory text, the second and third sentences of paragraph (c)(2) introductory text, the second sentence of paragraph (c)(3)(i), and the second and third sentences of paragraph (d) to read as follows:

§ 172.11 Allowable costs and oversight.

* * * * *

(b) * * *

(1) * * *

(iii) When the indirect cost rate has not been established by a cognizant agency in accordance with paragraph (b)(1)(ii) of this section, the STA shall perform an evaluation of a consultant's or subconsultant's indirect cost rate prior to acceptance and application of the rate to contracts administered by the STA or its subrecipients. The evaluation performed by STAs to establish or accept an indirect cost rate shall provide assurance of compliance with the Federal cost principles and may consist of one or more of the following:

* * * * *

(c) * * *

(2) * * * An STA may employ a risk-based oversight process to provide reasonable assurance of consultant compliance with Federal cost principles on FAHP funded contracts administered by the STA or its subrecipients. If employed, this risk-based oversight process shall be incorporated into STA written policies and procedures, as specified in § 172.5(c). * * *

* * * * *

(3) * * *

(i) * * * The certification requirement shall apply to all indirect cost rate proposals submitted by consultants and subconsultants for acceptance by an STA. * * *

* * * * *

(d) * * * FHWA, STAs, and subrecipients of FAHP funds may share audit information in complying with the STA's or subrecipient's acceptance of a consultant's indirect cost rates pursuant to 23 U.S.C. 112 and this part provided that the consultant is given notice of each use and transfer. Audit information shall not be provided to other consultants or any other government agency not sharing the cost data, or to any firm or government agency for purposes other than complying with the STA's or subrecipient's acceptance of a consultant's indirect cost rates pursuant to 23 U.S.C. 112 and this part without the written permission of the affected consultants. * * *

[FR Doc. 2024–01705 Filed 1–29–24; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. CDC–2020–0024]

42 CFR Part 73

RIN 0920–AA71

Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review of the List of Select Agents and Toxins

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: In accordance with the Public Health Service Act, the Department of Health and Human Services (HHS) Centers for Disease Control and Prevention (CDC) reviewed the HHS list of select agents and toxins with the potential to pose a severe threat to public health and safety. HHS/CDC proposes to amend the list by removing three biological agents, raising one toxin's exclusion amounts, renaming a virus, designating a current agent as a Tier 1 agent, and removing the designation of Tier 1 status from one agent. HHS/CDC also proposes to clarify language and add requirements as discussed below.

DATES: Submit written or electronic comments by April 1, 2024.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2020–0024 or Regulation Identifier Number (RIN) 0920–AA71, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Division of Regulatory Science and Compliance, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–4,

Atlanta, Georgia 30329, ATTN: RIN 0920–AA71.

Instructions: All submissions received must include the agency name and RIN for this rulemaking. All relevant comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Do not send comments by email; CDC does not accept public comment by email.

Docket Access: For access to the docket to read background documents or comments received, or to download an electronic version of the notice of proposed rulemaking, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Samuel S. Edwin Ph.D., Director, Division of Regulatory Science and Compliance, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–7, Atlanta, Georgia 30329. Telephone: (404) 718–2000.

SUPPLEMENTARY INFORMATION: The Notice of Proposed Rulemaking (NPRM) is organized as follows:

I. Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Comments are welcomed on any topic related to this notice.

In addition, HHS/CDC invites comments specifically as to whether there are additional biological agents or toxins that should be added or removed from the HHS list of select agents and toxins based on the following criteria outlined under 42 U.S.C. 262a(a)(1)(B):

(1) ''The effect on human health of exposure to the agent or toxin''

(2) ''The degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans''

(3) ''The availability and effectiveness of pharmacotherapies to treat or immunizations to prevent any illness resulting from infection by the agent or exposure to the toxin''

(4) ''Any other criteria including the needs of children and other vulnerable populations'' and any other criteria that the commenter believes should be considered.

Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Commenters should not include any information in their comments or supporting materials that they consider confidential or inappropriate for public disclosure. HHS/CDC will carefully consider all comments submitted in preparation of a final rule. Do not send comments by email. CDC does not accept public comment by email.

II. Background

A. Legal Authority

Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Response Act), the HHS Secretary must establish by regulation, a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety (42 U.S.C. 262a(a)(1)). In determining whether to include a biological agent or toxin on the list, the Bioterrorism Response Act requires that the HHS Secretary consider the following criteria: the effect on human health of exposure to an agent or toxin; the degree of contagiousness of the agent and the methods by which the agent or toxin is transferred to humans; the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent illnesses resulting from an agent or toxin; and any other criteria, including the needs of children and other vulnerable populations that the HHS Secretary deems relevant (42 U.S.C. 262a(a)(1)(B)).

Under 42 U.S.C. 262a(a)(2), the HHS Secretary must review and republish the list of HHS select agents and toxins at least biennially. For this review, HHS/CDC evaluated as discussed below each agent and toxin based on: the degree of pathogenicity (ability of an organism to cause disease); dissemination efficacy; aerosol stability; matrix stability; ease of production; ability to genetically manipulate or alter; severity of illness; case fatality rate; long-term health effects; rate of transmission; available treatment; status of host immunity (*e.g.* whether an individual has already been exposed to the agent and generated an immune response); vulnerability of special populations; decontamination and restoration (the extent remediation efforts are needed due to agent persistence in the environment and population); and the burden or impact on the health care system.

As noted above, the list of HHS select agents and toxins is divided into two sections. The biological agents and toxins listed in 42 CFR 73.3 (HHS select agents and toxins) have the potential to pose a severe threat to human health and safety and are regulated only by HHS. The biological agents listed in 73.4 (overlap select agents and toxins) have not only the potential to pose a severe threat to human health and safety, but have also been determined by the USDA, pursuant to USDA's authority under the Agriculture Bioterrorism Protection Act of 2002 (7 U.S.C. 8401), to have the potential to pose a severe threat to animals and animal products. Accordingly, these biological agents are jointly regulated by HHS and USDA as ''overlap'' select agents. The Bioterrorism Response Act defines the term ''overlap agents and toxins'' to mean biological agents and toxins that are listed pursuant to 42 U.S.C. 262a(a)(1) and listed pursuant to 7 U.S.C. 8401(a)(1). *See* 42 U.S.C. 262a(l) and 7 U.S.C. 8401(l). If HHS/CDC removes any overlap select agents from its list, these agents might still be regulated as USDA select agents dependent on the outcome of the USDA biennial review. The Federal Select Agent Program (FSAP) is the collaboration of the CDC, Division of Regulatory Science and Compliance (previously known as the Division of Select Agents and Toxins) and the USDA Animal and Plant Health Inspection Service (APHIS), Division of Agricultural Select Agents and Toxins to administer the select agent regulations and coordinate federal oversight of select agents and toxins in

a manner to minimize the administrative burden on the regulated community.

B. 2020 ANPRM

On March 17, 2020, we published an advance notice of proposed rulemaking (ANPRM) (85 FR 15087) in which we stated that we were requesting comments on whether to retain or remove three species of *Brucella (B. abortus, B. melitensis,* and *B. suis*), *Rickettsia prowazekii, Coxiella burnetii, Bacillus anthracis* (Pasteur strain), Botulinum neurotoxin producing species of *Clostridium,* and Venezuelan Equine Encephalitis Virus (VEEV) 1AB and 1C. We received 335 comments from the ANPRM. Regarding the request for comment on whether to retain or remove *R. prowazekii, C. burnetii, B. anthracis* (Pasteur strain), Botulinum neurotoxin producing species of *Clostridium,* and VEEV from the select agent and toxins list, HHS/CDC received 27 comments from individuals, animal health groups, regulated communities and public health associations that had mixed opinions on removing and retaining the agents. Of the 16 commenters who supported delisting, the majority of comments supported the delisting of *C. burnetii* and *C. botulinum.* Six commenters believed that *C. burnetii* should be delisted to allow for effective research can be conducted towards the development of improved vaccination for livestock, diagnostics, and other livestock management options and one commenter argued many people may have already been exposed, approximately 60% of exposures remain asymptomatic, and a significant portion of the population may already have immunity. Besides the five comments that cited information found in the ANPRM as a basis for removal, one commenter added that the disease botulism is caused by intoxication with protein toxins, botulinum neurotoxins, and not by intoxication with *C. botulinum.* Another commenter indicated that spores of botulinum neurotoxin species of *Clostridium,* used to conduct food challenge studies should be excluded from the requirements of the regulations. There was only one comment each in support of delisting *R. prowazekii,* VEEV, and *B. anthracis* (Pasteur strain) that supported information found in ANPRM. After carefully reviewing the public comments and considerations for determining whether to include an agent or toxin on the list as articulated in 42 U.S.C. 262a, we are proposing to retain *Rickettsia prowazeckii, Coxiella burnetii,* VEEV, and *B. anthracis* (Pasteur strain) from the select agents and toxins list. The additional changes we are moving forward with in this proposed rule can be found listed below including proposing the removal of *Brucella abortus, Brucella melitensis,* and *Brucella suis.* We also are proposing to raise exclusion amounts for conotoxin, renaming Ebola virus, designating Nipah virus as a Tier 1 select agent, and removing the designation of Tier 1 status from Botulinum neurotoxin producing species of *Clostridium.* We appreciate all comments received from the ANPRM and will consider these comments in future deliberations.

III. Summary of Proposed Changes to 42 CFR Part 73

The following changes to the list of HHS select agents and toxins are proposed based on comments received in response to the advance notice of proposed rulemaking (85 FR 15087) and final rule (82 FR 6278).

HHS/CDC newly proposes to add definitions and provisions to further clarify inactivation of select agents; adding requirements for reporting discoveries of select agents and toxins; provisions regarding effluent decontamination system; and biosafety provisions for facility verification requirements for registered biosafety level 3 and animal biosafety level 3 laboratories.

HHS/CDC also newly proposes to remove *Brucella abortus, Brucella melitensis,* and *Brucella suis* from the select agent list; update the terminology and clarify the specific clade that is a select agent by changing ''Monkeypox virus'' to ''Mpox virus (clade I)''; and to change ''SARS coronavirus (SARS–CoV)'' to ''Severe acute respiratory syndrome coronavirus (SARS–CoV)'' to correct the nomenclature; and to remove the exclusion regarding South American genotype of Eastern Equine Encephalitis virus as this terminology is no longer the correct nomenclature. HHS/CDC is interested in comments regarding these proposed revisions.

In addition, HHS/CDC is proposing to incorporate existing policies previously published and found at *www.selectagents.gov* into regulations and is soliciting public comments on these policies, further discussed below, regarding roles of the Responsible Official and Alternate Responsible Official, chemical inactivation of tissues, conclusion of patient care, annual internal inspections, inactivation certificates, deviation from a validated inactivation procedure or a viable select agent removal method, studies involving naturally infected animals, formalin-fixed paraffin-embedded tissues containing a select agent, validated inactivation procedures, and in-house validation. This is a standard practice for HHS/CDC to utilize policy to first refine its practices before codification. This helps to ensure that regulated entities are able to implement the requirements. In addition, HHS/CDC proposes to correct editorial errors. By codifying these existing policies into regulation, HHS/CDC aims to provide clarity and stability in program requirements, make compliance more straightforward for regulated entities, and ensure enforcement is consistent and predictable across the regulated community.

Specifically, HHS/CDC is seeking comments on whether any of the proposed changes would create an additional burden in implementing the proposed changes.

A. Definitions

HHS/CDC is proposing to add or revise the following eight terms to section 73.1 of the regulations (Definitions) to clarify the use of these terms in the regulations.

The ''loss,'' ''release,'' and ''theft'' definitions are proposed to be added to assist the regulated community on what is to be reported as required under Section 19. The definition of ''discovery'' relates to the proposed new reporting requirement further discussed below. The addition of proposed definitions of ''validated removal procedure'' and ''verification viability testing protocol'' and the revisions of ''validated inactivation procedure'' and ''viability testing protocol'' will provide clarity on inactivation provisions outlined in regulations in Sections 3, 4, 9 and 17. The new terms include:

- Discovery means the finding of a select agent or toxin by an individual or entity that is not aware of the select agent or toxin's existence. Examples include, but are not limited to, the following:

(1) A registered individual or entity finds a select agent or toxin not accounted for in their inventory; or

(2) A non-registered individual or entity finds a select agent or toxin.

- Loss means the inability to account for a select agent or toxin known to be in the individual's or entity's possession.
- Release means any of the following:

(1) an incident resulting in occupational exposure to a select agent or toxin,

(2) an incident resulting in animal/plant exposure to a select agent or toxin,

(3) the failure of equipment used to contain a select agent or toxin such that

it is reasonably anticipated that a select agent or toxin was released,

(4) the failure of or breach in personal protective equipment in the presence of a select agents or toxin, or

(5) the failure of biosafety procedures such that it is reasonably anticipated that a select agent or toxin was outside of containment.

- Theft means the unauthorized taking and removing of a select agent or toxin from the possession of an individual or entity.
- Validated removal procedure means a procedure, whose efficacy has been confirmed by data generated in-house from a viability testing protocol, to remove all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.
- Verification viability testing protocol means a protocol, used on samples that have been subjected to a validated inactivation or removal procedure, to confirm the material is free of all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.

Existing definitions being revised include:

- Validated inactivation procedure means a procedure, whose efficacy has been confirmed by data generated from an in-house viability testing protocol, to render a select agent non-viable but allows the select agent to retain characteristics of interest for future use; or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.
- Viability testing protocol means a protocol used to confirm the efficacy of the inactivation or removal procedure by demonstrating the material is free of all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.

B. Removal of Brucella abortus, Brucella melitensis, and Brucella suis

HHS/CDC is proposing removing *B. abortus, B. melitensis,* and *B. suis* from the select agents and toxins list based on a review of considerations outlined under 42 U.S.C. 262a(a)(1)(B). That provision calls for consideration of (1) an agent's effect on human health, (2) degree of contagiousness, (3) the availability and effectiveness of pharmacotherapies and immunizations, and (4) other appropriate criteria as determined by the HHS Secretary. With regard to the effect on human health, *Brucella* infections have a low case fatality rate, with an untreated fatality rate usually ranging from 1–2% of those identified with the infection (Spickler, 2018). Brucellosis typically causes mild clinical symptoms (flu-like illness) (Olsen et al., 2018). With regard to the degree of contagiousness, there is no indication that *Brucella* is transmitted between people by casual contact under ordinary conditions. Humans are typically infected from exposure to animal reservoirs or animal products; transmission to humans from wildlife is a rare event unless an individual directly handles infected animals, such as in butchering meat (Godfroid et al., 2013). With regard to the availability of effective pharmacotherapies, disease caused by these bacteria is treatable with antibiotics (Spickler, 2018).

In the ANPRM, HHS/CDC sought comments on whether *B. abortus, B. melitensis,* and *B. suis* should be removed or retained on the select agents and toxins list, with a substantial majority supporting removal of the agents. HHS/CDC received four comments recommending the retention of *B. abortus, B. melitensis,* and *B. suis* on the list of select agents and toxins. One commenter indicated that if state public health laboratories no longer accept specimens suspected as containing these *Brucella* species for confirmatory testing, then the burden of such confirmatory testing will fall upon the sentinel laboratories of the Laboratory Response Network (LRN). The commenter further argued that all clinical laboratories do not have the engineering controls (*e.g.,* biological safety cabinets) needed to perform these procedures safely and there could be a risk of occupational health and safety concerns if identification activities are not done with appropriate care. Regardless of an agent's status on the select agent list, clinical laboratories will likely continue to be exposed to these agents when conducting diagnostic procedures or working with unknown samples if sufficient biosafety and personal protective measures are not taken. Furthermore, removing an agent from the select agents and toxins list does not preclude state laboratories from providing testing; HHS/CDC does not direct the testing provided by these laboratories. The other commenter agreed with retention because Brucellosis is a very serious human disease and *Brucella* spp. are easily spread in a laboratory environment where laboratory acquired cases are not rare. Another commenter stated that *Brucella* species are known to have a low infectious dose and therefore present an increased risk of infection due to laboratory exposures. In addition, *Brucella* is the top laboratory acquired infection reported by clinical laboratories to public health laboratories. If removed from the select agent list, the commenter stated that it is likely that hospitals will no longer report these exposures, leaving many laboratorians at risk. For these reasons, the commenter recommended that *Brucella* should be stringently regulated and therefore remain as a select agent. While HHS/CDC agrees with the commenters that *Brucella* has a low infectious dose, the case fatality rate and person-to-person transmission for *Brucella* continues to be very low. In addition, the human illnesses are readily recognized and treated.

HHS/CDC received 36 comments that supported removal based on the considerations provided in the ANPRM and stated that the agents should be removed so that important research can be conducted to include vaccine development. Another 286 commenters supported the removal of *B. abortus* to reduce the regulatory burden so that effective research can be conducted towards the development of improved vaccination for livestock, diagnostics, and other livestock management options. Two commenters supported the removal of *B. abortus* and *B. suis* to reduce the regulatory burden to further the development of diagnostic testing, effective vaccines, and further assistance in controlling the agent. Another commenter believes *B. abortus* and *B. suis* to be poor selections for a biological agent. While *B. suis* was one of the first bioweapons developed by the United States in the 1950s, there have been many more insidious and potent pathogens that have been identified in the past 70 years (Olsen et al., 2018). Although *B. abortus* and *B. suis* have zoonotic capabilities, humans are essentially dead-end hosts for brucellosis making it improbable that an infected person can transmit the disease to another person (Olsen et al., 2018). Other disease characteristics of brucellosis, including mild clinical symptoms, the long incubation period, positive response to antibiotic/pharmacotherapy treatment, low risk of human-to-human transmission, and low mortality rate, further decrease the attractiveness of *B. abortus, B. melitensis,* and *B. suis* as bioweapons (Centers for Disease Control and Prevention, 2017; Cross et al., 2019; Shakir, 2021).

In accordance with the criteria and considerations for determining whether to include an agent or toxin on the list as articulated in 42 U.S.C. 262a, HHS/CDC is proposing to remove *B. abortus, B. melitensis,* and *B. suis* from the HHS select agents and toxins list. The minimal effects on human health upon exposure to these agents, the degree of

contagiousness of these agents, the methods by which these agents are transferred to humans, and the availability and effectiveness of pharmacotherapies to treat illness resulting from these agents are key considerations for this proposal. HHS/CDC would be interested in comments on this proposal. Please provide a detailed explanation for your response. Since *B. abortus, B. melitensis,* and *B. suis* are overlap select agents, even if HHS/CDC removes them from its list, these agents might still be regulated as USDA select agents dependent on the outcome of USDA biennial review.

C. Botulinum Neurotoxin Producing Species of Clostridium

Botulism is a serious paralytic disease caused by a neurotoxin produced during the growth of the spore-forming bacterium *Clostridium botulinum* (or rarely, *C. argentinense* (Puig de Centorbi et al., 1997), *C. butyricum,* or *C. baratii*) (Sobel, 2005). In the ANPRM, HHS/CDC requested comment on whether this agent should be removed or retained from the select agents and toxins list because the organism does not normally cause disease. At this time, HHS/CDC is proposing to retain Botulinum neurotoxin producing species of *Clostridium* as an HHS select agent because it produces the highly toxic Botulinum neurotoxin (a select toxin). Given the risk that the agent can produce such a potent toxin, HHS/CDC is proposing to retain this organism as an HHS select agent; however, HHS/CDC is also proposing that because the organism itself does not normally cause disease, it no longer be listed as a Tier 1 agent.

HHS/CDC received mixed reactions on whether to retain or remove the agent. Six comments supported the retention of the agent; however, five supported the removal. Besides the information included in the ANPRM for removal, that the organism does not cause disease, one commenter added that the disease botulism is caused by intoxication with protein toxins, botulinum neurotoxins, and not by intoxication with *C. botulinum.* Therefore, the commenter further explained that human botulism cases are rare and can be managed with antitoxin treatments.

HHS/CDC received one comment that spores of botulinum neurotoxin species of *Clostridium,* used to conduct experimental food challenge studies, should be excluded from the HHS list of select agents because:

- Basic biological safety practices are already sufficient to protect laboratory personnel and the public.
- Inoculated food samples replicate the concentrations of spores that may be naturally found in the foods or soils or sediments.
- Botulinum spores are not infectious to the general public of healthy individuals older than 1 year of age.
- Toxin production for inoculated samples is no greater than that which may occur naturally if a consumer were to mishandle or temperature-abuse low acid foods.

HHS/CDC disagreed that experimental food challenge studies should be excluded from the regulations. Since this work would require possession and manipulation of the select agent Botulinum neurotoxin producing species of *Clostridium,* and is not diagnostic in nature, this work is not exempted from the select agent and toxin regulations. Cells or spores of botulinum neurotoxin producing species of *Clostridia* are introduced into the samples intentionally. Therefore, this work would be regulated by the select agent regulations.

Six commenters did not support the removal of botulinum neurotoxin producing species of *Clostridia.* One commenter recommended that the organism not be considered as Tier 1 select agent. Two commenters argued the bacteria grows and produces toxin relatively easily (Peck, 2009). One commenter further claimed that normally the bacterium exists in the environment as a dormant spore; however, in environments such as in canned foods, deep wounds, or the intestinal tract, the spores germinate into vegetative bacteria. Two commenters stated that with access to these strains, a simplistic grocery-grade broth filled to the maximum volume or neck of a container is enough for the criminals to drive the fermentation process following inoculation of such strains. Another commenter argued that a botulism outbreak, whether natural or deliberate, can quickly overwhelm local health care systems. Commenters further disagreed with the comparison of the organism to *S. aureus* not being regulated, but that its toxins are because the commenters stated that Staphylococcal enterotoxins are not nearly as potent and fatal as botulinum neurotoxin. The other commenter disagreed because in order to produce the purified botulinum neurotoxins that are used in medicine, food safety, and other fields, the commenter argued that it is essential to secure strains or recombinant organisms of neurotoxigenic *Clostridia* for consistent production of high-quality botulinum neurotoxins (*i.e.,* those strains that produce true toxins). Another commenter argued that a terrorist could use the crude toxin cell extracts and not purified toxin for weaponization purposes. Two commenters stated that the removal of the agent status could set a wrong precedence for recombinant strains to express biologically active toxin for easy and bulk production. A commenter also indicated that medical clinicians often use highly purified toxins, but these still need to be made by neurotoxigenic organisms including special strains. As the toxin produced by these species remains regulated, a commenter stated that the agent should be retained since it is not currently standard practice for public health laboratories to quantify toxin levels following identification of *C. botulinum.* If the agent is retained as an HHS select agent, two commenters requested that changes be made to the regulations to: (i) relax the current inventory format of maintaining stocks or working stocks; (ii) relax or remove in-house validation and verification requirements (to test 10% volume or sample size subjected to agent inactivation and/or removal procedures), while implementation of a terminal filtration step to remove the cells or spore forms from the research or analytical samples needs to be continued to ensure the security of the agent; and (iii) include more waiver provisions for *bona fide* research as needed, or on a case by case basis (*e.g.,* food challenge studies, countermeasure development, emergencies, proficiency testing and diagnostics etc.). HHS/CDC disagreed with the commenters that certain provisions should be relaxed. If an individual or entity is registered to possess, use, or transfer a select agent, then the individual or entity is required to meet all the regulatory requirements for the select agent. It should be noted that the current regulations do not contain provisions regarding ''working stocks'' and contain a provision for an individual or entity to obtain a waiver for ''a select agent or regulated nucleic acids that can produce infectious forms of any select agent virus not subjected to a validated inactivation procedure or material containing a select agent not subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is determined by the HHS Secretary to be effectively inactivated or effectively free of select agent'' (*See* 73.3 (d)(6)).

In accordance with the criteria and considerations for determining whether to include an agent or toxin on the list articulated in 42 U.S.C. 262a, HHS/CDC agreed with the six commenters to retain botulinum neurotoxin producing species of *Clostridia* as an HHS select

agent. HHS/CDC made the determination because the toxin is easily secreted by botulinum neurotoxin producing species of Clostridia which makes it simple to isolate the lethal toxin.

HHS/CDC also agreed and has determined that the botulinum neurotoxin producing species of Clostridia should no longer be identified as a Tier 1 select agent. Tier 1 select agents and toxins pose a severe threat to public health and safety and are considered to present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence. Because the organism itself does not meet this definition and does not normally cause widespread disease, HHS/CDC does not believe the organism should be designated as a Tier 1 select agent. HHS/CDC would continue to retain Botulinum neurotoxins as a Tier 1 agent. HHS/CDC would be interested in comments on retaining botulinum neurotoxin producing species of Clostridia as an HHS select agent and not as a Tier 1 select agent. Please provide a detailed explanation for your response.

D. Hantaviruses

In the 2020 ANPRM, HHS/CDC requested public comment on whether Sin Nombre virus (SNV), Andes virus (ANDV), Hantaan virus (HTNV), and Dobrava virus (DOBV) should be considered HHS select agents given the fatality rate and low infectious/lethal doses of these viruses. Based on a review of considerations outlined under 42 U.S.C. 262a(a)(1)(B) and the public comments submitted by subject matter experts, HHS/CDC is not proposing to add these viruses to the select agent list. Specifically, the very limited direct person-to-person transmission of hantaviruses, the difficulty of propagating the organisms in a laboratory setting, and the fact that the infectious dose of hantavirus for humans is higher than the doses provided in ANPRM indicate that these viruses are not appropriate for inclusion on the select agent list.

HHS/CDC received one comment that supported this addition of the viruses as HHS select agents. HHS/CDC received three comments that did not support the addition of these viruses as HHS select agents. The commenters who did not support listing argued that adding these viruses will result in a significant burden on research institutions. For those institutions that already have a select agent program and registered laboratories established, one commenter argued adding new agents may crowd existing laboratory spaces and will likely result in slowed research and development of vaccines and treatments for all agents studied within the space. The commenter further explained that new requirements would take considerable time, delay critical research programs, and require increased funding. Two commenters presented the following reasons to not include these viruses as select agents:

- Current laboratory practices and biosafety regulations do not expose research personnel and the larger community to high risk of hantavirus infection (*e.g.,* direct person-to-person transmission of hantaviruses has not been documented for any hantavirus, except for very limited confirmed events for Andes virus in South America; laboratory-acquired infections have not been documented for these viruses since the adoption of ABSL–3 (HTNV, DOBV) and ABSL–4 (SNV, ANDV) practices; and lack of approved therapeutics and vaccines is not sufficient criteria for select agent inclusion based on other emerging RNA virus classifications (such as West Nile virus, Zika virus, Powassan virus, many non-endemic Influenza A viruses, chikungunya virus).
- The infectious dose of any hantavirus for humans is likely much higher than those presented in the proposal, as evidenced by non-human primate studies and strikingly rare infections despite endemicity in rodent reservoirs and significant ecological overlap between humans and reservoirs.
- These viruses do not pose a national security threat as potential bioweapons due to the notoriously challenging culture conditions of even laboratory-adapted strains and the scarcity of tractable animal models or amplifying hosts.
- This designation of select agent status will significantly disrupt ongoing research operations.

HHS/CDC agreed with two commenters and has decided not to propose adding these Hantaviruses as HHS select agents. As explained above, there has been very limited direct person-to-person transmission. In addition, the infectious dose for humans is likely higher than the doses provided in ANPRM, and it is difficult to propagate in a laboratory setting. HHS/CDC would be interested in comments on adding these Hantaviruses as HHS select agents. Please provide a detailed explanation for your response.

E. Toxin Review: Changes to Exclusion Limits for Short, Paralytic Alpha Conotoxins

HHS/CDC is proposing to increase the exclusion amount for short, paralytic alpha conotoxins from 100mg to 200mg based on assessments of lethal doses of conotoxin compared to other regulated toxins and the amount of the toxin that would be needed if a bad actor sought to weaponize it.

In the 2020 ANPRM (85 FR 15087), HHS/CDC requested comments on whether any toxins should be retained, removed, or if the exclusion amount for each toxin should be increased or decreased. Specifically, HHS/CDC requested comments for short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$. Alpha conotoxins are low, molecular weight toxins that are isolated from the venom bulb of the marine cone snail. These toxins present a public health threat because they are highly toxic, more stable, and can persist for longer periods of time in the environment. Additional toxins requested for public comment include Diacetoxyscirpenol and Staphylococcal enterotoxins.

One commenter agreed with the proposal to remove short, paralytic alpha conotoxins and diacetoxyscirpenol. However, the commenter did not provide any rationale to why these toxins should be removed. The same commenter did not support the removal of Staphylococcal enterotoxins because the toxins, while rarely fatal, cause severe cases of food poisoning. Furthermore, the commenter stated that the toxins have been explored as a potential biological weapon during the cold war. In the 1960's, three different occurrences of laboratory exposure were reported, and the pathogenic dose is extremely low (Pinchuk et al., 2010). The commenter argued that the isolation of Staphylococcal enterotoxins is relatively easy and would make for a nearly untraceable method of bioterrorism as illnesses would most likely be treated as food poisoning due to the mishandling of food. HHS/CDC agreed with the commenter that Staphylococcal enterotoxins should remain as a select toxin because the enterotoxins can cause severe food poisoning and, in rare cases, can be fatal. Since no rationale was provided to remove diacetoxyscirpenol as a select toxin, HHS/CDC has decided it should be retained as an HHS select toxin.

In response to the Notice of Proposed Rulemaking (81 FR 2805), one commenter supported the removal of

short paralytic alpha-conotoxin and one comment opposed the removal of short paralytic alpha-conotoxin. The commenter that opposed removal stated that: (1) the LD_{50} (lethal dose, 50% or median lethal dose, the amount of the substance required (usually per body weight) to kill 50% of the test population) of 20 µg/kg for the short paralytic alpha-conotoxin is not a low toxicity compared to other select agents, and this LD_{50} is actually in line with other marine toxins included on the list, such as Tetrodotoxin and Saxitoxin; (2) the LD_{50} of actual cone snail venom may be lower due to the synergistic effect of multiple conotoxins; and (3) conotoxins can be readily synthesized. The commenter further asserted when using solid phase peptide synthesis, ten grams of toxin is not difficult to produce. HHS/CDC agreed with the commenter and determined that conotoxins (short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$) should be retained as an HHS select toxin because the ability to produce the toxin synthetically is easier now with more modern technology.

While HHS/CDC did not receive any comments regarding whether the exclusion amount for each toxin should be increased or decreased, likely due to insufficient evidence on LD_{50} levels in humans through various routes of intoxication, HHS/CDC is not proposing any changes to the current exclusion limits for the toxins, with the exception of short, paralytic alpha conotoxins. To assess the amount necessary to weaponize a biological toxin, the Department of Homeland Security (DHS) developed toxin parameters and attack scenarios for potential inhalation and ingestion exposures to select toxins. The DHS models determined the impact of the dissemination of varying concentrations of toxin on public health. HHS/CDC believes the amount of each toxin, with the exception of conotoxins, that could be possessed without regulation by a principal investigator, a treating physician or veterinarian, or a commercial manufacturer or distributor was determined on the basis of toxin potency and how much one could safely possess without constituting a potential threat to public safety or raising concerns about use as a weapon that would have a widespread effect. HHS/CDC reviewed the LD_{50} used for the calculations and the ingestion/inhalation scenarios, and the lethal doses of conotoxins are comparable to other regulated toxins with a much higher permissible amount. Therefore, HHS/CDC believes that the exclusion limit can be increased and still not pose a severe threat to public health. In 2017, HHS/CDC inadvertently did not propose an increase in the exclusion limit for short, paralytic alpha conotoxins in the Notice of Proposed Rulemaking (81 FR 2805). Based on the DHS model, HHS/CDC proposes to raise the exclusion limit for conotoxin from 100 mg to 200 mg based on the toxin parameters and attack scenarios for potential inhalation and ingestion exposures to this select toxin. HHS/CDC would be interested in any comments regarding raising the exclusion limit from 100 mg to 200 mg. Please provide a detailed explanation for your response.

F. Renaming Ebola Virus to the Genus Ebolavirus

Recently, the International Committee on Taxonomy of Viruses (ICTV) published a report on the virus family *Filoviridae,* which classified the species of Ebola and Ebola-like viruses that are in the genus *Ebolavirus (*Kuhn et al., 2019). To date, there are six species in the genus *Ebolavirus,* including Ebola virus, Bombali virus, Reston virus, Bundibugyo virus, Sudan virus, and Taï Forest virus. Currently, the HHS/CDC select agent list includes the name Ebola virus to encompass all of the six viruses listed above in the genus *Ebolavirus.* HHS/CDC is seeking public comment on whether Ebola virus, on the HHS/CDC select agent list as a Tier 1 select agent, should be renamed as *Ebolavirus* to agree with the recent taxonomic change by ICTV. Please provide a detailed explanation for your response.

G. Designating Nipah Virus as a Tier 1 Select Agent

Executive Order 13546 ''Optimizing the Security of Biological Select Agents and Toxins in the United States'' directed the HHS Secretary to designate a subset of select agents and toxins that present the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence. This subset of select agents and toxins is identified as Tier 1. In the ANPRM, HHS/CDC sought public comment on whether Nipah virus should be identified as a Tier 1 select agent because the public health threat posed by Nipah virus is similar to that of Marburg and Ebola viruses, in terms of human transmissibility and high case fatality rate, which are both currently Tier 1 agents. It was also noted in the ANPRM that entities that are currently registered to possess Nipah virus are also in possession of other Tier 1 select agents. HHS/CDC received only one comment in support of this proposal. HHS/CDC is proposing Nipah virus should be identified as a Tier 1 select agent because of its:

- Human transmissibility (person-to-person transmission has occurred) (Centers for Disease Control and Prevention, 2014; Gurley et al., 2007; Luby et al., 2012; and Luby et al., 2009).
- High case fatality rate (estimated between 40–100%) (World Health Organization, 2017 and Harcourt et al., 2004).
- Low infectious dose (ranging from 10^1–10^7 plaque forming units depending on route of infection) (DeWit et al., 2014; Geisbert et al., 2010; and Mathieu et al., 2012).
- High severity of illness, including fever, headache, dizziness, vomiting, cough, reduced levels of consciousness, respiratory distress, and in some cases, death (Hossain et al., 2008; and Lo et al., 2008).
- Severe long-term effects, including neurological complications including encephalopathy, cranial nerve palsies, and dystonia (Sejvar et al., 2007 and Lo et al., 2008). These complications and long-term side effects in survivors of Nipah virus infection can also include persistent convulsions and personality changes.

HHS/CDC would be interested in comments on this proposal. Please provide a detailed explanation for your response.

H. Adding a Footnote to the HHS Select Agent List

For viruses, the International Committee on Taxonomy of Viruses (ICTV) is the international group that sets the standards for names of viruses. Commonly accepted names are still used in the virus community, but there is an effort to create a standard nomenclature. The committees are made up of virus specialists around the world (including from HHS/CDC specialists) to standardize nomenclature and work to avoid confusion. HHS/CDC is working to harmonize list of select agent viruses with ICTV to match the international standard. However, we want to ensure that the common names are also reflected (or at least captured) so if a name changes or is modified, then the list of select agent viruses is still accurate. As such, HHS/CDC proposes to add a footnote to the list for HHS select agents indicating that the current nomenclature will be available on the FSAP website (*https://www.selectagents.gov*).

I. Discovery of Select Agents or Toxins

Since the implementation of the select agent and toxin regulations in 2003 (HHS/CDC, 2003), unless a regulatory exemption or exclusion is applied, individuals and entities are required to register with HHS or USDA to possess a select agent or toxin. Possession of regulated material without proper registration is a regulatory violation that could result in civil, criminal, and/or administrative penalties. Since this time, there have been at least 100 instances of reports from entities that ''discovered'' a select agent or toxin in their possession that the individual or entity was neither registered to possess as required. Many of the agents and toxins ''discovered'' were from studies associated with personnel who had left their entity, and the custodianship of samples was not reassigned. Some of the materials were labeled with obsolete pathogen names, while other ''discovered'' material were found in laboratories where their active use had ceased, in some cases, decades prior to the establishment of the select agent and toxin regulations.

HHS/CDC continues to receive reports from entities who find themselves in possession of select agents and toxins that they are not registered to possess. Given these instances, HHS/CDC is proposing to amend section 73.2 of the regulations to clearly state that any individual or entity in possession of a select agent or toxin, for which (1) an exclusion or exemption listed in 42 CFR part 73 does not apply, and (2) that is not included on a certificate of registration issued by the HHS Secretary or USDA Administrator for that individual or entity, must immediately report such possession to either the HHS Secretary or USDA Administrator. This proposal ensures that all discoveries of possession of a select agent or toxin is reported using the proposed new form regardless of if the individual or entity is registered with the program. As such, registered entities that knowingly come into possession of a material prior to amending their registration would report the possession using the proposed form. HHS/CDC would be interested in comments regarding the proposal to ensure the reporting of discovered select agents and toxins including if there is an undue burden being placed on registered entities to report the discovery as well as amending their registration.

To facilitate such reporting, HHS and USDA plan to create, in compliance with the Paperwork Reduction Act, a new APHIS/CDC Form 6 to specify the information that must be submitted regarding the discovery of the select agent or toxin. Establishing a standard form for reporting will enable HHS and USDA to better understand the circumstances and assess regulatory violations related to the possession of ''discovered'' select agents and toxins.

J. Non-Possession of Select Agent or Toxin by a Registered Entity

HHS/CDC is proposing to clarify throughout the regulations that whenever an individual or entity is registered to possess, use or transfer a select agent or toxin, the individual or entity is required to meet all of the regulatory requirements for those select agents and toxins listed on the individual or entity's certificate of registration regardless of whether the select agent or toxin is in the actual possession of the individual or entity and without regard to the amount of toxin possessed. Registration permits an individual or entity to possess select agents and toxins at any time and indicates its readiness to do so.

K. The Electronic Federal Select Agent Program (eFSAP) Information System

HHS/CDC utilizes a highly secure information system, the eFSAP information system, to conduct all select agent program activities. The eFSAP information system is a two-way communication portal, which is accessible by both CDC and APHIS staff and the regulated community. For users at registered entities, benefits of the system include reduced paperwork, increased ease of validating and submitting information, and reduced processing time for requests (as real-time information exchange allows for increased responsiveness). Based on the implementation of the eFSAP information system, HHS/CDC is proposing to update provisions to indicate that reports (*e.g.,* APHIS/CDC Forms 2, 3, and 4) and requests (*e.g.,* amendments to registration) can be submitted via the eFSAP information system (or successor IT system as specified by CDC in guidance). In addition, the electronic documentation in the eFSAP information system serves as official records required by the select agent and toxin regulations, and once submitted in the eFSAP information system, there is no requirement for entities to retain a separate copy.

L. Registration

The certificate of registration is the document issued by the Federal Select Agent Program to an individual or entity that denotes approval to possess, use and/or transfer specified select agents and toxins; the specific activities related to the registered select agents and/or toxins; persons authorized to access the select agents and/or toxins; and the locations (buildings, rooms, suites of rooms, storage facilities, etc.) where select agents and/or toxins are authorized to be present as described in the individual or entity's APHIS/CDC Form 1. The issuance of a certificate of registration may be contingent upon inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared to meet requirements of the select agent and toxin regulations. In addition, the certificate of registration is required to be amended prior to making any changes and must be reauthorized at least every three years from the date it was initially issued or renewed. The individual or entity's certificate of registration must be amended to reflect changes in circumstances relative to the possession and use of select agent and toxins (*e.g.,* replacement of the Responsible Official or other personnel changes, changes in ownership or control of the individual or entity, changes in the locations and activities involving any select agents or toxins, or the addition or removal of select agents or toxins). As such, HHS/CDC is proposing clarification to language to explain that an amendment ''must'' be submitted instead of ''may'' for any changes to the approved certificate of registration. The proposal corrects a discrepancy between language found in (i) that states an amendment may be

submitted versus language found in (i)(1), which states that the Responsible Official must apply for amendment. An entity must submit an amendment prior to making any change. Therefore, the use of ''may'' is not an accurate term. With the use of eFSAP information system instead of the submission of a revised form, HHS/CDC proposes to update language to replace ''additional documents'' to ''additional information'' since information is what is being revised in the system and not documents.

M. Tier 1 Security Enhancements

HHS/CDC is proposing to clarify security enhancements regarding screening visitors for those entities possessing Tier 1 select agents and toxins because HHS/CDC believes the new language clearly specifies the requirements and will aid in compliance. The proposed provision has been revised to read: ''Entities with Tier 1 select agents and toxins must prescribe the following security enhancements: Procedures for screening visitors, their property, and, where appropriate, vehicles at entry and exit points to registered space based on the entity's site-specific risk assessment.'' While HHS/CDC does not have any evidence of non-compliance, HHS/CDC has received feedback from the registered entities requesting clarification on the current provision that reads: ''Procedures for allowing visitors, their property, and vehicles at the entry and exit points to the registered space, or at other designated points of entry to the building, facility, or compound that are based on the entity's site-specific risk assessment.'' HHS/CDC believes the proposed provision will clarify there are multiple checkpoints needed to ensure compliance with the Tier 1 requirement.

N. Biosafety—Facility Verification

HHS/CDC is proposing to require facility verification every 12 months for registered entities that maintain biosafety level 3 and animal biosafety level 3 laboratories. The proposal is to codify the 2014 policy that provided specific provisions for the verifications regarding BSL–3/ABSL–3 facilities to meet the requirements outlined under 42 CFR 73.12(b) ''biosafety and containment procedures must be sufficient to contain the select agent or toxin (*e.g.,* physical structure and features of the entity, and operational and procedural safeguards).'' The verifications also must be documented and validate the facility's containment functions such as inward directional airflow, decontamination systems, and preventative maintenance. Therefore, HHS/CDC is proposing to require the entity to document facility verification and require the entity to verify the facility's containment functions.

HHS/CDC does not believe that the new provisions will create an additional burden to entities that maintain biosafety level 3 and animal biosafety level 3 laboratories since these entities are already performing annual facility verifications. However, if a registered entity has not been performing annual facility verifications for biosafety level 3 and animal biosafety level 3 laboratories, HHS/CDC would be interested in comments concerning the cost and burden of annual facility verifications, especially if the entity is considered a small business.

O. Biosafety—Effluent Decontamination System

Biosafety level 3 and biosafety level 4 facilities are highly sophisticated facilities built to contain biological agents and toxins with the highest potential to threaten agricultural, plant and public health and safety. Any defect, such as a crack or leaky pipe, could have severe consequences. In August 2007, foot-and-mouth disease was discovered at farms in the United Kingdom. The source of the contamination was determined to be long-term damage and leakage of a drainage system used by a high-containment laboratory working with the foot-and-mouth disease virus. Given these risks, HHS/CDC is proposing to amend the security, biosafety, and incident response sections of the select agents and toxins regulations to address risks posed by the effluent decontamination systems used by biosafety level 3 and biosafety level 4 facilities.

If an effluent decontamination system is used by an entity, the entity must include in its plans how it will address security, biosafety, and incident response as it relates to the system. Specifically, the biosafety plan must provide for verification that the liquid waste generated from registered space is sufficiently treated to prevent the release of a select agent or toxin prior to discharge of the waste from the facility. The security plan, for any space not listed on the entity's registration that contains a portion of an effluent decontamination system, must describe procedures to prevent the theft, loss, or unauthorized access to a select agent or toxin. The incident response plan must fully describe the entity's response procedures for the theft, loss, or release of a select agent or toxin; the failure of an effluent decontamination system resulting in a release of a select agent or toxin, and how personnel will access an area potentially containing a select agent or toxin due to the failure of an effluent decontamination system.

P. Restricted Experiments

HHS/CDC proposes to clarify the provision that the receiving entity must amend their certificate of registration and receive approval by CDC or APHIS to possess the products of a restricted experiment. Entities are currently required to obtain approval to conduct restricted experiments and possess the product of a select agent or toxin that results from a restricted experiment. However, the current provisions do not address if the entity comes into possession of a product of a restricted experiment based on the transfer of the agent. This proposal aligns with the registration section where the Responsible Official must apply for an amendment and receive approval prior to any change in the registration, such as the receipt of a product of a restricted experiment. The proposed provisions also ensure receiving entities have the appropriate safeguards in place to receive and possess the product from a transfer.

Q. Training

HHS/CDC is proposing revisions to the training requirements in accordance with the new mandate in the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (42 U.S.C. 262a(k)(1); Pub. L. 117–328). These revisions have been made in an effort to comply with the statutory amendment that states training requirements for (1) unapproved individuals whose responsibilities routinely place them in close proximity to laboratory facilities and (2) those individuals who perform administrative or oversight functions. Trainings must be completed within 6 months after the final rule is published.

R. Records

HHS/CDC proposes to clarify the records provisions to ensure accurate, current inventory is maintained for each select agent held in long-term storage and all toxins to more clearly specify the requirements and aid in compliance. HHS/CDC is proposing that records contain: (1) the quantity acquired and the name of the individual by whom the select agent or toxin was acquired; (2) the location where it is stored (*e.g.,* building, room number or name, and freezer identification or other storage container); (3) for removal and return of the select agent or toxin from storage, the date the select agent or toxin was

removed and returned, the purpose for using it, the name of the individual who removed and returned it, and when applicable, date of final disposition of the select agent or toxin and by whom; and (4) for intra-entity transfers (sender and the recipient are covered by the same certificate of registration), name of the select agent or toxin, the date of the transfer, the number of items or quantity of the select agent or toxin transferred, the name of the sender, and the name of the recipient. HHS/CDC believes the proposed provision will clarify information needed to ensure the inventory is accurate and complete from the select agents and toxins origination to destruction. Due to prior inquiries received from the regulated community, HHS/CDC is seeking comments on whether the proposed changes are specific enough to ensure proper records are maintained.

S. Codifying Existing Policies

HHS/CDC is proposing to incorporate five existing policies previously published and found at *www.selectagents.gov* into regulations and are soliciting public comments on these policies, further discussed below. By codifying these existing policies into regulation, HHS/CDC aims to provide clarity and stability in program requirements, make compliance more straight-forward for regulated entities, and ensure enforcement is consistent and predictable across the regulated community.

1. Conclusion of Patient Care

HHS/CDC proposes to codify in regulation the current policy that for an individual who has been admitted to a medical facility, the ''conclusion of patient care'' and the point when ''delivery of patient (*i.e.,* human) care by heath care professionals has concluded'' is when an individual is no longer receiving treatment provided by the medical facility or physician. If the patient is seen by the physician or medical facility for follow-up care (*e.g.,* six-month follow-up visit), this would be considered a new delivery of patient care.

The policy also clarified that select agent waste generated during the delivery of patient care applies only to the treatment of humans. Accordingly, specimens or waste associated with that individual (*e.g.,* tissue samples, body fluids, fomites and any other contaminated material likely to transmit an infection to people through the environment if it is unable to be decontaminated) must be destroyed or transferred to a registered individual or entity within seven days after an individual is no longer receiving treatment provided by the medical facility.

2. When Animals Naturally Infected With Select Agents Are Excluded

HHS/CDC proposes to codify in regulation the current policy regarding when animals naturally infected with select agents are excluded from the requirements of the regulations. Sections 73.3(d)(1) and 73.4(d)(1) provide for exclusion of select agents occurring in their natural environment. Mere possession of an animal that is naturally infected with a select agent, either within its natural environment or having been transported to an artificially established environment, meets the criteria of this exclusion. However, the removal of an animal which is naturally infected with a select agent from its natural environment to an artificially established environment for the purpose of

(1) the intentional exposure or introduction of a select agent to a naïve or experimental animal; or

(2) the introduction of a naïve animal to a natural environment where there is an animal that is naturally infected with a select agent for the purpose of the intentional exposure or introduction of a select agent to the naïve or experimental animal, does not meet the exclusion criteria.

If an animal is confirmed to be naturally infected with a select agent, there may be additional transfer and/or transport restrictions based upon other federal or state requirements.

3. Inactivation

HHS/CDC proposes to codify into regulation the current policies regarding inactivation, clarifying and reorganizing the existing provisions regarding select agent inactivation and select agent removal, and clarifying that a certificate must be generated prior to excluding inactivated or select agent-free material.

For chemical inactivation of whole tissue or homogenized tissue, two options are acceptable when choosing appropriate tissue for procedure validation. The first option is to use the tissue that is expected to have the highest concentration of the specific agent to serve as a surrogate for other tissues, including those in other animal models, so long as all standardized conditions (*e.g.,* the agent used, tissue volume, and ratio of tissue to volume of inactivating chemical) are held constant. The second option is to determine the agent concentration in a tissue before performing the inactivation procedure and set this concentration as the maximum agent limit for subsequent inactivation procedures. A safety margin must be incorporated into the final chemical inactivation procedure to ensure the effective inactivation of the agent.

Any select agent or regulated nucleic acid that can produce infectious forms of any select agent virus is excluded if the material is contained in a formalin-fixed paraffin-embedded tissue or fixed to slides (*e.g.,* Gram stain) that have been effectively inactivated by a recognized method for that particular agent or regulated nucleic acid. HHS/CDC also proposes to codify the policy that allows individuals approved by HHS or USDA to access select agents and toxins besides the Responsible Official (*e.g.,* Principal Investigators) to revise the inactivation procedures, if necessary. Principal investigator is defined in the regulations as the one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program. When a Principal investigator is unavailable (such as out of the office) to review the results of a select agent that has been subjected to a validated inactivation or removal procedure, a temporary designee (appointed by the principal investigator and approved of by the responsible official) may sign the inactivation certificate to allow for work to continue. The temporary designee must be listed on the entity's registration and have the knowledge and expertise to provide scientific and technical direction regarding the validated inactivation procedure or the procedure for removal of viable select agent to which the certificate refers. The appointment of a designee to sign certificates is not for regular substitution of the principal investigator, such as the principal investigator relinquishing this requirement to other individuals in the laboratory due to normal work demands or general unavailability. In addition, HHS/CDC is proposing to codify in regulation the current policies regarding records for inactivated or select agent-free material, to clarify what records are needed for inactivated or select agent-free material (to include allowance of a knowledgeable designee to sign the certificate of inactivation on behalf of a Principal Investigator during his/her absence, a timeframe after inactivation or select agent removal for when certificates must be signed and for how long they must be kept by the entity), and a requirement that certificates accompany all transfers including intra-entity transfers. These proposed provisions clarify the recordkeeping

requirements regarding inactivation procedures and inactivated or select agent-free material. It also allows Principal Investigators to designate individuals to sign on their behalf within seven days after completion of the validated inactivation or validated viable select agent removal, and require a certificate to be maintained for as long as the material is in the possession of the registered individual or entity plus an additional 3 years. The inclusion of the policies into the regulations verifies the material has been inactivated by the subject matter expert and the verification document is available throughout its possession by the entity.

4. Responsible Official and Alternate Responsible Official

HHS/CDC proposes to codify in regulation the current policy that the Responsible Official (RO) cannot be approved as RO at more than one registered individual or entity. We also propose to clarify the policy that a RO cannot be approved to be the sole Alternate Responsible Official (ARO) at another registered individual or entity. This means that the RO can serve as ARO at another registered individual or entity as long as they are not the only ARO at the other individual or entity. In addition, HHS/CDC proposes to codify in regulation that an individual who has been approved as an ARO at one individual or entity can be approved to be an ARO at another registered individual or entity. The 2017 policy statement regarding Approval of a person to be a Responsible Official at only one entity, was necessary and was based on the federal regulations that specify that the RO must ''have a physical (and not merely a telephonic or audio/visual) presence at the registered entity to ensure that the entity is in compliance with the select agent regulations and be able to respond in a timely manner to onsite incidents involving select agents and toxins in accordance with the entity's incident response plan.''

5. Annual Internal Inspections

HHS/CDC proposes to codify in regulation the current policy that an individual or entity's annual internal inspections must address whether:

1. The individual or entity's biosafety/biocontainment plan is being effectively implemented, as outlined in Section 12.

2. The individual or entity's security plan is being effectively implemented, as outlined in Section 11.

3. The individual or entity's incident response plan is implemented to ensure whether the entity is able to respond, as outlined in Section 14.

4. Each individual with access approval from the HHS Secretary or Administrator has received the appropriate training as outlined in Section 15.

The proposal codified the 2019 policy that clarified the language of section 9 (a) based on the HHS' Office of Inspector General's Report, ''Entities Generally Met Federal Select Agent Program Internal Inspection Requirements But CDC Could Do More To Improve Effectiveness'' (OEI–04–15–00431) recommendation ''to clarify to DSAT inspectors and to entities the breadth and depth required for internal inspections, including which of the regulatory sections and subsections of 42 CFR part 73 must be addressed as inspection standards.''

IV. Alternatives Considered

One alternative to the proposed rule considered by HHS was not to propose to codify the current operational policies listed above and to propose the delisting of the select agents. However, we decided to propose codification for the sake of consistency with USDA and transparency with our stakeholders. The proposed changes are currently operationalized, and codification of the policies has been recommended by various governmental entities. Without codification we would not have transparency and consistency throughout agencies which is important when requiring strict adherence to our proposed regulatory policies for select agents; thus, we have rejected the alternative to not codify our operational policies that are closely coordinated between USDA and HHS. Moving forward with codifying the current operational policies listed above and not proposing to delist the select agents through federal notice would not be meeting the regulatory mandate under 42 U.S.C. 262a(a)(2) where the HHS Secretary must review and republish the list of HHS select agents and toxins at least biennially.

V. Required Regulatory Analyses

A. Executive Orders 12866, 13563, and 14094

HHS/CDC has examined the impacts of the NPRM under Executive Order 12866, Regulatory Planning and Review (58 FR 51735, October 4, 1993) and Executive Order 13563, Improving Regulation and Regulatory Review, (76 FR 3821, January 21, 2011). Both Executive Orders direct agencies to evaluate any rule prior to promulgation to determine the regulatory impact in terms of costs and benefits to United States populations and businesses. Further, together, the two Executive Orders set the following requirements: quantify costs and benefits where the new regulation creates a change in current practice; qualitatively describe costs and benefits; choose approaches that maximize net benefits; and support regulations that protect public health and safety. HHS/CDC has analyzed the NPRM as required by these Executive Orders and has determined that it is consistent with the principles set forth in the Executive Orders and the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA).

Executive Order 12866, as reaffirmed by E.O. 13563 and E.O. 14094, provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is significant.

Executive Order 14094 reaffirms the principles of E.O. 12866 and E.O. 13563 and states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and are consistent with E.O. 12866, 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. We have developed this proposed rule in a manner consistent with these requirements. 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. In administering the Federal Select Agent Program (FSAP), HHS, along with USDA, regularly interact with the affected registered entities via email, phone, online webinars, and interactions through the eFSAP information system and through registered entity designated points of contact. All proposed changes are being proposed as a direct result of entity questions received and/or interaction with registered entities who have contacted FSAP when they had questions or regulatory interpretation requests. Therefore, HHS/CDC believes this proposed rule serves the public interest. Additionally, HHS/CDC further encourages public participation and will inform registered entities of this proposed rule via a Select Agent (SA) Gram to ensure they are aware that they have a chance to provide public

comments. The proposed rule will also be communicated to the general public via a GovD message to ensure the public has a chance to review and provide comments. The Federal Select Agent Program website (*www.selectagents.gov*) will also be updated to share what the proposed changes are and will provide a link to web visitors so that they can review and provide comments on our **Federal Register** notice. Lastly, outreach notes summarizing the proposed rule will be emailed directly to national partner organizations (The Association of Public Health Laboratories, American Society for Microbiology, American Biological Safety Association, etc.) so that they can share among their constituents.

We have prepared an economic analysis for this NPRM. The economic analysis provides a cost-benefit analysis, as required by Executive Order 12866. This regulatory flexibility analysis also examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available at the Supporting Materials tab of the docket, or at *www.select agents.gov*.

Summary of the Regulatory Impact Analysis

HHS/CDC has proposed modifications to the list of select agents and toxins as well as revisions to several of the select agent and toxin regulations. These proposed revisions to the select agent and toxin regulations will increase their usability as well as provide for enhanced program oversight. Specifically, HHS/CDC is proposing to add definitions for several terms (*Discovery, Theft, Loss, Release, Validated Removal Procedure, Verification viability testing protocol*); codify policies regarding the role of responsible officials and alternate responsible officials, conclusion of patient care, and annual internal inspections; and revise or clarify provisions related to validated inactivation procedures and viable select agent removal methods, recordkeeping, non-possession of select agents and toxins, eFSAP, registration, Tier 1 enhancements, and exclusion of naturally infected animals. HHS/CDC is also proposing to add requirements for reporting discoveries of select agents and toxins, provisions regarding effluent decontamination system, biosafety provisions for facility verification requirements for registered biosafety level 3 and animal biosafety level 3 laboratories, new requirement related to restricted experiments, as well as to correct editorial errors. These proposed changes would economically benefit producers, research and reference laboratories, and State and Federal oversight agencies, while also maintaining adequate program oversight of select agents and toxins.

Currently, there are 236 entities registered with APHIS and CDC. Of these entities, there are 13 Private entities, 30 Federal entities, 42 Commercial entities, 84 Academic entities, and 67 State entities registered with APHIS and CDC. Less than 4 percent of all firms operating within these North American Industry Classification (NAICS) categories are considered to be small entities. The NPRM will not have a significant economic impact on a substantial number of small entities.

The benefits of strengthened safeguards against the unintentional or deliberate release of a select agent or toxin greatly exceed compliance costs of the rules. As an example of losses that can occur, the October 2001 anthrax attacks caused 5 fatalities and 17 illnesses, disrupted business and government activities (including $2 billion in lost revenues for the Postal Service), and required more than $23 million to decontaminate one Senate office building and $3 billion to decontaminate postal facilities and procure mail-sanitizing equipment. Deliberate introduction greatly increases the probability of a select agent becoming established and causing wide-ranging and devastating impacts to the economy, other disruptions to society, and diminished confidence in public and private institutions.

The proposed amendments to the regulations will enhance the protection of human, animal, and plant health and safety. The proposal is to reduce likelihood of the accidental or intentional release of a select agent or toxin. Benefits of the rules will derive from the greater probability that a release will be prevented from occurring.

B. The Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA)

HHS/CDC has examined the impacts of the proposed rule under the Regulatory Flexibility Act (5 U.S.C. 601–612). Unless HHS/CDC certifies that the proposed rule is not expected to have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. HHS/CDC certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA.

This regulatory action is not a major rule as defined by Sec. 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This proposed rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

C. Paperwork Reduction Act of 1995

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), HHS/CDC has determined that the Paperwork Reduction Act does apply to information collection and recordkeeping requirements included in this rule. HHS/CDC notes that the information collection and recordkeeping requirements are already approved by the Office of Management and Budget (OMB) under OMB Control Number 0920–0576, expiration 1/31/2024. HHS/CDC will be seeking renewal of the information collection prior to the publication of the final rule. HHS/CDC will also pursue OMB approval for the proposed Form 6 through a separate process, through a standard clearance with OMB, rather than in this rulemaking.

The total estimated annualized burden for all data collection was calculated using the 2021 Annual Report of the Federal Select Agent Program available at *https://www.selectagents.gov/resources/publications/annualreport/2021.htm* or FSAP IT system and is estimated as 3,655.5 hours and includes additional 30 minutes added to the average burden per response (in hours) for the training proposal in accordance with the new mandate in the Consolidated Appropriations Act, 2023, Public Law 117–328 (division H, title II, section 2311), ''Improving Control and Oversight of Select Biological Agents and Toxins'' (Section 351A of the Public Health Service Act (42 U.S.C. 262a)) amendment of subsection (b)(1). Information will be collected through FSAP IT system, fax, email and hard copy mail from respondents.

ESTIMATED ANNUALIZED BURDEN HOURS

Section	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Sections 3 & 4	Request for Exclusions	1	1	1	1
Sections 5 & 6	Form 4—Report of Identification of a Select Agent or Toxin.	917	1	1	917
Sections 5 & 6	Form 5—Request of Exemption	1	1	1	1
Section 7	Form 1—Application for Registration	5	1	5	25
Section 7	Form 1 Sec 6A—Amendment to a Certificate of Registration.	144	5	1	720
Section 9	Documentation of self-inspection	233	1	1	233
Section 10	Request for Expedited Review	1	1	30/60	1
Section 11	Security Plan	233	1	1	233
Section 12	Biosafety Plan	233	1	1	233
Section 13	Request Regarding a Restricted Experiment	3	1	2	6
Section 14	Incident Response Plan	233	1	1	233
Section 15	Training	233	1.5	1.5	339.5
Section 16	Form 2—Request to Transfer Select Agents and Toxins	229	1	1.5	380
Section 17	Records	233	1	30/60	117
Section 19	Form 3—Notification of Theft, Loss, or Release	185	1	1	185
Section 20	Administrative Review	22	1	1	22
Total					3,655.5

D. E.O. 12988: Civil Justice Reform

This rule has been reviewed under E.O. 12988, Civil Justice Reform. Once the final rule is in effect, HHS/CDC notes that: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) No retroactive effect will be given to this rule; and (3) Administrative proceedings will not be required before parties may file suit in court challenging this rule.

E. E.O. 13132: Federalism

HHS/CDC has reviewed this proposed rule in accordance with Executive Order 13132 regarding Federalism and has determined that it does not have ''federalism implications.'' The rule does not ''have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

In accordance with section 361(e) of the PHSA [42 U.S.C. 264(e)], nothing in this rule would supersede any provisions of State or local law except to the extent that such a provision conflicts with this rule.

F. Plain Language Act of 2010

Under the Plain Language Act of 2010 (Pub. L. 111–274, October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. HHS/CDC has attempted to use plain language in promulgating this rule consistent with the Federal Plain Writing Act guidelines.

VI. References

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List of Subjects

Biologics, Packaging and containers, Penalties, Reporting and recordkeeping requirements, Transportation.

For the reasons discussed in the preamble, HHS proposes to amend 42 CFR part 73 as follows:

PART 73—SELECT AGENTS AND TOXINS

■ 1. The authority citation for part 73 is revised to read as follows:

Authority: 42 U.S.C. 262a; sections 201–204, 221 and 231 of Title II of Pub. L. 107–188, 116 Stat. 637 (42 U.S.C. 262a).

§ 73.0 [Removed]

■ 2. Remove § 73.0.
■ 3. Section 73.1 is amended by:
■ a. Adding in alphabetical order definitions for ''Discovery'', ''Loss'', ''Release'', and ''Theft'';
■ b. Revising the definition of ''Validated inactivation procedure'';
■ c. Adding in alphabetical order definitions for ''Validated removal procedure'' and ''Verification viability testing protocol''; and
■ d. Revising the definition of ''Viability testing protocol''.

The additions and revision read as follows:

§ 73.1 Definitions.

* * * * *

Discovery means the finding of a select agent or toxin by an individual or entity that is not aware of the select agent or toxin's existence. Examples include, but are not limited to, the following:

(1) A registered individual or entity finds a select agent or toxin not accounted for in their inventory; or

(2) A non-registered individual or entity finds a select agent or toxin.

* * * * *

Loss means the inability to account for a select agent or toxin known to be in the individual or entity's possession.

* * * * *

Release means any of the following:

(1) An incident resulting in occupational exposure to a select agent or toxin,

(2) An incident resulting in animal/plant exposure to a select agent or toxin,

(3) The failure of equipment used to contain a select agent or toxin such that it is reasonably anticipated that a select agent or toxin was released,

(4) The failure of or breach in personal protective equipment in the presence of a select agent or toxin, or

(5) The failure of biosafety procedures such that it is reasonably anticipated

that a select agent or toxin was outside of containment.

* * * * *

Theft means the unauthorized taking and removing of a select agent or toxin from the possession of an entity or individual.

* * * * *

Validated inactivation procedure means a procedure, whose efficacy has been confirmed by data generated from an in-house viability testing protocol, to render a select agent non-viable but allows the select agent to retain characteristics of interest for future use; or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.

* * * * *

Validated removal procedure means a procedure, whose efficacy has been confirmed by data generated in-house from a viability testing protocol, to confirm removal of all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.

* * * * *

Verification viability testing protocol means a protocol, used on samples that have been subjected to a validated inactivation or removal procedure, to confirm the material is free of all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.

* * * * *

Viability testing protocol means a protocol used to confirm the efficacy of the inactivation or removal procedure by demonstrating the material is free of all viable select agent, or nucleic acids of any select agent virus capable of producing infectious virus.

* * * * *

■ 5. Section 73.2 is revised to read as follows:

§ 73.2 Purpose and scope.

(a) This part implements the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Public Health Service Act, 42 U.S.C. 262a, as amended, setting forth the requirements for possession, use, and transfer of select agents and toxins. The biological agents and toxins listed in this part have the potential to pose a severe threat to public health and safety, to animal health, or to animal products. Overlap select agents and toxins are subject to regulation by both CDC and APHIS.

(b) Any individual or entity in possession of a select agent or toxin, for which an exclusion or exemption listed in this part does not apply, and that is not included on a certificate of registration issued by the HHS Secretary or Administrator for that individual or entity, must immediately report such possession to either the HHS Secretary or Administrator by the submission of an APHIS/CDC Form 6.

■ 6. Section 73.3 is amended by:

■ a. Revising paragraphs (b), (d)(1), and (d)(4) through (6);

■ b. Redesignating paragraphs (d)(7) through (11) as paragraphs as (d)(8) through (12), respectively.

■ c. Adding new paragraph (d)(7);

■ d. In newly redesignated paragraph (d)(8) introductory text, removing the text ''100 mg of Conotoxins'' and adding in its place the text ''200 mg of Conotoxins'';

■ e. In newly redesignated paragraph (d)(12) by removing the text ''of the conclusion of patient care'' and adding in its place ''from when the individual has been released from the medical facility where treatment was being provided'';

■ f. In paragraph (e)(1), removing the text ''National Select Agent Registry website'' and adding in its place ''Federal Select Agent Program website'';

■ g. In paragraph (f)(3)(i), removing the text ''*Bacillus cereus* Biovar *anthracis,* Botulinum neurotoxins, Botulinum neurotoxin producing species of *Clostridium,* Ebola viruses, *Francisella tularensis,* Marburg virus, Variola major virus (Smallpox virus), Variola minor (Alastrim), or *Yersinia pestis*'' and adding in its place ''Tier 1 agents and toxins'' and removing the text ''telephone, facsimile, or email'' and adding in its place the text ''eFSAP information system, telephone, or email'';

■ h. In paragraph (f)(3)(iii), adding the text ''not submitted through eFSAP information system'' between the words ''APHIS/CDC Form 4'' and ''must''; and

■ k. In paragraph (f)(4), adding the text ''not submitted through eFSAP information system'' between the words ''form'' and ''must''.

The revisions and additions read as follows:

§ 73.3 HHS select agents and toxins.

* * * * *

(b) HHS select agents and toxins:

Abrin
Bacillus cereus Biovar *anthracis* *
Botulinum neurotoxins *
Botulinum neurotoxin producing species of *Clostridium*
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$) [1]
Coxiella burnetii
Crimean-Congo hemorrhagic fever virus [2]
Diacetoxyscirpenol
Eastern equine encephalitis virus [2]
Ebolavirus * [2]
Francisella tularensis *
Lassa fever virus [2]
Lujo virus [2]
Marburg virus * [2]
Mpox virus (clade I) [2]
Reconstructed replication competent forms of the 1918 pandemic influenza A virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 influenza A virus) [2]
Ricin
Rickettsia prowazekii
Severe acute respiratory syndrome coronavirus (SARS-CoV) [2]
Saxitoxin
South American hemorrhagic fever viruses [2]:
  Chapare
  Guanarito
  Junin
  Machupo
  Sabia
Staphylococcal enterotoxins (subtypes A,B,C,D,E)
T–2 toxin
Tetrodotoxin
Tick-borne encephalitis virus [4]
  Far Eastern subtype
  Siberian subtype
Kyasanur Forest disease virus [2]
Omsk haemorrhagic fever virus [2]
Variola major virus (Smallpox virus) * [2]
Variola minor virus (Alastrim) * [2]
Yersinia pestis *

[1] C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins a-MI and a-GI (shown above) as well as a-GIA, Ac1.1a, a-CnIA, a-CnIB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; ''Des X'' = ''an amino acid does not have to be present at this position.'' For example, if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

[2] Please refer to *https://www.selectagents.gov* for current information on historical or proposed nomenclature for the HHS select agents on the list.

* * * * *

(d) * * *

(1) * * * Except for:

(i) Any animal which is naturally infected with a select agent from its natural environment to an artificially

established environment for the purpose of the intentional exposure or introduction of a select agent to a naïve or experimental animal; or

(ii) Any animal which is naturally infected with a select agent for the purpose of the intentional exposure or introduction of a select agent to the naïve or experimental animal is placed with a naïve animal in their natural environment.

* * * * *

(4) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure, provided that:

(i) In-house validation of the inactivation procedure is completed prior to use;

(ii) A certificate of inactivation has been generated in accordance with § 73.17(a)(8);

(iii) For use of a select agent surrogate to validate an inactivation procedure:

(A) Select agent surrogates must be known to possess equivalent properties with respect to inactivation;

(B) If there are known variations in the resistance of a select agent to an inactivation procedure, including strain to strain, then an inactivation procedure must also be validated using the most resistant select agent surrogate.

(iv) For use of a whole tissue or homogenized tissue surrogate to validate a chemical inactivation procedure for other tissues, including those in other animal models:

(A) All standardized conditions must be held constant, such as the select agent used, tissue volume, and ratio of tissue to volume of inactivating chemical;

(B) A safety margin must be incorporated into the final chemical inactivation procedure to ensure the effective inactivation of the select agent;

(C) The tissue surrogate must meet the following criteria:

(*1*) The tissue is expected to have the highest concentration of the specific select agent to be inactivated; or

(*2*) The concentration of the select agent in the tissue must be determined and this select agent concentration must not be exceeded when applying the validated inactivation procedure on subsequent tissue samples.

(5) Any select agent or regulated nucleic acids that can produce infectious forms of any select agent virus contained in a formalin-fixed paraffin-embedded (FFPE) tissue if the FFPE process used is a recognized procedure for that particular select agent or regulated nucleic acids.

(6) Material containing a select agent that is subjected to a validated viable select agent removal procedure that has rendered the material free of all viable select agent provided that:

(i) In-house validation of the viable select agent removal procedure is completed prior to use;

(ii) A certificate of viable select agent removal has been generated in accordance with § 73.17(a)(8);

(iii) For use of a surrogate to validate a viable select agent removal procedure, only surrogates known to possess equivalent properties with respect to removal are used.

(A) Select agent surrogates must be known to possess equivalent properties with respect to inactivation.

(B) If there are known variations in the resistance of a select agent to an inactivation procedure, including strain to strain, then an inactivation procedure must also be validated using the most resistant select agent surrogate.

(iv) A portion of each subsequent sample has been subjected to a verification viability testing protocol to ensure that the validated viable select agent removal procedure has rendered the material free of all viable select agent.

(7) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus not subjected to a validated inactivation procedure or material containing a select agent not subjected to a validated viable select agent removal procedure that removes all viable select agent cells, spores, or virus particles if the material is determined by the HHS Secretary to be effectively inactivated or effectively removed. To apply for a determination, an individual or entity must submit a written request and supporting scientific information to APHIS or CDC. A written decision granting or denying the request will be issued.

* * * * *

■ 7. Section 73.4 is amended by:

■ a. Revising paragraphs (b), (d)(1), and (d)(4) through (6);

■ b. Redesignating paragraphs (d)(7) through (9) as paragraphs (d)(8) through (d)(10), respectively.

■ c. Adding new paragraph (d)(7);

■ d. In newly redesignated paragraph (d)(9), removing the text ''of the conclusion of patient care'' and adding in its place ''from when the individual has been released from the medical facility where treatment was being provided'';

■ e. Revising newly redesignated paragraph (d)(10);

■ f. In paragraph (e)(1), removing the text ''National Select Agent Registry website'' and adding in its place ''Federal Select Agent Program website'';

■ g. In paragraph (f)(3)(i), removing the text ''*Bacillus anthracis, Burkholderia mallei* and *Burkholderia pseudomallei*'' and adding in its place ''Tier 1 agents'' and removing the text ''telephone, facsimile, or email'' and adding in its place the text ''eFSAP information system, telephone, or email'';

■ h. In paragraph (f)(3)(iii), adding the text ''not submitted through eFSAP Information System'' between the text ''APHIS/CDC Form 4'' and ''must'';

■ i. In paragraph (f)(4), adding the text ''not submitted through eFSAP information system'' between the words ''form'' and ''must''.

The revisions and addition read as follows:

§ 73.4 Overlap select agents and toxins.

* * * * *

(b) Overlap select agents and toxins:

Bacillus anthracis *
Bacillus anthracis Pasteur strain
Burkholderia mallei *
Burkholderia pseudomallei *
Hendra virus
Nipah virus *
Rift Valley fever virus
Venezuelan equine encephalitis virus

* * * * *

(d) * * *

(1) Except for:

(i) Any animal which is naturally infected with a select agent from its natural environment to an artificially established environment for the purpose of the intentional exposure or introduction of a select agent to a naïve or experimental animal; or

(ii) Any animal which is naturally infected with a select agent for the purpose of the intentional exposure or introduction of a select agent to the naïve or experimental animal is placed with a naïve animal in their natural environment.

* * * * *

(4) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure, provided that:

(i) In-house validation of the inactivation procedure is completed prior to use;

(ii) A certificate of inactivation has been generated in accordance with § 73.17(a)(8);

(iii) For use of a select agent surrogate to validate an inactivation procedure:

(A) Select agent surrogates must be known to possess equivalent properties with respect to inactivation;

(B) If there are known variations in the resistance of a select agent to an inactivation procedure, including strain to strain, then an inactivation procedure

must also be validated using the most resistant select agent surrogate;

(iv) For use of a whole tissue or homogenized tissue surrogate to validate a chemical inactivation procedure for other tissues, including those in other animal models:

(A) All standardized conditions must be held constant, such as the select agent used, tissue volume, and ratio of tissue to volume of inactivating chemical;

(B) A safety margin must be incorporated into the final chemical inactivation procedure to ensure the effective inactivation of the select agent;

(C) The tissue surrogate must meet the following criteria:

(*1*) The tissue is expected to have the highest concentration of the specific select agent to be inactivated; or

(*2*) The concentration of the select agent in the tissue must be determined and this select agent concentration must not be exceeded when applying the validated inactivation procedure on subsequent tissue samples.

(5) Any select agent or regulated nucleic acids that can produce infectious forms of any select agent virus contained in a FFPE tissue if the FFPE process used is a recognized procedure for that particular select agent or regulated nucleic acids.

(6) Material containing a select agent that is subjected to a validated viable select agent removal procedure to ensure that the validated viable select agent removal procedure has rendered the material free of all viable select agent except for:

(i) In-house validation of the viable select agent removal procedure is completed prior to use;

(ii) A certificate of viable select agent removal has been generated in accordance with § 73.17(a)(8);

(iii) For use of a surrogate to validate a viable select agent removal procedure, only surrogates known to possess equivalent properties with respect to removal are used; and

(iv) A portion of each subsequent sample has been subjected to a verification viability testing protocol to ensure that the validated viable select agent removal procedure has rendered the material free of all viable select agent.

(7) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus not subjected to a validated inactivation procedure or material containing a select agent not subjected to a validated viable select agent removal procedure that removes all viable select agent cells, spores, or virus particles if the material is determined by the HHS Secretary to be effectively inactivated or effectively removed. To apply for a determination an individual or entity must submit a written request and supporting scientific information to APHIS or CDC. A written decision granting or denying the request will be issued.

* * * * *

■ 8. Section 73.5 is amended as follows:

■ a. By revising paragraph (a)(1);

■ b. In paragraph (a)(3) by removing the text ''delivery of patient (*i.e.,* human) care by health care professionals has concluded'' and adding in its place ''the individual has been released from the medical facility where treatment was being provided''.

■ c. By revising paragraph (a)(4)(i);

■ d. In paragraph (a)(4)(iv) by adding the text ''not submitted through eFSAP Information System'' between the text ''APHIS/CDC Form 4'' and ''must'';

■ e. In paragraph (b) introductory text by removing the article ''a'' and adding in its place the article ''an'' before ''HHS'';

■ f. By revising paragraph (b)(1); and

■ g. In the last sentence of paragraph (b)(3) by adding the text ''not submitted through eFSAP Information System'' between the words ''form'' and ''must''.

The revisions read as follows:

§ 73.5 Exemptions for HHS select agents and toxins.

(a) * * *

(1) Unless directed otherwise by the HHS Secretary, within seven calendar days after identification of the select agent or toxin (except for Botulinum neurotoxin), or within 30 calendar days after identification of Botulinum neurotoxin, the select agent or toxin is transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization process or inactivated for future use in accordance with section 73.3 (d)(4).

* * * * *

(4) The identification of the agent or toxin is reported to CDC or APHIS, the specimen provider, and to other appropriate authorities when required by Federal, State, or local law through the eFSAP information system, telephone, or email. This report must be followed by submission of APHIS/CDC Form 4 to APHIS or CDC within seven calendar days after identification.

(i) The identification of HHS Tier 1 select agents or toxin must be immediately reported through the eFSAP information system, telephone, or email. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after identification.

* * * * *

(b) * * *

(1) Unless directed otherwise by the HHS Secretary, within 90 calendar days of receipt, the select agent or toxin is transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization process or inactivated for future use in accordance with § 73.3(d)(4).

* * * * *

■ 9. Section 73.6 is amended as follows:

■ a. By revising paragraphs (a) introductory text and (a)(1);

■ b. In paragraph (a)(3) by removing the text ''delivery of patient care by health care professionals has concluded'' and adding in its place ''the individual has been released from the medical facility where treatment was being provided'';

■ c. By revising paragraph (a)(4)(i);

■ d. In paragraph (a)(4)(iv) by adding the text ''not submitted through eFSAP information system'' between ''APHIS/CDC Form 4'' and ''must'';

■ e. By revising paragraph (b)(1); and

■ f. In the last sentence of paragraph (b)(3) by adding the text ''not submitted through eFSAP information system'' between the words ''form'' and ''must''.

The revisions read as follows:

§ 73.6 Exemptions for overlap select agents and toxins.

(a) Clinical or diagnostic laboratories and other entities that possess, use, or transfer an overlap select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the HHS Secretary or Administrator, within seven calendar days after identification, the select agent or toxin is transferred in accordance with § 73.16 or 9 CFR 121.16 or destroyed on-site by a recognized sterilization process, or inactivated for future use in accordance with § 73.4(d)(4),

* * * * *

(4) The identification of the agent or toxin is reported to CDC or APHIS, the specimen provider, and to other appropriate authorities when required by Federal, State, or local law through the eFSAP information system, telephone, or email. This report must be followed by submission of APHIS/CDC Form 4 to APHIS or CDC within seven calendar days after identification.

(i) The identification of overlap Tier 1 select agents or toxin must be immediately reported through the eFSAP information system, telephone, or email. This report must be followed by submission of APHIS/CDC Form 4

within seven calendar days after identification.

* * * * *

(b) * * *

(1) Unless directed otherwise by the HHS Secretary or Administrator, within 90 calendar days of receipt, the select agent or toxin is transferred in accordance with § 73.16 or 9 CFR part 121.16 or destroyed on-site by a recognized sterilization process or inactivated for future use in accordance with § 73.4 (d)(4),

* * * * *

■ 10. Section 73.7 is amended as follows:

■ a. In paragraph (f) by removing ''the relevant page(s) of'' and adding in its place ''information related to'';

■ b. By revising paragraph (g);

■ c. In paragraph (i) by removing the word ''may'' and adding in its place the word ''must'' and by removing the word ''circumstances'' and adding in its place the phrase ''the possession and use of the select agents and toxins''; and

■ d. In paragraph (i)(1) by removing ''the relevant page(s) of'' and adding in its place ''information related to''.

The revision reads as follows:

§ 73.7 Registration and related security risk assessments.

* * * * *

(g) The issuance of a certificate of registration may be contingent upon inspection and submission of additional information to include any or all of the following: the security plan, biosafety plan, incident response plan, or any other information related to the requirements of this part.

* * * * *

■ 11. Section 73.9 is amended as follows:

■ a. By redesignating paragraphs (a)(5) through (9) as paragraphs as (a)(6) through (10);

■ b. By adding new paragraph (a)(5);

■ c. By revising newly redesignated paragraphs (a)(7), (9), and (10);

■ d. In paragraph (b) by adding a new second sentence;

■ e. By revising paragraph (c)(1); and

■ f. In the last sentences of paragraphs (c)(2) and (d) by adding the phrase ''not submitted through eFSAP information system'' between the words ''form'' and ''must''.

The addition and revision read as follows:

§ 73.9 Responsible Official.

* * * * *

(a) * * *

(5) Not be approved as Responsible Official or alternate Responsible Official at another registered entity,

* * * * *

(7) Ensure that annual inspections are conducted for each registered space to determine compliance with the requirements in accordance with the regulations of this part. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected and the corrections documented. The annual inspection must address whether:

(i) The entity's biosafety/biocontainment plan is being effectively implemented, as outlined in § 73.12.

(ii) The entity's security plan is being effectively implemented, as outlined in § 73.11.

(iii) The entity's incident response plan is implemented to ensure whether the entity is able to respond, as outlined in § 73.14.

(iv) Each individual with access approval from the HHS Secretary or Administrator has received the appropriate training as outlined in § 73.15.

* * * * *

(9) Investigate to determine the reason for any failure of a validated inactivation or validated viable select agent removal procedure to render material free from viable select agent. If the Responsible Official is unable to determine the cause of the failure from a validated inactivation or validated viable select agent removal procedure or receives a report of any inactivation failure after the movement of material to another location, the Responsible Official must report immediately through the eFSAP information system, telephone or email the inactivation or viable select agent removal procedure failure to CDC or APHIS.

(10) Review each of the entity's validated select agent inactivation procedure or validated viable select agent removal procedure and ensure they are revised as necessary. The review must be conducted annually or after any change in Principal Investigator, change in the validated inactivation or validated viable select agent removal procedure, or failure of the validated inactivation or validated viable select agent removal procedure. The review must be documented, and training must be conducted if there are any changes to the validated select agent inactivation or validated viable select agent removal procedure, or viability testing protocol.

(b) * * * An alternate Responsible Official can serve at multiple registered entities. * * *

(c) * * *

(1) The identification of any Tier 1 agents or toxins must be immediately reported through the eFSAP information system, telephone, or email. The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within seven calendar days after identification (except for Botulinum neurotoxin and/or Staphylococcal enterotoxin (Subtypes A–E)), which is within 30 calendar days after identification). A copy of the completed form not submitted through eFSAP information system must be maintained for three years.

* * * * *

§ 73.10 [Amended]

■ 12. Section 73.10 is amended in paragraph (c) by removing the words ''to select agents or toxins'' and adding in their place ''access approval from the HHS Secretary or Administrator''.

■ 13. Section 73.11 is amended as follows:

■ a. By redesignating paragraphs (c)(9) and (10) as paragraphs (c)(10) and (11);

■ b. By adding a new paragraph (c)(9);

■ c. In paragraph (d)(4) by removing the text ''the area where select agents or toxins are used or stored'' and adding in its place ''registered space'';

■ d. In paragraph (f) introductory text by removing the word ''possessing'' and adding in its place ''registered for'';

■ e. In paragraph (f)(1) by removing the words ''will have'' and adding in their place ''are registered for'';

■ f. By revising paragraph (f)(4)(iii); and

■ g. By removing paragraph (g) and redesignating paragraph (h) as paragraph (g).

The addition and revision read as follows:

§ 73.11 Security.

* * * * *

(c) * * *

(9) Describe procedures to prevent the theft, loss, or unauthorized access to a select agent or toxin from an effluent decontamination system originating from a registered laboratory.

* * * * *

(f) * * *

(4) * * *

(iii) Procedures for screening visitors, their property, and, where appropriate, vehicles at entry and exit points to registered space based on the entity's site-specific risk assessment;

* * * * *

■ 14. Section 73.12 is amended as follows:

■ a. In paragraphs (c)(1) and (2) by removing the words ''National Select Agent Registry website'' and adding in their place ''Federal Select Agent Program website'';

■ b. By revising paragraph (d); and

■ c. By adding paragraphs (f), (g), and (h).

The revision and additions read as follows:

§ 73.12 Biosafety.

* * * * *

(d) The biosafety plan must include an occupational health plan for individuals listed on the individual or entity's registration for access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health plan.

* * * * *

(f) When an effluent decontamination system is used, the plan must provide for verification that the liquid waste generated from registered space is sufficiently treated to prevent the release of a select agent or toxin prior to discharge of the waste from the facility.

(1) For a new effluent decontamination system, verification is required before initial use.

(2) For an effluent decontamination system in place, verification is required at least once every 12 months and following any major change to the effluent decontamination system.

(3) The verification must be documented.

(g) When an effluent decontamination system is used, the plan must provide that monthly routine maintenance is conducted of the effluent decontamination system, including at a minimum verification that:

(1) Alarms are functioning according to established specifications;

(2) Piping, pumps, valves, and tanks are not leaking; and

(3) Methods used to monitor and record performance measurements and are functioning according to established specifications.

(h) An individual or entity must document every 12 months the following facility verification requirements for registered biosafety level 3 and animal biosafety level 3 laboratories.

(1) Accuracy of devices that monitor directional air-flow;

(2) Confirmation that decontamination systems (*e.g.,* autoclave, room decontamination systems, digesters, liquid effluent decontamination systems) are operating to ensure the containment of the select agent and toxin;

(3) Confirmation that systems are in place to monitor, maintain and validate performance of mechanical systems to ensure that airflows and differential pressures are appropriate to maintain containment during normal/operational conditions;

(4) Verification that the facility mechanical, electrical, and drain waste and ventilation systems responsible for containment are inspected, maintained, and function as designed manufacturer specifications;

(5) Verification that the facility systems perform as intended in response to failure conditions as defined and tested during commissioning to prevent the release of select agent or toxin and verify secondary containment:

(i) Evaluate using work objectives, use of space, and facility infrastructure systems against the verified original design and standards (*e.g.,* Biosafety in Microbiological and Biomedical Laboratories, NIH Design Requirements Manual).

(ii) Implement controls and alarms to identify and alert personnel when systems fail, malfunction, or are unable to maintain containment during such an event.

(6) Certification of laboratory ventilation system HEPA filters, if present;

(7) Confirmation that room integrity has been evaluated and repairs are addressed (*e.g.,* sealed penetrations);

(8) Primary containment equipment is certified based on manufacturer's specifications (or recommendations) (*e.g.,* biological safety cabinets, flexible film isolators, animal caging);

(9) Seals on centrifuges not used in primary containment have been checked and replaced if needed; and

(10) Showers, eye wash stations, and hands-free sinks are operating properly.

§ 73.13 [Amended]

■ 15. Section 73.13 is amended in paragraph (a) introductory text by adding ''or transfer'' after ''possess''.

■ 16. Section 73.14 is amended as follows:

■ a. In paragraph (b) by adding the words ''the failure of an effluent decontamination system resulting in a release of a select agent or toxin;'' after ''a select agent or toxin;'';

■ b. By revising paragraph (c); and

■ c. In paragraph (e) introductory text by removing the words ''Entities with'' and adding in their place ''An individual or entity registered for''.

The revision reads as follows:

§ 73.14 Incident response.

* * * * *

(c) The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such select agent or toxin in registered space including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent, or an effluent decontamination system originating from registered space.

* * * * *

■ 17. Section 73.15 is amended as follows:

■ a. By adding paragraphs (a)(3) and (4);

■ b. In paragraph (b) by removing the words ''Entities with'' and adding in their place ''An individual or entity registered for''; and

■ c. By revising paragraph (d).

The additions and revision read as follows:

§ 73.15 Training.

* * * * *

(a) * * *

(3) Each individual not approved for access to HHS and overlap select agents and toxins by the HHS Secretary or APHIS Administrator whose responsibilities routinely place them in close proximity (*e.g.,* shared laboratory space) to areas where select agents or toxins are transferred, possessed, or used. The training must be based on the particular needs of the individual and risks associated with working near areas where select agents and toxins are handled or stored. The training must also instruct each individual on the notification requirements related to select agents and toxins. Training must be accomplished prior to the individual's close proximity to areas where select agents or toxins are handled or stored and refresher training must be provided annually.

(4) Each individual not approved for access to HHS and overlap select agents and toxins by the HHS Secretary or APHIS Administrator who performs administrative or oversight functions of the facility related to the transfer, possession or use of such agents or toxins on behalf of the entity (*e.g.,* administrative professionals, facility managers, etc.). The training must instruct each individual on the regulatory requirements relevant to their administrative or oversight functions. The training must also instruct each individual on the notification requirements related to select agents and toxins. Training must be accomplished prior to the individual performing these functions and refresher training must be provided annually.

(d) The Responsible Official must ensure a record of the training provided for each individual listed in paragraph (a) of this section is maintained. The record must include the name of the individual who received the training, the date of the training, a description of the training provided, and the means used to verify that the individual understood the training.

* * * * *

§ 73.16 Amended]

■ 18. Section 73.16 is amended in paragraph (l) introductory text by removing the article ''a'' and adding in its place the article ''an'' before ''HHS''.

■ 19. Section 73.17 is amended as follows:

■ a. By revising paragraphs (a)(1), (2), (3), and (8);

■ d. By removing the last sentence from paragraph (c); and

■ e. By adding paragraph (d).

The revisions and addition read as follows:

§ 73.17 Records.

* * * * *

(a) * * *

(1) An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including:

(i) The name and characteristics (*e.g.,* strain designation, GenBank Accession number);

(ii) The quantity acquired from another individual or entity (*e.g.,* containers, vials, tubes), date of acquisition, by whom, and the source;

(iii) Location where it is stored (*e.g.,* building, room number or name, and freezer identification or other storage container);

(iv) The date the agent was removed and returned, the purpose for using the agent, the name of the individual who removed and returned the agent, and when applicable, date of final disposition of the agent and by whom;

(v) Records created under § 73.16;

(vi) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), name of the select agent, the date of the transfer, the number of items transferred, the name of the sender, and the name of the recipient; and

(vii) Records created under § 73.19.

(2) An accurate, current accounting of any animals or plants intentionally or accidentally exposed to or infected with a select agent (including number and species, location, and appropriate disposition);

(3) Accurate, current inventory for each toxin held, including:

(i) The name and characteristics;

(ii) The quantity acquired from another individual or entity (*e.g.,* containers, vials, tubes, volume including concentration), date of acquisition, by whom, and the source;

(iii) The initial and current amount (*e.g.,* milligrams, milliliters, grams);

(iv) Location where the toxin is stored (*e.g.,* building, room number or name, and freezer identification or other storage container);

(v) When the toxin was accessed, the name of the toxin, the location where the toxin was accessed, the date the toxin was accessed, the purpose for accessing the toxin, the name of the individual accessing the toxin, the date the toxin was returned back to storage, the name of the individual returning the toxin back to storage, and date of final disposition of the toxin and by whom;

(vi) Records created under § 73.16;

(vii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), name of the toxin, the date of the transfer, the number of vials transferred, the date of transfer, the name of the sender, and the name of the recipient; and

(viii) Records created under § 73.19.

* * * * *

(8) For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a validated viable select agent removal procedure:

(i) A written description of the validated inactivation procedure or validated viable select agent removal procedure used, including validation data;

(ii) A written description of the viability testing protocol used;

(iii) A written description of the investigation conducted by the entity's Responsible Official involving a validated inactivation or validated viable select agent removal failure and the corrective actions taken;

(iv) The name of each individual performing the validated select agent inactivation or validated viable select agent removal;

(v) The date(s) the validated inactivation or validated viable select agent removal was completed;

(vi) The location where the validated inactivation or validated viable select agent removal was performed; and

(vii) A signed certificate. The certificate must:

(A) Include the date(s) the validated inactivation or validated viable select agent removal was completed;

(B) Include the validated inactivation procedure or validated viable select agent removal procedure used;

(C) Include the name of the principal investigator;

(D) Include an attestation statement certifying that the information on the certificate is true, complete, and accurate, and that the validated inactivation or validated viable select agent removal was performed as described in paragraph (a)(8)(i) of this section;

(E) Be signed by the principal investigator or designee within 7 days after completion of the validated inactivation or validated viable select agent removal. Such designee must be listed on the entity's registration and have the knowledge and expertise to provide scientific and technical direction regarding the validated inactivation procedure or the validated viable select agent removal procedure to which the certificate refers;

(F) Be maintained for as long as the material is in the possession of the registered individual or entity plus an additional 3 years;

(G) A copy of the certificate must accompany all transfers of inactivated or select agent removed material, including intra-entity transfers.

* * * * *

(d) All records created in accordance with the regulations of this part must be maintained for 3 years unless otherwise stated.

§ 73.19 [Amended]

■ 20. Section 73.19 is amended in paragraphs (a)(1) introductory text and (b)(1) introductory text by adding ''eFSAP information system,'' before the word ''telephone'' and removing the word ''email'' and adding in its place ''email''.

Dated: January 22, 2024.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–01513 Filed 1–26–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

OFFICE OF FEDERAL PROCUREMENT POLICY

48 CFR Parts 1, 2, 12, 22, and 52

[FAR Case 2023–021; Docket No. FAR–2023–0021; Sequence No. 1]

RIN 9000–AO69

Office of Federal Procurement Policy; Federal Acquisition Regulation: Pay Equity and Transparency in Federal Contracting

AGENCY: Department of Defense (DoD), General Services Administration (GSA), National Aeronautics and Space Administration (NASA), and Office of Federal Procurement Policy (OFPP).

ACTION: Proposed rule.

SUMMARY: DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to implement a proposed Governmentwide policy developed by the Administrator for Federal Procurement Policy (OFPP Administrator), pursuant to the Administrator's authority that would prohibit contractors and subcontractors from seeking and considering information about job applicants' compensation history when making employment decisions for certain positions. Under the proposed policy and the proposed regulatory amendments, contractors and subcontractors would also be required to disclose the compensation to be offered to the hired applicant in job announcements for certain positions.

DATES: Interested parties should submit written comments to the Regulatory Secretariat Division at the address shown below on or before April 1, 2024 to be considered in the formation of the final rule.

ADDRESSES: Submit comments in response to FAR Case 2023–021 to the Federal eRulemaking portal at *https://www.regulations.gov* by searching for ''FAR Case 2023–021''. Select the link ''Comment Now'' that corresponds with ''FAR Case 2023–021''. Follow the instructions provided on the ''Comment Now'' screen. Please include your name, company name (if any), and ''FAR Case 2023–021'' on your attached document. If your comment cannot be submitted using *https://www.regulations.gov,* call or email the point of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Instructions: Please submit comments only and cite ''FAR Case 2023–021'' in all correspondence related to this case. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. Public comments may be submitted as an individual, as an organization, or anonymously (see frequently asked questions at *https://www.regulations.gov/faq*). To confirm receipt of your comment(s), please check *https://www.regulations.gov,* approximately two to three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact Ms. Mahruba Uddowla, Procurement Analyst, at 703–605–2868 or by email at *mahruba.uddowla@gsa.gov.* For information pertaining to status, publication schedules, or alternate instructions for submitting comments if *https://www.regulations.gov* cannot be used, contact the Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.* Please cite FAR Case 2023–021.

SUPPLEMENTARY INFORMATION:

I. Proposed Policy of the OFPP Administrator

Pursuant to 41 U.S.C. 1121(b), the Senior Advisor, Office of Federal Procurement Policy (OFPP), performing by delegation the duties of the Administrator for Federal Procurement Policy, is proposing a Government-wide procurement policy that would:

(1) prohibit contractors and subcontractors from seeking and considering information about job applicants' compensation history when making employment decisions about personnel working on or in connection with a government contract; and

(2) require contractors and subcontractors to disclose, in all advertisements for job openings involving work on or in connection with a government contract placed by or on behalf of the contractor or subcontractor, the compensation to be offered to the hired applicant, for any position to perform work on or in connection with the contract.

The Administrator is proposing this policy based on her determination, described in more detail in section IV below, that compensation history bans and compensation disclosure requirements (the latter are also collectively referred to as pay transparency), both together and separately, would promote economy, efficiency, and effectiveness in the procurement of property and services by the Federal Government. Compensation history bans and pay transparency requirements have been shown to promote pay equity by closing pay gaps, which leads to increased worker satisfaction, better job performance, and overall increased worker productivity-all factors associated with promoting economy, efficiency, and effectiveness of the Federal contractor workforce. When workers feel that they are valued and their pay is fair, it can foster a higher level of commitment to an employer associated with better job performance and increased productivity. Compensation history bans [1] have been found to reduce pay gaps that have been shown to disadvantage certain populations, including women, workers of color, and workers entering the labor market during recessions. Similar to compensation history bans, compensation disclosure requirements reduce gender, racial and ethnic pay gaps by reducing pay secrecy and helping workers negotiate. Pay transparency requirements also promote economy, efficiency, and effectiveness in recruitment and retention. By disclosing the compensation upfront, employers can effectively lower recruiting costs, both in terms of direct expenses, such as job advertising costs, and indirect expenses, such as those related to the selection and negotiation process. In addition to pay equity, compensation history bans and compensation disclosure requirements can help companies attract and retain better talent and lower worker turnover. These practices demonstrate a commitment to fairness for all workers and increase hiring efficiencies and reduce the costs for employers to hire new workers for Federal contracts. A fuller discussion of how the proposed policy would further economy, efficiency and effectiveness in Federal

[1] The state and local laws restricting the use of compensation history in pay-setting and employment decisions are commonly referred to as ''salary history bans.'' When referring to those laws and the studies analyzing their effects, the terms ''salary history'' and ''compensation history'' may be used interchangeably. For this rulemaking, ''compensation history'' means the compensation an applicant is currently receiving or the compensation the applicant has been paid in a previous job, where ''compensation'' is defined as ''any payments made to, or on behalf of, an employee or offered to an applicant as remuneration for employment, including but not limited to salary, wages, overtime pay, shift differentials, bonuses, commissions, vacation and holiday pay, allowances, insurance and other benefits, stock options and awards, profit sharing, and retirement.''

procurement may be found in section IV below.

This proposed policy also accords with Executive Order (E.O.) 14069 of March 15, 2022, titled ''Advancing Economy, Efficiency, and Effectiveness in Federal Contracting by Promoting Pay Equity and Transparency.'' E.O. 14069 established an administration policy of eliminating discriminatory pay practices that inhibit the economy, efficiency, and effectiveness of the Federal workforce and the procurement of property and services by the Federal Government; highlighted regulatory efforts by the Office of Personnel Management to address the use of salary history in hiring and pay-setting processes for Federal employees (see Office of Personnel Management, Proposed Rule, Advancing Pay Equity in Governmentwide Pay Systems, 88 FR 30251 (May 11, 2023), *https://www.govinfo.gov/content/pkg/FR-2023-05-11/pdf/2023-09564.pdf*); and directed the Federal Acquisition Regulatory Council (FAR Council), in consultation with the Secretary of Labor and other agency heads as appropriate, to consider issuing proposed rules to advance economy, efficiency, and effectiveness in Federal procurement by promoting pay equity and transparency for job applicants and employees of Federal contractors and subcontractors. Pursuant to 41 U.S.C. 1121(b), the OFPP Administrator proposes these pay equity policies to be implemented in the FAR through rulemaking. See 41 U.S.C. 1121(b), 1303. The OFPP Administrator invites public comment on this proposed policy and the analysis supporting it, which is set forth in section IV below.

II. Proposed FAR Rule: Discussion and Analysis

To implement the OFPP Administrator's proposed policy, which is reinforced by E.O. 14069, DoD, GSA, and NASA are proposing to amend the FAR to limit or prohibit contractors and subcontractors from seeking and considering information about job applicants' compensation history when making employment decisions on certain positions and to require contractors and subcontractors to disclose the compensation to be offered to the hired applicant in job announcements for certain positions.

The proposed rule would establish a new FAR subpart 22.XX entitled ''Prohibition On Compensation History Inquiries and Requirement For Compensation Disclosures By Contractors'' to incorporate the proposed policy of the OFPP Administrator described in section I. A summary of the proposed changes follows:

A. FAR Part 1

FAR 1.106, OMB approval under the Paperwork Reduction Act, will include the OMB control number associated with the notification of rights to job applicants, the compensation disclosures, and the complaints process.

B. FAR Part 2

FAR 2.101, Definitions, has a conforming change to the clause prescription in the new subpart, showing ''United States'' will include outlying areas (*e.g.,* territories).

C. FAR Part 12

FAR 12.301(d)(11) is added to clarify that use of the new clause is required for acquisitions of commercial products and commercial services.

D. FAR Part 22

This new subpart at FAR 22.XX communicates the policy that contractors and subcontractors are prohibited from seeking and considering information about job applicants' compensation history when making employment decisions on certain positions. The prohibition would apply to the recruitment and hiring for any position to perform work on or in connection with the contract, and applicants are to be provided with notice of this requirement as either part of the job announcement or application process. In addition, the proposed new subpart must communicate the policy that contractors and subcontractors are required to disclose in all advertisements for job openings placed by or on behalf of the contractor or subcontractor, for any position to perform work on or in connection with the contract, the compensation thereof to be offered to the hired applicant.

The new subpart contains the prescription for a new clause at FAR 52.222–ZZ entitled ''Prohibition on Compensation History Inquiries and Requirement for Compensation Disclosures by Contractors During Recruitment and Hiring'', and proposed to be included in all solicitations and contracts, where the principal place of performance will be in the United States, which is defined as including its outlying areas.

The proposed policy provides that an applicant for a position covered by the proposed policy may submit a complaint relating to the contractor's noncompliance with the clause to a central collection point of the agency that issued the solicitation or awarded the contract or order. The complaint must be submitted within 180 days of the date the violation occurred. The FAR text provides a link to where the list of agency central collection points is posted. The proposed rule states that the contracting agency will review the complaint, consult with the complainant as necessary to confirm the complainant is a covered applicant, and take action as appropriate. The subpart reiterates that complaints alleging discrimination prohibited by E.O. 11246, Section 503 of the Rehabilitation Act of 1973, and the Vietnam Era Veterans' Readjustment Assistance Act by the contractor or subcontractor should be submitted directly to the Department of Labor's Office of Federal Contract Compliance Programs (OFCCP). If complaints alleging discrimination are submitted to an agency central collection point rather than directly with OFCCP, the complaints will be forwarded to OFCCP.

E. FAR Part 52

FAR clauses 52.213–4, Terms and Conditions—Simplified Acquisitions (Other Than Commercial Products and Commercial Services) and 52.244–6, Subcontracts for Commercial Products and Commercial Services, are revised to reflect the application of the new policy to both prime contracts and subcontracts for commercial products and commercial services and both prime contracts and subcontracts under the simplified acquisition threshold (see Section III of this preamble).

New FAR clause 52.222–ZZ entitled ''Prohibition on Compensation History Inquiries and Requirement for Compensation Disclosures by Contractors During Recruitment and Hiring'' is added to FAR part 52. With regard to compensation history, the clause prohibits contractors from seeking an applicant's compensation history either directly or indirectly, from requiring disclosure of compensation history as a condition of an applicant's candidacy, and from retaliating against any applicant for failing to respond to an inquiry regarding their compensation history. The clause also prohibits contractors from relying on an applicant's compensation history, even if an applicant for employment volunteers their compensation history without prompting at any stage in the selection process.

With regard to compensation disclosure, the clause requires contractors to, in solicitations or advertisements for job openings placed by or on behalf of the contractor for any position to perform work on or in connection with the contract, disclose

the compensation to be offered to the hired applicant. The disclosure must indicate the salary or wages, or range thereof, that the contractor in good faith believes that it will pay for the advertised position and may reflect, as applicable, the contractor's pay scale for that position, the range of compensation for those currently working in similar jobs, or the amount budgeted for the position. The disclosure must also include a general description of the benefits and other forms of compensation applicable to the job opportunity. Where at least half of the expected compensation for the advertised position is derived from commissions, bonuses, and/or overtime pay, the contractor must specify the percentage of overall compensation or dollar amount, or ranges thereof, for each form of compensation, as applicable, that it in good faith believes will be paid for the advertised position.

The proposed new clause requires contractors to provide any applicants that are covered by the prohibitions and disclosure requirements in the clause with a notice of their rights as either part of the job announcement or application process. Specific language for the notice is provided in the clause, along with a fill-in where the contractor would inform the applicant of the agency that issued the solicitation or awarded the contract so that applicants know which agency should receive any complaints of noncompliance.

The clause includes language to ensure it will flow down the compensation disclosure requirement and the prohibition on compensation history inquiries to all subcontracts at any tier, to be performed within the United States including its outlying areas.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items) or for Commercial Services

This rule proposes a new FAR clause at 52.222–ZZ. The proposed clause is prescribed at FAR 22.XX04 for use in all solicitations and contracts. The clause is applicable to acquisitions at or below the SAT and to acquisitions for commercial products and commercial services, including COTS items.

The benefits of the pay equity and transparency requirements in this proposed rule are equally impactful in commercial and noncommercial settings as well as to large or small dollar contracts. For this reason, an increasing number of states and localities have imposed requirements similar to those described in this proposed rulemaking for sales of any goods or services in any dollar amount, whether business to business, business to consumer, or business to government. Limiting application would forgo the various ways in which pay equity promotes economy, efficiency, and effectiveness. In addition, because many entities who sell in those states or localities also sell in the Federal marketplace, it is believed that many government contractors, including small businesses, already have incorporated these requirements into their existing human capital management practices. Moreover, limiting the application of the proposed rule could create unintended confusion and ambiguity for contractors and prospective employees. Many contractors who do business with the government have contracts below and above the SAT, and provide both commercial and government unique products and services. Carve-outs to the rule could result in contractor employees performing the same or similar functions receiving disparate treatment during hiring and recruiting for work on or in connection with government contracts, which would perpetuate inequity and deprive the Federal marketplace of economy, efficiency, and effectiveness in the procurement of property and services. The FAR Council will consider public feedback before making a final determination on the scope of the final rule.

IV. Expected Impact on Economy, Efficiency, and Effectiveness

In implementing the OFPP Administrator's proposed policy, this proposed rule provides that for any recruitment and hiring for work on or in connection with a government contract, the contract would prohibit the contractor and subcontractor from seeking an applicant's compensation history, requiring disclosure of compensation history as a condition of an applicant's candidacy, or retaliating against or refusing to interview or otherwise consider, hire, or employ any applicant for failing to respond to an inquiry regarding their compensation history. Furthermore, the contractor and subcontractor would be prohibited from relying on an applicant's compensation history as a criterion in screening or considering the applicant for employment, or relying on an applicant's compensation history in determining the compensation for such individual at any stage in the selection process. These prohibitions are collectively referred to as a compensation history ban in this section.

This rule would also require contractors and subcontractors to disclose in all advertisements for job openings involving work on or in connection with a government contract placed by or on behalf of the contractor or subcontractor, the compensation to be offered to the hired applicant. This requirement is referred to as a compensation disclosure in this section.

The OFPP Administrator has outlined the results of an analysis of economy, efficiency and effectiveness regarding the proposed compensation history bans and compensation disclosure requirements in this section. The OFPP Administrator invites public comments on existing literature or ongoing research that may further inform this analysis.

Expected Benefits

A. Promoting Economy, Efficiency, and Effectiveness through Compensation History Bans

State and local governments are increasingly adopting laws and regulations that prohibit employers from requesting compensation history information from job applicants. A running list of states and localities that have outlawed pay history questions from various employers reveals 22 statewide bans and 22 local bans.[2] The OFPP Administrator's analysis shows that compensation history bans promote economy, efficiency and effectiveness in various ways.

1. Compensation history bans were found to reduce pay gaps that disadvantage certain populations, including women, workers of color and workers entering the labor market during recessions. Closing pay gaps increases job satisfaction, helps attract and retain staff, and increases performance, retention, and productivity. This, in turn, may lead to improved economy, efficiency and effectiveness in Government procurement.

Many employers set pay offers on the basis of workers' past pay. This is problematic because research has documented the persistence of racial, ethnic, and gender discrimination in the labor market that may be reflected in pay-setting.[3]

[2] HRDive. (Aug 2023). Salary history bans: A running list of states and localities that have outlawed pay history questions. Retrieved January 4, 2024 from *https://www.hrdive.com/news/salary-history-ban-states-list/516662/*.

[3] Mandel, H., & Semyonov, M. (2014). Gender pay gap and employment sector: Sources of earnings disparities in the United States, 1970–2010.

Continued

Closing pay gaps is important to the economy, efficiency, and effectiveness of contract performance because it has been shown to increase the satisfaction, commitment, and motivation of employees.[4] When workers feel that they are valued and their pay is fair, they are more likely to be committed to their employer, which leads to improved job performance and enhanced productivity. In contrast, when employees think they are underpaid or undervalued, those perceptions can lead to dissatisfaction. Worker dissatisfaction is a very strong predictor of workers' quit intentions.[5] Consequently, this leads to higher staff turnover.[6] Turnover is costly to employers, requiring employers to invest in new searches, hiring, and training at the same time that they are losing the contributions of the departed worker. Kuhn and Yu [7] estimated the costs of employee turnover in small retail sales teams using daily sales data and an advance notice requirement and found that turnover has a negative impact on productivity, especially when it involves high-performing workers or workers with longer tenure. Kuhn and Yu's study estimated that 10 percent higher turnover is about as costly as a 0.6 percent wage increase. Thus, reductions in turnover can improve Federal contractor and Federal Government—procurement efficiencies.

A growing body of evidence indicates that compensation history bans effectively reduce pay gaps. Davis, Ouimet and Wang [8] evaluated compensation history bans covering all public sector employees in 36 states. They found that on average, compensation history bans lead to a 1.5 percent increase in wages of women relative to men, though this decrease in the gender pay gap was driven in part by overall wage decreases of around 3 percent in the new hire sample. Mask [9] studied the effect of compensation history bans on workers who enter the labor market during recessions. During a recession, increased competition forces inexperienced job market entrants to accept lower wages than those who start their careers during an economic boom. This penalty does not reflect workers' skills, experiences, or ability to do their job but simply the misfortune to enter the labor market during an economic downturn. In other words, workers who had the misfortune of working in areas with larger economic shocks have worse employment and wage outcomes years later, unrelated to their own initial skills or experience.[10] This effect is referred to as ''scarring,'' defined as the negative long-term effect that unemployment has on future labor market possibilities.[11] Mask found by breaking the linkage between past wages and current offers, compensation history bans could reduce this scarring effect. Moreover, Mask found that compensation history bans increase job mobility, hourly wages, and weekly earnings for scarred workers relative to non-scarred workers, and reduce the gap in wages caused by scarring.

Several working papers support the claim as well. For example, Sinha [12] analyzed the effects of U.S. salary history bans with the option to voluntary share information and showed that these policies narrowed the gender pay gap significantly by 2 percentage points, driven almost entirely by an increase in female earnings. Another working paper by Bessen, Meng and Denk [13] found that following salary history bans, employers posted wages more often and increased pay for job changers, particularly for women (6.2 percent) and non-whites (5.9 percent). A working paper published in the NBER Working Series [14] showed that the gender earnings ratio increased by 1 percent in states with salary history bans, and that the increase was mainly driven by workers who switched jobs, especially women and non-whites.

2. Compensation history bans were found to increase the pool of applicants to Federal contractors who might have relevant skills or experiences but who otherwise might not apply. Better aligning hiring and compensation decisions with workers' skills and experiences results in a broader applicant pool for Federal contractors, thus increasing efficiencies in federal procurement.

If workers know that Federal contractors base hiring and compensation decisions on workers' past pay, and in turn, that past pay reflects arbitrary factors, workers may be less likely to seek new positions with Federal contractors because they know that their past pay may hamper their ability to secure a job offer or to receive higher pay. This likely is especially true for workers disadvantaged by current hiring and pay-setting practices. In turn, this effect may limit applicant pools for Federal contractors, thereby reducing the availability of workers with relevant skills and experiences and reducing Federal contractor productivity.

For instance, a Harvard Business Review article by Bessen, Denk and Kossuth [15] reported that job seekers or applicants are more likely to apply if salary history is banned. Barach and Horton [16] found that without access to applicant wage histories, employers

Demography, 51(5), 1597–1618.; Blau, F.D., & Kahn, L.M. (2017). The gender wage gap: Extent, trends, and explanations. Journal of economic literature, 55(3), 789–865.; Manduca, R. (2018). Income inequality and the persistence of racial economic disparities. Sociological Science, 5, 182–205.

[4] Kular, S., & Gatenby, M. (2019). Performance-related pay and employee well-being: Investigating relationships between rewards, pay, satisfaction, and engagement. Human Resource Management International Digest, 27(4), 11–14. *https://doi.org/10.1108/HRMID-03-2019-0080.*; Rosenfeld, J. (2021). You're Paid What You're Worth. In You're Paid What You're Worth. Harvard University Press.; Lam, L., Cheng, B.H., Bamberger, P., & Wong, M.-N. (2022). Research: The unintended consequences of pay transparency. Harvard Business Review. *https://hbr.org/2022/08/research-the-unintended-consequences-of-pay-transparency.*

[5] Xue, J., Wang, H., Chen, M., Ding, X., & Zhu, M. (2022). Signifying the relationship between psychological factors and turnover intension: the mediating role of work-related stress and moderating role of job satisfaction. Frontiers in Psychology, 13, 847948.; Pelly, D. (2023). Worker well-being and quit intentions: is measuring job satisfaction enough?. *Social Indicators Research, 169*(1), 397–441.

[6] Kulik, C.T., & Perera, S. (2016). Help or hindrance? Work-life practices and women in management. The Leadership Quarterly, 27(3), 504–5184.; Li, J., & Nelson, J. (2022). Employee development and organizational performance: A review of literature. Journal of Human Resource Development International, 23(1), 1–14.; Li, J., & Nelson, J. (2023). Employee turnover and organizational performance: Testing a hypothesis using longitudinal data from over 800 similar workplaces in the United States. Journal of Public Administration Research and Theory, 18(4), 573–592.

[7] Kuhn, P., & Yu, L. (2021). How costly is turnover? Evidence from retail. Journal of Labor Economics, 39(2), 461–496.

[8] Davis, J., Ouimet, P., & Wang, X. (2022). Hidden Performance: Salary History Bans and the Gender Pay Gap. The Review of Corporate Finance Studies, 11(3), 511–553.

[9] Mask, J. (2023). Salary history bans and healing scars from past recessions. Labor Economics, 84, 102408.

[10] Yagan, Danny (2019). ''Employment hysteresis from the Great Recession.'' Journal of Political Economy, 127.5: 2505–2558.

[11] Huckfeldt, C. (2022). Understanding the scarring effect of recessions. *American Economic Review, 112*(4), 1273–1310.

[12] Sinha, Sourav, Salary History Bans: Strategic Disclosure by Job Applicants and the Gender Pay Gap (January 24, 2022). Retrieved January 4, 2024, from *https://ssrn.com/abstract=4025580.*

[13] Bessen, James E. and Meng, Chen and Denk, Erich, Perpetuating Inequality: What Salary History Bans Reveal About Wages (June 2020). Retrieved January 4, 2024 from *https://ssrn.com/abstract=3628729.*

[14] Hansen, B., & McNichols, D. (2020). Information and the persistence of the gender wage gap: Early evidence from California's salary history ban (National Bureau of Economic Research Working Paper No. w27054). Retrieved January 4, 2024 from *https://www.nber.org/system/files/working_papers/w27054/w27054.pdf.*

[15] Bessen, J., Denk, E., & Kossuth, J. (2020). Stop asking job candidates for their salary history. Harvard Business Review. Retrieved January 4, 2024 from: Stop Asking Job Candidates for Their Salary History (*hbr.org*).

[16] Barach, M.A., & Horton, J.J. (2021). How do employers use compensation history? Evidence from a field experiment. Journal of Labor Economics, 39(1), 193–218.

who had salary history bans tend to consider a wider group of candidates, invite more candidates in for interviews, and ask more questions of each candidate, thus leading to recruiting more diverse and qualified set of candidates. Barach and Horton found that employers evaluated about 7 percent more applicants following a salary history ban. A strong applicant pool may lead to efficiencies in procurement in terms of reduced time-to-hire and greater possibility of finding stronger shortlist of candidates.

It is important to note, however, that the benefit of a large applicant pool holds true only in the absence of reliance on voluntary disclosures of compensation histories, known as unravelling. In addition to reversing the benefits outlined in this section, unravelling can impose disclosure costs on applicants who must decide whether or not to voluntarily disclose their compensation history. Agan et al.[17] suggest that job candidates also face different direct costs for disclosing; for example, an innate feeling of harm or vulnerability from disclosing. These costs tend to be higher for some groups. In Agan et al.'s study, women are more likely to report discomfort with disclosing than men and tend to ask for lower salaries from employers in the first place. The proposed rule would prevent contractors from using voluntarily-disclosed salary histories as a criterion in screening or considering the applicant for employment, or relying on an applicant's voluntarily-disclosed compensation history in determining the compensation for such individual at any stage in the selection process, which should will likely prevent unravelling. A Columbia Business School research paper [18] used information from a survey of the U.S. labor force to evaluate the connections between voluntary disclosure, wage history, and associated bans. In locations where it is illegal for employers to request pay history, the study found that a significant portion of employees (28 percent) nevertheless provide it. In addition, the study found that if enough of the applicant pool for the position discloses their compensation history, an additional 47 percent will do so.

3. Compensation history bans expand the pool of applicants, thereby facilitating the hiring of more quality candidates. In turn, hiring quality candidates reduces the risks of turnover and leads to overall productivity gains.

By limiting Federal contractors' ability to make hiring and compensation-setting decisions based on workers' past pay, a compensation history ban will more closely align employment decisions with quality factors relevant for the job, thereby improving the quality of the contracting workforce. A working paper by Sran et al.[19] studied the effects of pay history inquiry bans on employers' pay offers and hiring practices. They found some evidence that the number of online job postings increases and that postings are more likely to include salary information after salary history bans. Another article by Bessen et al.[20] showed that employers are more likely to include work experience and other skill expectations in job postings following the passage of compensation history bans, indicating that employers tend to be more explicit about these job-relevant characteristics with bans in place.

Hiring the right employee is crucial to an organization as it reduces employee burnout, thereby reducing the risk of understaffing and turnovers. Hiring an unqualified candidate can lead to significant decrease in productivity within the organization resulting in cost overruns and schedule disruptions for Federal contracts. A survey conducted by CareerBuilder [21] asked companies how a bad hire affected their organization and found that 37 percent of companies cited less productivity, 32 percent reported lost time in recruiting and training another worker, and 31 percent experienced compromised quality of work. The study calculated an average of $14,900 lost on every bad hire.

4. Compensation history bans strengthen incentives for prospective and current Federal contractor workers to invest in job-relevant skills and experiences. Better aligning hiring and compensation decisions with workers' skills and experiences incentivizes workers to invest in relevant skills and experiences, increasing efficiencies in Federal procurement.

If workers are aware that Federal contractors are making pay setting decisions based on their skills and experiences, rather than their past pay, they likely will be motivated to invest in enhancing their skill sets and gaining relevant experiences. This investment, in turn, will better equip them for employment opportunities within Federal contractor jobs, increasing the quality of Federal contract work and reducing the potential for cost overruns and schedule delays in Federal contracts. By prioritizing the employment of high-quality workers, the risk of understaffing and turnover can be significantly reduced, leading to further cost savings in terms of hiring expenses.

Seminal theories in labor economics document that unequal treatment among groups, including in hiring and pay, can create self-fulfilling prophecies, whereby minorities believe that their investments in skills and training will not be fully rewarded by employers, leading those groups to under-invest in training and creating inefficiencies for employers and the economy as a whole.[22]

B. Promoting Economy, Efficiency, and Effectiveness Through Salary Range Disclosure

Pay transparency laws at the state and local level are becoming increasingly prevalent. These regulations require employers to be more transparent with salary ranges and benefits, and they aim to help promote fairness and equity in the workplace. According to the Center for American Progress,[23] as of March 2023, 8 states had enacted, and at least 15 states were considering, salary range transparency laws. There are a number of ways that salary range disclosures

[17] Agan, A., Cowgill, B., & Gee, L.K. (2020, May). Do workers comply with salary history bans? a survey on voluntary disclosure, adverse selection, and unraveling. In AEA Papers and Proceedings (Vol. 110, pp. 215–219). 2014 Broadway, Suite 305, Nashville, TN 37203: American Economic Association. Retrieved January 4, 2024 from *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3522170.*

[18] Cowgill, Bo and Agan, Amanda Y. and Gee, Laura, The Gender Disclosure Gap: Salary History Bans Unravel When Men Volunteer their Income (May 9, 2022). Columbia Business School Research Paper No. 4104743. Retrieved on January 4, 2024 from *https://ssrn.com/abstract=4104743.*

[19] Sran, G., Vetter, F., & Walsh, M. (2020). Employer responses to pay history inquiry bans. Retrieved January 4, 2024 from *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3587736.*

[20] Bessen, J., Denk, E., & Kossuth, J. (2020). Stop asking job candidates for their salary history. Harvard Business Review. Retrieved January 4, 2024 from *https://hbr.org/2020/07/stop-asking-job-candidates-for-their-salary-history.*

[21] CareerBuilder. (2017, December 7). Nearly three in four employers affected by a bad hire, according to a recent CareerBuilder survey. Retrieved January 24, 2024 from *https://press.careerbuilder.com/2017-12-07-Nearly-Three-in-Four-Employers-Affected-by-a-Bad-Hire-According-to-a-Recent-CareerBuilder-Survey.*

[22] Lundberg, S.J., & Startz, R. (1983). Private discrimination and social intervention in competitive labor markets. American Economic Review, 73(3), 340–347.; Coate, S., & Loury, G.C. (1993). Will affirmative-action policies eliminate negative stereotypes? American Economic Review, 83(5), 1220–1240.

[23] Center for American Progress. (Mar. 9, 2023). Quick Facts About State Salary Range Transparency Laws. Retrieved Jan. 8, 2024 from *https://www.americanprogress.org/article/quick-facts-about-state-salary-range-transparency-laws/#:~:text=These%20laws%20create%20an%20environment,are%20penalized%20more%20than%20men.*

promote economy, efficiency, and effectiveness in Federal procurement.

1. Similar to compensation history bans, salary range disclosure requirements reduce gender and racial/ethnic pay gaps by reducing pay secrecy and helping workers negotiate. This may reduce the costs for Federal contracting.

Pay transparency measures can also effectively identify compensation differences and reduce broader gender inequalities in the labor market. Arnold et al.[24] is a working paper which studies the impact of a January 2021 law in Colorado that required job postings to contain expected salary information. Arnold et al. used data from Burning Glass Technologies and found that this law increased the fraction of postings with salary information by 30 percentage points, although there remains substantial non-compliance. For employers that posted salaries both before and after the policy, the Arnold et al. found that posted salaries increased by about 3.6 percent, on average, following the policy. Note, however, that while the results of Arnold et al. support the intended policy effect of raising workers' salaries, the study did not look at effect of pay transparency on inequality, gender pay gaps, and racial pay disparities.

Lyons and Zhang[25] examined whether salary transparency influences gender pay inequality in the context of Canadian universities. The authors relied on a policy change enacted in one Canadian province that required salary disclosure through a publicly searchable database, thus lowering the cost of monitoring the gender pay gap, and found that, on average, salary disclosure improves gender pay equality but institutions respond in different ways. Similarly, Baker et al.[26] examined the impact of public sector salary disclosure laws on university faculty salaries in Canada. The laws, which enable public access to the salaries of individual faculty, were introduced in different provinces at different times. Using detailed administrative data covering the majority of faculty in Canada, and an event-study research design that exploits within-province variation in exposure to the policy across institutions and academic departments, Baker et al. found robust evidence that the laws reduced the gender pay gap between men and women by approximately 20–40 percent.

2. Salary range disclosure requirements reduce turnover rates. Employee retention is critical to organizational success. Keeping the turnover rate low strengthens contracting relationships, which ultimately boosts productivity and improves the ability of contractors to stay on budget and on time.

Salary transparency may help build workforce loyalty by building trust in management.[27] While pay impacts where people decide to work initially, some reports have shown that pay transparency also impacts whether or not workers stay at their current jobs.[28] A recent study conducted by Payscale,[29] a Seattle-based compensation software firm, showed that pay transparency decreases intent to quit by 30 percent when analyzed in isolation. Payscale's first Retention Report suggests that workers are eager for greater transparency from their employer in general, with crowdsourced data from more than 578,000 workers indicating that they want information about the health of the business and how their pay is determined.

3. The proposed salary range disclosure may lower recruiting costs. By disclosing the salary range upfront, employers can effectively lower recruiting costs related to the selection and negotiation process. This reduces the costs for Federal contracting.

Studies have found that candidates are more likely to click on job advertisements that include a salary range.[30] Thus, implementing pay transparency can streamline the hiring process. Upfront information aligns expectations between employers and applicants on pay and improves time-to-fill open positions. Salary transparency at the outset of the hiring process facilitates pay negotiations later on, eliminates candidates who would later turn down an offer due to salary, and frees up candidate interviews to cover other topics.

C. The Combined Impact of Compensation History Bans and Salary Range Disclosures

Compensation history bans and salary range disclosure requirements are relatively new policies. As of August 2023, 22 states have enacted compensation history bans and 10 states have enacted a pay transparency law with their ban. The States that have implemented these policies have, consistent with the literature discussed above, highlighted the important benefits of these policies to ''increas[ing] efficiency and achiev[ing] cost savings in state government.'' Pa. Exec. Order No. 2018–03 (June 6, 2016); see also Office of Governor of Va., Press Release, Governor Northam Announces Employment Equity Initiative for State Agencies (June 20, 2019) (''This initiative adopts industry-wide best practices in compensation and employment, which will help attract and retain top talent in our state workforce and bring greater equity and overdue improvements to our state policies.''); and Hawai'i Senate Bill 1057 (July 3, 2023) (''[I]nitial experiences have benefited employers, current employees, and prospective employees.'').

Moreover, despite the important benefits of these policies, including in reducing turnover, increasing the quality of applicants, and streamlining the hiring process, absent a Government-wide policy individual contractors cannot reasonably be expected to adopt these policies with sufficient uniformity.

Expected Costs

The FAR Council has identified certain nonrecurring costs associated with the initial rule familiarization, review and revisions of existing policies, and preparation of training for those involved in the recruitment and hiring process discussed below, and welcomes public feedback on these and any potential additional costs associated with implementation of the proposed rule.

Federal contractors like all businesses establish market-based compensation to recruit and retain a diverse and talented workforce. Likewise, to be a competitive and viable business, companies need to

[24] Arnold, David and Quach, Simon and Taska, Bledi, The Impact of Pay Transparency in Job Postings on the Labor Market (August 9, 2022). Retrieved Jan. 9, 2024 from *https://ssrn.com/abstract=4186234.*

[25] Lyons, E., & Zhang, L. (2023). Salary transparency and gender pay inequality: Evidence from Canadian universities. Strategic Management Journal.

[26] Baker, M., Halberstam, Y., Kroft, K., Mas, A., & Messacar, D. (2023). Pay transparency and the gender gap. American Economic Journal: Applied Economics, 15(2), 157–183.

[27] Salary transparency: One organization's story, Nonprofit Quarterly/Jeanne Bell, 2021. Retrieved January 4, 2024 from *https://nonprofitquarterly.org/salary-transparency-one-organizations-story/.*

[28] How Salary Transparency can Impact retention. Insights2Action Perspective/McAneny, 2022. Retrieved January 4, 2024 from *https://action.deloitte.com/insight/3037/how-salary-transparency-can-impact-retention.;* Show me the money: More job listings have salary details, The Wall Street Journal/Kate Linebaugh and Ryan Knutson, 2022. Retrieved January 4, 2024 from *https://www.wsj.com/podcasts/the-journal/show-me-the-money-more-job-listings-have-salary-details/7490aa9e-6100-4ff0-9197-cfc78a0cff55.*

[29] Pay Transparency Reduces Turnover, Payscale Research Indicates. HRDive/Tornone, 2022. Retrieved January 4, 2024 from Pay transparency reduces turnover, Payscale research indicates | HR Dive.

[30] Salary transparency: One organization's story, Nonprofit Quarterly/Jeanne Bell, 2021. Retrieved January 4, 2024 from *https://nonprofitquarterly.org/salary-transparency-one-organizations-story/.*

establish some level of budgeting and human capital management. Regardless of the size of the entity or the sophistication level of their processes, companies will, regardless of the proposed rule, go through a process to determine budgets and set expected compensation levels. Companies will seek market information from public sources such as Bureau of Labor Statistics Economic Cost Indices or purchase compensation survey data. The FAR Council has not identified any additional expected costs related to budgeting that would be incurred as a result of not asking a job applicant their compensation history, or more than a de minimis amount for including a good faith estimate of compensation as part of existing human resource practices.

Identified Costs

Category	Costs
Rule Familiarization	$15,754,521
Review and Modification of Existing Policies	31,509,043
Preparation of Training	47,263,564
Total Nonrecurring Costs	94,527,128

Rule Familiarization

Active SAM Registrants (1)	486,551
Hours (2)	1
Rate (3)	32.38
	15,754,521

(1) Based on SAM data as of November 30, 2023, there are 486,551 active registrants. We estimate this is the universe of entities that may seek to do business with the Government. Since the actual number of prime contractors during 2022 was less than 120,000 we believe this represents the upper limit of impacted entities inclusive of subcontractors.

(2) Based on the short length, limited complexity and assumptions it is estimated that each entity would spend one hour on initial general familiarization of the rule.

(3) For this function we have assigned a rate based on the Employer Cost for Compensation Table 4 for Office and administrative support occupations.

REVIEW AND MODIFICATION OF POLICIES

Active SAM Registrants	486,551
Hours (1)	2
Rate (2)	32.38
	$31,509,043

(1) Based on the short length, limited complexity and assumptions we estimate each entity will spend on average 2 hours reviewing and modifying their existing policies and procedures.

(2) For this function we have assigned a rate based on the Employer Cost for Compensation Table 4 for the Office and administrative support occupations.

PREPARATION AND TRAINING

Active SAM Registrants	486,551
Hours (1)	3
Rate (2)	32.38
	$47,263,564

(1) Based on the short length, limited complexity and assumptions we estimate each entity will spend on average 3 hours for preparation and conduction of training.

(2) For this function we have assigned a rate based on the Employer Cost for Compensation Table 4 for the Office and administrative support occupations.

V. Request for Public Comment

Interested parties are invited to submit comments on both the proposed policy of the OFPP Administrator and the proposed implementing rule developed by DoD, GSA, and NASA. We encourage commenters to identify whether their comments are directed to the proposed policy, proposed implementing rule, or both.

A. Comments on the Proposed Policy of the OFPP Administrator

The OFPP Administrator requests comments on the proposed policy and especially welcomes input in response to the questions below. Such information will be useful for better understanding the effect of regulations on pay-setting by Federal contractors.

1. How might states' experiences with salary history bans inform future regulatory actions? State pay equity statutes often provide workers with protections beyond those in Federal laws such as Title VII of the Civil Rights Act of 1964 and the Equal Pay Act. Many states are updating equal pay statutes and increasing access to equal pay protections and pay transparency, such as limiting salary history questions during the job offer stage, requiring employers to provide pay ranges on job postings, increasing pay reporting requirements for employers, or expanding the classes protected under existing equal pay laws to include identities such as gender identity, race, age, sexuality, religion, and country of origin. For example, some state laws require equal pay for ''substantially similar'' work rather than for the narrower ''equal work'' set out in Federal law.

2. What data should the Federal Government consider when measuring the effects of greater pay equity achieved through this rule, including effects on worker engagement, turnover, and productivity, as well as effects on worker equity, dignity, and fairness?

3. What factors should the OFPP Administrator consider for positions of high occupational segregation—that is, the occupations predominantly held by women that are often paid and valued less, compared to those predominantly held by men at the same level of skill or education?

4. Is there additional literature or ongoing research that would inform formulation of the final policy?

B. Proposed FAR Rule

The FAR Council agencies likewise request comments on all aspects of their proposed rule to implement the OFPP Administrator's proposed policy, including:

1. Which contractors and subcontractors are covered, including small businesses;

2. The scope of contracts included in the proposed rule;

3. The parameters of the prohibition on compensation history inquiries;

4. The parameters of the compensation disclosure requirement;

5. The notice of rights policy for employers to provide;

6. The applicant complaint process; and

7. Additional costs and benefits that should be considered, including as it relates to workers, Federal contractors, including small businesses, and other stakeholders.

VI. Severability

The OFPP Administrator has determined that both the proposed compensation history ban and compensation disclosure requirement, separately and independently, would promote economy, efficiency, and effectiveness in the procurement of property and services by the Federal Government. The OFPP Administrator accordingly intends that the discrete components of the proposed policy described in section I, which are capable of operating independently, be legally severable. Likewise, DoD, GSA, and NASA would intend that the proposed rule implementing the OFPP Administrator's proposed policy be severable. If any portion of the proposed policy or implementing rule were held to be invalid or unenforceable facially, or as applied to any entity or circumstance, that portion shall be severable from the remainder of the policy or rule, and shall not affect the

remainder thereof, or their application to entities not similarly situated or to other dissimilar circumstances.

VII. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 (as amended by E.O. 14094) and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

VIII. Regulatory Flexibility Act

This proposed rule, if finalized, may have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act 5 U.S.C. 601–612. The Initial Regulatory Flexibility Analysis (IRFA) is summarized as follows:

DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to implement the Administrator for Federal Procurement Policy's proposed pay equity policy, which would require that Government agencies, in order to promote economy, efficiency, and effectiveness in Federal procurement, enhance pay equity and transparency for job applicants and employees of contractors and subcontractors.

The objective of the rule is to implement the acquisition policy established by the Administrator for Federal Procurement Policy, pursuant to 41 U.S.C. 1121(b), to promote pay equity for any recruitment and hiring for work on or in connection with a Government contract, which prohibits contractors and subcontractors from seeking and considering information about job applicants' current or past compensation when making employment decisions. In addition, businesses awarded a contract or subcontract containing the new clause will be required in all advertisements for job openings placed by or on behalf of the contractor or subcontractor to disclose the compensation to be offered to the hired applicant, for any position to perform work on or in connection with the contract. The disclosure must indicate the salary or wages, or range thereof, that the contractor or subcontractor in good faith believes that it will pay for the advertised position, and may reflect, as applicable: the contractor's or subcontractor's pay scale for that position, the range of compensation for those currently working in similar jobs, or the amount budgeted for the position. The disclosure must also include a general description of the benefits and other forms of compensation applicable to the job opportunity. Where at least half of the expected compensation for the advertised position is derived from commissions, bonuses, and/or overtime pay, the contractor must specify the percentage of overall compensation or dollar amount, or ranges thereof, for each form of compensation, as applicable, that it in good faith believes will be paid for the advertised position.

The proposed rule also provides guidance on appropriate accountability measures associated with the prohibition and disclosure requirement.

Promulgation of this FAR rule is authorized by 41 U.S.C. 1121(b); 41 U.S.C. 1303; 40 U.S.C. 121(c); 10 U.S.C. chapter 4 and 10 U.S.C. chapter 137 legacy provisions (see 10 U.S.C. 3016); and 51 U.S.C. 20113.

The proposed rule may have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601–612.

The proposed rule will apply to both contractors and subcontractors and the prohibition and disclosure requirement will apply to employees or applicants that will be performing work on or in connection with the contract or subcontract. The proposed rule will apply the prohibition and disclosure requirement to all contracts over the micro-purchase threshold, which is generally $10,000.

Based on data obtained from the Federal Procurement Data System, 58,882 unique small entities out of the total 76,414 unique entities were awarded contracts in fiscal year 2022.

With regard to an estimate of the number of small entities that will be impacted by the rule as a subcontractor, data from the Federal Funding Accountability and Transparency Act Subaward Reporting System (FSRS) at *www.USASpending.gov* was used. However, this system does not distinguish small businesses from other than small businesses. Data for fiscal year 2022 show there were a total of 203,802 subcontracts reported; these subcontracts were awarded to 24,190 unique entities. For estimating purposes, DoD, GSA, and NASA assumed that 20 percent of subcontracts have a second-tier subcontractor, 10 percent of second-tier subcontractors have a third-tier subcontractor, and 5 percent of third-tier subcontractors have a fourth-tier subcontractor. This calculation estimates the total number of unique subcontractors is 29,536. Because the FSRS data does not distinguish small businesses from other than small businesses, this number is likely an overestimate of the small entities to which this rule will apply.

Considering there is no way to determine how many of the small entities overlap as both a prime contractor and a subcontractor, the two figures of 58,882 and 29,536 are not added together to estimate the number of total small entities to which the rule will apply.

The proposed rule does not include any new recordkeeping requirements for small businesses. However, the proposed rule does create new reporting and compliance requirements for contractors and subcontractors, including small businesses.

In terms of reporting, small businesses awarded a contract or subcontract containing the new clause will be required, in all advertisements for job openings placed by or on behalf of the contractor or subcontractor, to disclose the compensation to be offered to the hired applicant, for any position to perform work on or in connection with the contract. The disclosure must indicate the salary or wages, or range thereof, that the contractor or subcontractor in good faith believes that it will pay for the advertised position, and may reflect, as applicable: the contractor's or subcontractor's pay scale for that position; the range of compensation for those currently working in similar jobs; or the amount budgeted for the position. The disclosure must also include a general description of the benefits and other forms of compensation applicable to the job opportunity. Where at least half of the expected compensation for the advertised position is derived from commissions, bonuses, and/or overtime pay, the contractor or subcontractor must specify the percentage of overall compensation or dollar amount, or ranges thereof, for each form of compensation, as applicable, that it in good faith believes will be paid for the advertised position. The proposed rule also requires a small business awarded a contract or subcontract to provide applicants with notice of this requirement as either part of the job announcement or application process. Since these reporting requirements counts as information collections under the Paperwork Reduction Act (44 U.S.C. 3501–3521), the Regulatory Secretariat Division has submitted a request for approval of a new information collection requirement to the Office of Management and Budget.

In terms of compliance requirements, the proposed rule prohibits small businesses awarded a contract or subcontract from seeking and considering information about job applicants' compensation history when making employment decisions. The prohibition would apply to the recruitment and hiring for any position to perform work on or in connection with the contract. This compliance requirement is in addition to the compliance requirement to disclose compensation information listed above. While some small businesses may already be subjected to a prohibition from seeking and considering applicants' compensation history (*e.g.,* small businesses located in states or localities that have enacted laws similar to the prohibition applied in this proposed rule) and some small businesses may already disclose compensation information in their job announcements, the requirements of this proposed rule may be new for other small businesses.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

DoD, GSA, and NASA considered minimizing the impact of the rule on small entities by—

- Exempting commercially available off-the-shelf (COTS) contracts or contracts for commercial products or commercial services;
- Exempting subcontracts;
- Exempting contracts under the simplified acquisition threshold (which is generally $250,000);

• Exempting contracts with small businesses; or

• Not issuing a rule to implement the policy established by the Administrator for Federal Procurement Policy, pursuant to 41 U.S.C. 1121(b), to promote pay equity for any recruitment and hiring for work on or in connection with a Government contract. DOD, GSA & NASA did not agree to pursue this alternative approach.

Limiting the application of a compensation history ban through any of these alternatives could result in employees performing the same or similar functions receiving disparate treatment during hiring and recruiting for work on or in connection with Government contracts. This, in turn, increases the risk of pay disparity among employees working on Government contracts and, for the many reasons explained above, deprives the Federal marketplace of the economy, efficiency, and effectiveness in the procurement of property and services by the Federal Government when there is pay equity. The benefits of the pay equity and transparency requirements in this proposed rule are equally impactful in commercial and noncommercial settings as well as to large or small dollar contracts. For this reason, an increasing number of states and localities have imposed requirements similar to those described in this proposed rulemaking for sales of any goods or services in any dollar amount, whether business to business, business to consumer, or business to government. Limiting application would forgo the various ways in which pay equity promotes economy, efficiency, and effectiveness. In addition, because many entities who sell in those states or localities also sell in the Federal marketplace, it is believed that many Government contractors, including small businesses, already have incorporated these requirements into their existing human capital management practices. Moreover, limiting the application of the proposed rule could create unintended confusion and ambiguity for contractors and prospective employees. Many contractors who do business with the government have contracts below and above the simplified acquisition threshold, and provide both commercial and government unique products and services. Carve-outs to the rule could result in contractor employees performing the same or similar functions receiving disparate treatment during hiring and recruiting for work on or in connection with Government contracts, which would perpetuate inequity and deprive the Federal marketplace of economy, efficiency, and effectiveness in the procurement of property and services.

DoD, GSA, and NASA have narrowed the scope of the rule by only applying it to prime contracts and subcontracts with a principal place of performance within the United States including its outlying areas (see 22.XX01, 22.XX04, and 52.222–ZZ(g)).

The FAR Council will consider public feedback before making a final determination on the scope of the final rule.

The Regulatory Secretariat Division has submitted a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the IRFA may be obtained from the Regulatory Secretariat Division. DoD, GSA, and NASA invite comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD, GSA, and NASA will also consider comments from small entities concerning the existing regulations in subparts affected by the rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (FAR Case 2023–021), in correspondence.

IX. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501–3521) applies because the proposed rule contains information collection requirements. Accordingly, the Regulatory Secretariat Division has submitted a request for approval of a new information collection concerning ''Pay Equity and Transparency in Federal Contracting'' to the Office of Management and Budget (OMB).

A. Public Reporting Burden. Public reporting burden for this information collection, includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

1. The annual reporting burden estimated for compensation disclosure requirements is as follows:

Respondents	96,132
Total annual responses	96,132
Hours/response	×1
Total burden hours	96,132

2. The annual reporting burden associated with applicant notification of rights is estimated as follows:

Respondents	96,132
Total annual responses	96,132
Hours/response	×1
Total burden hours	96,132

3. The annual reporting burden associated with the complaints process is estimated as follows:

Respondents	753
Total annual responses	753
Hours/response	×1
Total burden hours	753

B. Request for Comments Regarding Paperwork Burden

Submit comments on this collection of information no later than April 1, 2024 through *https://www.regulations.gov* and follow the instructions on the site. All items submitted must cite OMB Control No. 9000–XXXX, Pay Equity and Transparency in Federal Contracting. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *https://www.regulations.gov,* approximately two to three days after submission to verify posting. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov*.

Public comments are particularly invited on:

• The necessity of this collection of information for the propoer performance of the functions of Federal Government acquisitions, including whether the information will have practical utility;

• The accuracy of the estimate of the burden of this collection of information;

• Ways to enhance the quality, utility, and clarity of the information to be collected; and

• Ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of informatiion technology.

Requesters may obtain a copy of the supporting statement from the General Services Administration, Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov*. Please cite OMB Control Number 9000–XXXX, Pay Equity and Transparency in Federal Contracting.

List of Subjects in 48 CFR Parts 1, 2, 12, 22, and 52

Government procurement.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA propose amending 48 CFR parts 1, 2, 12, 22, and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 1, 2, 12, 22, and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 4 and 10 U.S.C. chapter 137 legacy provisions (see 10 U.S.C. 3016); and 51 U.S.C. 20113.

PART 1—FEDERAL ACQUISITION REGULATIONS SYSTEM

■ 2. In section 1.106 amend in the table following the introductory text by adding in numerical order an entry for ''52.222–ZZ'' to read as follows:

1.106 OMB approval under the Paperwork Reduction Act.

* * * * *

FAR segment	OMB control No.
* * * * *	
52.222–ZZ	9000–XXXX
* * * * *	

* * * * *

PART 2—DEFINITIONS OF WORDS AND TERMS

■ 3. Amend section 2.101, in paragraph (b)(2) in the definition of ''United States'', by redesignating paragraphs (9) through (12) as paragraphs (10) through (13); and adding a new paragraph (9) to read as follows:

2.101 Definitions.

* * * * *

(b) * * *

(2) * * *

United States * * *

(9) For use in subpart 22.XX, see the definition at 22.XX01.

* * * * *

PART 12—ACQUISITION OF COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES

■ 4. Amend section 12.301 by redesignating paragraphs (d)(11) through (14) as paragraphs (d)(12) through (15); and adding a new paragraph (d)(11) to read as follows:

12.301 Solicitation provisions and contract clauses for the acquisition of commercial products and commercial services.

* * * * *

(d) * * *

(11) Insert the clause at 52.222–ZZ, Prohibition on Compensation History Inquiries and Requirement for Compensation Disclosures by Contractors During Recruitment and Hiring, as prescribed in 22.XX04.

* * * * *

PART 22—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS

■ 5. Add subpart 22.XX to read as follows:

Subpart 22.XX—Prohibition on Compensation History Inquiries and Requirement for Compensation Disclosures by Contractors

Sec.

Subpart 22.XX—Prohibition on Compensation History Inquiries and Requirement for Compensation Disclosures by Contractors

22.XX00 Scope of subpart.

This subpart implements the policy established by the Administrator for Federal Procurement Policy, pursuant to 41 U.S.C. 1121(b), to promote pay equity for any recruitment and hiring for work on or in connection with a Government contract.

22.XX01 Definitions.

As used in this subpart—

Applicant means a prospective employee or current employee applying for a position to perform work on or in connection with the contract.

Compensation means any payments made to, or on behalf of, an employee or offered to an applicant as remuneration for employment, including but not limited to salary, wages, overtime pay, shift differentials, bonuses, commissions, vacation and holiday pay, allowances, insurance and other benefits, stock options and awards, profit sharing, and retirement.

Compensation history means the compensation an applicant is currently receiving or the compensation the applicant has been paid in a previous job.

United States means the 50 States, the District of Columbia, and outlying areas.

Work on or in connection with the contract means work called for by the contract or work activities necessary to the performance of the contract but not specifically called for by the contract.

22.XX02 Policy.

(a) Pursuant to 41 U.S.C. 1121(b) the Administrator for OFPP has established that it is the policy of the Federal Government to eliminate pay practices that inhibit the economy, efficiency, and effectiveness of the procurement of property and services.

(b) Contractors and subcontractors are prohibited from seeking and considering information about job applicants' compensation history when making employment decisions. The prohibition applies to the recruitment and hiring for any position to perform work on or in connection with the contract.

(c) Contractors and subcontractors are required to disclose, in all advertisements for job openings placed by or on behalf of the contractor or subcontractor, the compensation to be offered to the hired applicant, for any position to perform work on or in connection with the contract. The disclosure must indicate the salary or wages, or range thereof, the contractor or subcontractor in good faith believes that it will pay for the advertised position. The disclosure must also include a general description of the benefits and other forms of compensation applicable to the job opportunity. Where at least half of the expected compensation for the advertised position is derived from commissions, bonuses, and/or overtime pay, the contractor or subcontractor must specify the percentage of overall compensation or dollar amount, or ranges thereof, for each form of compensation, as applicable, that it in good faith believes will be paid for the advertised position.

(d) Contractors and subcontractors are required to provide applicants with notice of these requirements as either part of the job announcement or application process.

22.XX03 Applicant complaint procedures.

(a) Applicants alleging violations of the requirements in the clause at 52.222–ZZ may submit a complaint to the central collection point of the agency that issued the solicitation or awarded the contract or order, as identified at *www.dol.gov/general/labor-advisors.* The complaint must be submitted within 180 days of the date the alleged violation occurred.

(b)(1) Except as provided in paragraph (2), the contracting agency will review the complaint, consult with the complainant as necessary to confirm the complainant is a covered applicant, and take action as appropriate.

(2) Applicants who wish to submit complaints that allege discrimination prohibited by Executive Order 11246, Section 503 of the Rehabilitation Act of 1973, and the Vietnam Era Veterans' Readjustment Assistance Act should submit such complaints directly to the Department of Labor's Office of Federal Contract Compliance Programs (OFCCP) at *https://www.dol.gov/agencies/ofccp/contact/file-complaint.* If complaints alleging discrimination are submitted to an agency central collection point rather than directly with OFCCP, the complaints will be forwarded to OFCCP.

22.XX04 Contract clause.

The contracting officer shall insert the clause at 52.222–ZZ, Prohibition on Compensation History Inquiries and Requirement for Compensation Disclosures by Contractors During Recruitment and Hiring, in all solicitations and contracts where the principal place of performance is within the United States.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 6. Amend section 52.213–4 by—
■ a. Revising the date of the clause and revising paragraph (a)(2)(vii);
■ b. Redesignating paragraphs (b)(2)(iv) and (v) as paragraphs (b)(2)(v) and (vi); and
■ c. Adding a new paragraph (b)(2)(iv)

The revisions and addition read as follows:

52.213–4 Terms and Conditions—Simplified Acquisitions (Other Than Commercial Products and Commercial Services).

* * * * *

Terms and Conditions—Simplified Acquisitions (Other Than Commercial Products and Commercial Services) (DATE)

(a) * * *

(2) * * *

(vii) 52.244–6, Subcontracts for Commercial Products and Commercial Services (DATE).

* * * * *

(b) * * *

(2) * * *

(iv) 52.222–ZZ, Prohibition on Compensation History Inquiries and Requirement for Compensation Disclosures by Contractors During Recruitment and Hiring (DATE)

* * * * *

■ 7. Add section 52.222–ZZ to read as follows:

52.222–ZZ Prohibition on Compensation History Inquiries and Requirement for Compensation Disclosures by Contractors During Recruitment and Hiring.

As prescribed in 22.XX04, insert the following clause:

Prohibition on Compensation History Inquiries and Requirements for Compensation Disclosures by Contractors During Recruitment and Hiring (DATE)

(a) *Definitions.* As used in this clause—

Applicant means a prospective employee or current employee applying for a position to perform work on or in connection with the contract.

Compensation means any payments made to, or on behalf of, an employee or offered to an applicant as remuneration for employment, including but not limited to salary, wages, overtime pay, shift differentials, bonuses, commissions, vacation and holiday pay, allowances, insurance and other benefits, stock options and awards, profit sharing, and retirement.

Compensation history means the compensation an applicant is currently receiving or the compensation the applicant has been paid in a previous job.

Work on or in connection with the contract means work called for by the contract or work activities necessary to the performance of the contract but not specifically called for by the contract.

(b) *Applicability.* The prohibition on compensation history inquiries and requirement to disclose compensation described in this clause apply to the recruitment and hiring for any position to perform work on or in connection with the contract. Contractors are also encouraged to apply the prohibitions and requirements in paragraphs (c) and (d) of this clause, respectively, to other positions, including to the recruitment and hiring for any position that the Contractor reasonably believes could eventually perform work on or in connection with the contract.

(c) *Prohibitions.* For any recruitment and hiring under paragraph (b) of this clause the Contractor shall not—

(1) Seek an applicant's compensation history, either orally or in writing, directly from any person, including the applicant or the applicant's current or former employer or through an agent;

(2) Require disclosure of compensation history as a condition of an applicant's candidacy;

(3) Retaliate against or refuse to interview or otherwise consider, hire, or employ any applicant for failing to respond to an inquiry regarding their compensation history;

(4) Rely on an applicant's compensation history—

(i) As a criterion in screening or considering the applicant for employment or

(ii) In determining the compensation for such individual at any stage in the selection process; and

(5) Violate the prohibitions of (c)(1) through (4) even if an applicant for employment volunteers their compensation history without prompting at any stage in the recruitment and hiring process.

(d) *Compensation disclosure requirements.* (1) The Contractor shall, in all advertisements for job openings placed by or on behalf of the Contractor for any position to perform work on or in connection with the contract, disclose the compensation to be offered to the hired applicant.

(2) The disclosure must indicate the salary or wages, or range thereof, the Contractor in good faith believes that it will pay for the advertised position, and may reflect, as applicable: the Contractor's pay scale for that position, the range of compensation for those currently working in similar jobs, or the amount budgeted for the position.

(3) The disclosure must also include a general description of the benefits and other forms of compensation applicable to the job opportunity. Where at least half of the expected compensation for the advertised position is derived from commissions, bonuses, and/or overtime pay, the Contractor must specify the percentage of overall compensation or dollar amount, or ranges thereof, for each form of compensation, as applicable, that it in good faith believes will be paid for the advertised position.

(e) *Applicant notification of rights requirements.* The Contractor shall ensure that any applicants that are covered by the prohibitions in paragraph (c) and the disclosure requirements in paragraph (d) of this clause are provided with notice of these requirements as either part of the job announcement or application process and provided with the following information in writing:

''This employer is a Federal contractor or subcontractor. Under 48 CFR (FAR) 52.222–ZZ, Prohibition on Compensation History Inquiries and Requirement for Compensation Disclosures by Contractors During Recruitment and Hiring, Federal contractors and subcontractors may not inquire about or rely on an applicant's compensation history to screen an applicant for employment or to determine the applicant's pay for a position on or in connection with a Federal contract or subcontract, even when the information is offered without prompting. The employer must also disclose the compensation for the position in all advertisements for the job opening.

Applicants alleging Federal contractor or subcontractor violations of these requirements:

These applicants may submit a complaint to the central collection point of the agency that issued the solicitation for the Federal contract or awarded the Federal contract or order, as identified at *www.dol.gov/general/labor-advisors*. The complaint must be submitted within 180 days of the date the violation occurred.

The agency that issued the solicitation or awarded the contract or order on which this applicant would primarily work is _____. [*Contractor to fill in with appropriate agency name*] For applicants supporting multiple agencies, complaints should copy the central collection point of all known agencies to be supported by the applicant's position.

Applicants alleging discrimination on the basis of race, color, religion, sex,

sexual orientation, gender identity, national origin, disability, or protected veteran status should file a complaint with the Office of Federal Contract Compliance Programs (OFCCP). If complaints alleging discrimination are submitted to an agency central collection point rather than directly with OFCCP, the complaints will be forwarded to OFCCP. Information on the process for filing a formal complaint of discrimination with OFCCP can be found at the following website: *https://www.dol.gov/agencies/ofccp/contact/file-complaint.*''

(f) *Relationship to other compensation data reporting requirements.* Nothing in this clause alleviates the Contractor from responsibilities that may be imposed by other clauses, such as for providing the contracting officer with employee compensation data required for the evaluation of proposals or claims.

(g) *Subcontracts.* The Contractor shall include the substance of this clause, including this paragraph (g) in all subcontracts at any tier, with a principal place of performance within the United States including its outlying areas.

(End of clause)

■ 8. Amend section 52.244–6 by—

■ a. Revising the date of the clause;

■ b. Redesignating paragraphs (c)(1)(xx) through (xxiii) as paragraphs (c)(1)(xxi) through (xxiv); and

■ c. Adding a new paragraph (c)(1)(xx).

The revision and addition read as follows:

52.222–6 Subcontracts for Commercial Products and Commercial Services.

* * * * *

Subcontracts for Commercial Products and Commercial Services (DATE)

* * * * *

(c) * * *

(1) * * *

(xx) 52.222–ZZ, Prohibition on Compensation History Inquiries and Requirement for Compensation Disclosures by Contractors During Recruitment and Hiring (DATE).

* * * * *

[FR Doc. 2024–01343 Filed 1–29–24; 8:45 am]

BILLING CODE 6820–EP–P

Notices

Federal Register
Vol. 89, No. 20
Tuesday, January 30, 2024

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

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

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

Comments regarding this information collection received by February 29, 2024 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: Supplemental Nutrition Assistance Program—Store Applications.

OMB Control Number: 0584–0008.

Summary of Collection: Section 9(a) of the Food and Nutrition Act of 2008 as amended, (7 U.S.C. 2018 *et seq.*) requires that the Food and Nutrition Service (FNS) provide for the submission of applications for approval by retailers, wholesalers, meal service providers, certain types of group homes, shelters, and state-contracted restaurants that wish to participate in the Supplemental Nutrition Program (SNAP). FNS is responsible for reviewing the application in order to determine whether or not applicants meet eligibility requirements, and make determinations whether to grant or deny authorization to accept and redeem SNAP benefits. FNS will collect information using forms FNS–252, Supplemental Nutrition Assistance Program Application for Store, FNS–252–E, On line Supplemental Nutrition Assistance Program Application for Store, FNS 252–2, Supplemental Nutrition Assistance Program for Meal Service Application, FNS–252–C, Corporate Supplemental Application, and FNS 252–R which includes an Online Recertification Application (ORA) version known as FNS 252–R–ORA, Supplemental Nutrition Assistance Program for Stores Reauthorization and FNS–252FE, Supplemental Nutrition Assistance Program Farmer's Market Application.

Need and Use of the Information: FNS will collect information to determine the eligibility of retail food stores, wholesale food concern, and food service organizations applying for authorization to accept and redeem SNAP benefits and to monitor these firms for continued eligibility, and to sanction stores for noncompliance with the Act, and for Program management. Disclosure of information other than Employer Identification Numbers and Social Security Numbers may be made to Federal and State law enforcement or investigative agencies or instrumentalities administering or enforcing specified Federal or State laws, or regulations issued under those laws. Without the information on the application or reauthorization application, the consequence to the Federal program is the Agency's reduced ability to effectively monitor accountability for program compliance and to detect fraud and abuse would be severely jeopardized.

Description of Respondents: Business for-and-not-for-profit, Farms; Federal Military Commissaries.

Number of Respondents: 55,708.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 49,300.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2024–01737 Filed 1–29–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–112, C–570–113]

Antidumping and Countervailing Duty Orders on Certain Collated Steel Staples From the People's Republic of China: Final Affirmative Determinations of Circumvention With Respect to the Kingdom of Thailand and the Socialist Republic of Vietnam

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that imports of certain collated steel staples (collated staples) that were exported from the Kingdom of Thailand (Thailand) or the Socialist Republic of Vietnam (Vietnam), using inputs (*i.e.,* steel wire and wire bands) manufactured in the People's Republic of China (China), as specified below, are circumventing the antidumping duty (AD) and countervailing duty (CVD) orders on collated staples from China.

DATES: Applicable February 29, 2024.

FOR FURTHER INFORMATION CONTACT: Brian Smith (Thailand) or Shane Subler (Vietnam), 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) 482–1766 and (202) 482–6241, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 20, 2020, Commerce published in the **Federal Register** the

AD and CVD orders on collated staples from China.[1] On December 14, 2022, Commerce initiated country-wide circumvention inquiries pursuant to section 781(b) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.226(d)(1)(ii) to determine whether imports of collated staples using Chinese-origin steel wire and wire bands that are completed or assembled (*e.g.,* processing galvanized steel wire or wire bands through staple-forming machines) in Thailand and Vietnam are circumventing the *Orders*.[2] On August 24, 2023, Commerce published in the **Federal Register** its *Preliminary Determinations* that imports of collated staples completed in Thailand using steel wire and wire bands produced in China and imports of collated staples completed in Vietnam using wire bands produced in China are circumventing the *Orders*.[3]

On September 25, 2023, Commerce extended the deadline for the final determinations of these circumvention inquiries to December 21, 2023.[4] On December 15, 2023, Commerce further extended the deadline for the final determinations in these circumvention inquiries to January 23, 2024.[5] For a summary of events that occurred since the *Preliminary Determinations,* as well as a full discussion of the issues raised by parties for consideration in the final determinations, *see* the Issues and Decision Memoranda.[6]

The Issues and Decision Memoranda are public documents and are on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memoranda can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Orders

The products covered by the *Orders* include certain collated steel staples. For a full description of the scope of the *Orders, see* the Issues and Decision Memoranda.

Merchandise Subject to the Circumvention Inquiry

These circumvention inquiries cover collated staples, assembled or completed in Thailand using Chinese-origin steel wire and/or wire bands, and in Vietnam using Chinese-origin steel wire and/or wire bands, that are subsequently exported from Thailand and Vietnam to the United States (inquiry merchandise).

Methodology

Commerce is conducting these circumvention inquiries in accordance with section 781(b) of the Act, and 19 CFR 351.226. *See Preliminary Determinations* Preliminary Decision Memoranda for a full description of the methodology.[7] We have continued to apply this methodology, without exception, and incorporate by reference this description of the methodology, for our final determinations.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in these inquiries are addressed in the Issues and Decision Memoranda. A list of the issues raised is attached to this notice at appendix I.

Based on our analysis of the comments received from interested parties, we made the following two changes with respect to the inquiry involving Thailand:

(1) We clarified the certification language (*see* appendix III), which we have modified to include mill certificates in the list of documents that parties have available and may provide, if requested by U.S. Customs and Border Protection (CBP) and/or Commerce, in support of their certification that the imports of collated staples produced in Thailand that are covered by their certification were not manufactured using steel wire and/or wire bands produced in China; and

(2) We revised the processing cost calculations for the two Thai mandatory respondents by including an amount for general and administrative expenses, interest expenses, and unrefunded taxes incurred for input purchases.

Further, based on our analysis of the comments received from interested parties, we made the following two changes with respect to the inquiry involving Vietnam:

(1) We found that imports of collated staples completed in Vietnam using steel wire or wire bands manufactured in China, as opposed to only wire bands manufactured in China, have circumvented the *Orders* on a country-wide basis; and

(2) We clarified the certification language (*see* Appendix IV), which we have modified to include mill certificates in the list of documents that parties have available and may provide, if requested by CBP and/or Commerce, in support their certification that the imports of collated staples produced in Vietnam that are covered by their certification were not manufactured using steel wire and/or wire bands produced in China.

Final Circumvention Determinations

We determine that collated staples, assembled or completed in Thailand and Vietnam by the entities identified in Appendix II to this notice, using Chinese-origin steel wire and/or wire bands that are subsequently exported from Thailand or Vietnam, are circumventing the *Orders.* For a detailed explanation of our determinations with respect to the entities identified in Appendix II, *see* the Preliminary Decision Memoranda, the Issues and Decision Memoranda, and the ''Use of Adverse Facts Available'' section of this notice below.

We also determine that U.S. imports of inquiry merchandise exported from Thailand and Vietnam are circumventing the *Orders* on a country-wide basis. As a result, in accordance with section 781(b) of the Act, we determine that this merchandise is covered by the *Orders. See* the ''Suspension of Liquidation and Cash

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[1] *See Certain Collated Steel Staples from the People's Republic of China: Antidumping Duty Order,* 85 FR 43815 (July 20, 2020) (*AD Order*); and *Certain Collated Steel Staples from the People's Republic of China: Countervailing Duty Order,* 85 FR 43813 (July 20, 2020) (*CVD Order*) (collectively, *Orders*).

[2] *See Certain Collated Steel Staples from the People's Republic of China: Initiation of Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders,* 87 FR 78047 (December 21, 2022), and accompanying Memorandum, ''Certain Collated Steel Staples from the People's Republic of China: Initiation of Circumvention Inquiries on the Antidumping and Countervailing Duty Orders,'' dated December 14, 2022.

[3] *See Antidumping and Countervailing Duty Orders on Certain Collated Steel Staples from the People's Republic of China: Preliminary Affirmative Determinations of Circumvention With Respect to the Kingdom of Thailand and the Socialist Republic of Vietnam,* 88 FR 57931 (August 24, 2023) (*Preliminary Determinations*), and accompanying Thailand Preliminary Decision Memorandum (Thailand PDM) and Vietnam Preliminary Decision Memorandum (Vietnam PDM) (collectively, Preliminary Decision Memoranda).

[4] *See* Memorandum, ''Extension of Deadline for Issuing Final Determination in Circumvention Inquiry,'' dated September 25, 2023.

[5] *See* Memorandum, ''Extension of Deadline for Issuing Final Determinations in Circumvention Inquiries,'' dated December 15, 2023.

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Final Affirmative Circumvention Determination of the Antidumping Duty and Countervailing Duty Orders on Certain Collated Steel Staples from the People's Republic of China with Respect to the Kingdom of Thailand'' (Thailand IDM); and Memorandum, ''Issues and Decision Memorandum for the Final Affirmative Circumvention Determination of the Antidumping Duty and Countervailing Duty Orders on Certain Collated Steel Staples from the People's Republic of China with Respect to the Socialist Republic of Vietnam'' (Vietnam IDM); each dated concurrently with, and hereby adopted by, this notice (collectively, Issues and Decision Memoranda).

[7] *See Preliminary Determinations* Thailand PDM at 6–23 and Vietnam PDM at 8–23.

Deposit Requirements'' section, below, for details regarding suspension of liquidation and cash deposit requirements. *See* the ''Certifications'' and ''Certification Requirements'' sections, below, for details regarding the use of certifications.

Use of Adverse Facts Available (AFA)

Within the context of the Vietnam inquiry, Commerce continues to find that necessary information is not available on the record with respect to Meihotech Vietnam Inc. (Meihotech) and Weifang Wenhe Pneumatic Tools Co., Ltd. (Weifang Wenhe) within the meaning of section 776(a)(1) of the Act, and that Meihotech and Weifang Wenhe withheld requested information, failed to provide requested information by the deadline or in the form or manner requested, and significantly impeded the inquiry pursuant to sections 776(a)(1), (A), (B), and (C) of the Act. Moreover, Commerce continues to find that these companies failed to cooperate by not acting to the best of their ability to provide requested information pursuant to section 776(b)(1) of the Act. Consequently, we have continued to use adverse inferences with respect to Meihotech and Weifang Wenhe in selecting from among the facts otherwise available on the record, pursuant to sections 776(a) and (b) of the Act, for the reasons discussed in the *Preliminary Determinations* and the Vietnam IDM.[8] Based on the AFA used, we determine that Meihotech and Weifang Wenhe exported inquiry merchandise and that U.S. entries of that merchandise are circumventing the *Orders.* Additionally, we are precluding Meihotech and Weifang Wenhe from participating in the certification program that we are establishing for exports of collated staples from Vietnam. U.S. entries of inquiry merchandise made on or after December 21, 2022, that are ineligible for certification based on the failure of these companies to cooperate, or for other reasons, shall remain subject to suspension of liquidation until final assessment instructions on those entries are issued, whether by automatic liquidation instructions, or by instructions pursuant to the final results of an administrative review. Interested parties that wish to have their suspended entries, if any, reviewed, and their ineligibility for the certification program reevaluated, should request an administrative review of the relevant suspended entries during the next anniversary month of these *Orders* (*i.e.,* July 2024).[9]

Suspension of Liquidation and Cash Deposit Requirements

Based on the affirmative country-wide determinations of circumvention for Thailand and Vietnam, in accordance with 19 CFR 351.226(l)(3), we will direct CBP to suspend liquidation and require a cash deposit of estimated duties on unliquidated entries of collated staples completed or assembled in Thailand or Vietnam using Chinese-origin steel wire and/or wire bands that were entered, or withdrawn from warehouse, for consumption on or after December 21, 2022, the date of publication of the initiation of this circumvention inquiry in the **Federal Register**.

For exporters of collated staples that have a company-specific cash deposit rate under the *AD Order* and/or *CVD Order,* the cash deposit rate will be the company-specific AD and/or CVD cash deposit rate established for that company in the most recently completed segment of the collated staples proceedings. For exporters of collated staples that do not have a company-specific cash deposit rate under the *AD Order* and/or *CVD Order,* the cash deposit rate will be the company-specific cash deposit rate established under the *AD Order* and/or *CVD Order* for the company that exported the Chinese-origin steel wire and/or wire bands that were incorporated into the imported collated staples to the producer/exporters in Thailand or Vietnam.

If neither the exporter of the collated staples from Thailand or Vietnam, nor the Chinese exporter of the steel wire and/or wire bands has a company-specific cash deposit rate, the AD cash deposit rate will be the China-wide rate (*i.e.,* 112.01 percent), and the CVD cash deposit rate will be the China all-others rate (*i.e.,* 12.32 percent).

Commerce has established the following third-country case numbers in the Automated Commercial Environment (ACE) for such entries: Thailand A–549–112/C–549–113; Vietnam A–552–112/C–552–113. The suspension of liquidation will remain in effect until further notice.

See Appendices III and IV for the revised importer and exporter certifications, which we have modified based on the changes explained in the ''Analysis of Comments Received'' section above.

Certified Entries

Entries for which the importer and exporter have met the certification requirements described below and in Appendices III and IV to this notice will not be subject to suspension of liquidation, or the cash deposit requirements described above. Failure to comply with the applicable requisite certification requirements may result in the merchandise being subject to antidumping and countervailing duties.

Certifications

To administer the country-wide affirmative determinations of circumvention for Thailand and Vietnam, Commerce established importer and exporter certifications which will permit importers and exporters to establish that specific entries of collated staples from Thailand or Vietnam are not subject to suspension of liquidation or the collection of cash deposits pursuant to these affirmative determinations of circumvention because the merchandise meets the requirements described in the certification (*see* appendix III (for Thailand) and appendix IV (for Vietnam) to this notice). Because Meihotech and Weifang Wenhe were non-cooperative, they are not eligible to use the certifications described above.[10]

Importers and exporters that claim that the entry of collated staples is not subject to suspension of liquidation or the collection of cash deposits based on the inputs used to manufacture such merchandise must complete the applicable certification and meet the certification and documentation requirements described below, as well as the requirements identified in the applicable certification.

Certification Requirements for Thailand and Vietnam

Importers are required to complete and maintain the applicable importer certification, maintain a copy of the applicable exporter certification, and retain all supporting documentation for both certifications. With the exception of the entries described below, the importer certification must be completed, signed, and dated by the time the entry summary is filed for the

[8] *See Preliminary Determinations,* 88 FR 57931–57932; *see also* Vietnam IDM at Comment 13.

[9] *See* 19 CFR 351.213(b).

[10] *See Preliminary Determinations* Vietnam PDM at the ''Use of Facts Available with Adverse Inferences'' section; *see also, e.g., Anti-circumvention Inquiry of the Antidumping Duty Order on Certain Pasta from Italy: Affirmative Preliminary Determination of Circumvention of the Antidumping Duty Order,* 63 FR 18364, 18366 (April 15, 1998), unchanged in *Anti-Circumvention Inquiry of the Antidumping Duty Order on Certain Pasta from Italy: Affirmative Final Determination of Circumvention of the Antidumping Duty Order,* 63 FR 54672, 54675–76 (October 13, 1998).

relevant entry. The importer, or the importer's agent, must submit both the importer's certification and the exporter's certification to CBP as part of the entry process by uploading them into the document imaging system (DIS) in ACE. Where the importer uses a broker to facilitate the entry process, the importer should obtain the entry summary number from the broker. Agents of the importer, such as a broker, however, are not permitted to certify on behalf of the importer.

Exporters are required to complete and maintain the applicable exporter certification and provide the importer with a copy of that certification and all supporting documentation (*e.g.,* invoice, purchase order, production records, mill certificates, *etc.*). With the exception of the entries described below, the exporter certification must be completed, signed, and dated by the time of shipment of the relevant entries. The exporter certification should be completed by the party selling the collated staples that were manufactured in Thailand or Vietnam to the United States.

Additionally, the claims made in the certifications and any supporting documentation are subject to verification by Commerce and/or CBP. Importers and exporters are required to maintain the certifications and supporting documentation until the later of: (1) the date that is five years after the latest entry date of the entries covered by the certification; or (2) the date that is three years after the conclusion of any litigation in United States courts regarding such entries.

For all collated staples from Thailand or Vietnam that were entered, or withdrawn from warehouse, for consumption during the period December 21, 2022 (the date of publication of the initiation of these circumvention inquiries), through the date of publication of the *Preliminary Determinations* in the **Federal Register**, where the entry has not been liquidated (and entries for which liquidation has not become final), the relevant certification should already be completed and signed.

For unliquidated entries (and entries for which liquidation has not become final) of collated staples that were declared as non-AD/CVD type entries (*e.g.,* type 01) and entered, or withdrawn from warehouse, for consumption in the United States during the period December 21, 2022 (the date of publication of the initiation of these circumvention inquiries), through the date of publication of the *Preliminary Determinations* in the **Federal Register**, for which none of the above certifications may be made, importers must file a Post Summary Correction with CBP, in accordance with CBP's regulations, regarding conversion of such entries from non-AD/CVD type entries to AD/CVD type entries (*e.g.,* type 01 to type 03). Importers should report those AD/CVD type entries using the third country CBP case numbers identified in the ''Suspension of Liquidation and Cash Deposit Requirements'' section, above. The importer should post cash deposits on those entries consistent with the regulations governing post summary corrections that require payment of additional duties, including antidumping and countervailing duties.

If it is determined that an importer or exporter has not met the certification and/or related documentation requirements for certain entries, Commerce intends to instruct CBP to suspend, pursuant to these country-wide affirmative determinations of circumvention and the *Orders,*[11] all unliquidated entries for which these requirements were not met and require the importer to post applicable cash deposits equal to the rates noted above.

Opportunity To Request an Administrative Review

Each year during the anniversary month of the publication of an AD or CVD order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Act, may request, in accordance with 19 CFR 351.213, that Commerce conduct an administrative review of that AD or CVD order, finding, or suspended investigation. An interested party who would like Commerce to conduct an administrative review should wait until Commerce announces via the **Federal Register** the next opportunity during the anniversary month of the publication of the *Orders* to submit such requests. The anniversary month for these *Orders* is July.

Administrative Protective Order

This notice will serve as the only reminder to all parties subject to an administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

[11] *See Orders.*

Notification to Interested Parties

These determinations are issued and published in accordance with section 781(b) of the Act and 19 CFR 351.226(g)(2).

Dated: January 23, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendices

Appendix No.	Appendix name
I	List of Topics Discussed in the Issues and Decision Memoranda.
II	Companies Found to Be Circumventing the *Orders*.
III	Certification Regarding Chinese Inputs—Thailand.
IV	Certification Regarding Chinese Inputs—Vietnam.

Appendix I

List of Topics Discussed in the Issues and Decision Memoranda

Thailand

Vietnam

Appendix II

Companies Found To Be Circumventing the Orders

Thailand

1. YF Technology Corporation, Ltd.
2. UM Industry, Co., Ltd.

Vietnam

1. Vina Hardwares Joint Stock Company
2. VN Fasteners Co., Ltd.
3. Vina Staples Company Limited
4. Meihotech Vietnam Inc. (based on AFA)
5. Weifang Wenhe Pneumatic Tools Co., Ltd. (based on AFA)

Appendix III

Certification Regarding Chinese Inputs (for Thailand) Importer Certification

I hereby certify that:

A. My name is {IMPORTING COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF IMPORTING COMPANY}, located at {ADDRESS OF IMPORTING COMPANY}.

B. I have direct personal knowledge of the facts regarding the importation into the Customs territory of the United States of the certain collated steel staples (collated staples) from the People's Republic of China (China) completed in Thailand that entered under the entry summary number(s), identified below, and are covered by this certification. ''Direct personal knowledge'' refers to the facts the certifying party is expected to have in its own records. For example, the importer should have direct personal knowledge of the exporter's and/or seller's identity and location.

C. If the importer is acting on behalf of the first U.S. customer, include the following sentence as paragraph C of this certification:

The collated staples covered by this certification were imported by {NAME OF IMPORTING COMPANY} on behalf of {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER}.

If the importer is not acting on behalf of the first U.S. customer, include the following sentence as paragraph C of this certification:

{NAME OF IMPORTING COMPANY} is not acting on behalf of the first U.S. customer.

D. The collated staples covered by this certification were shipped to {NAME OF PARTY IN THE UNITED STATES TO WHOM THE MERCHANDISE WAS FIRST SHIPPED}, located at {U.S. ADDRESS TO WHICH MERCHANDISE WAS SHIPPED}.

E. I have personal knowledge of the facts regarding the production of the imported products covered by this certification. ''Personal knowledge'' includes facts obtained from another party, (*e.g.,* correspondence received by the importer (or exporter) from the producer regarding the source of the inputs used to produce the imported products).

F. The importer certifies that the collated staples produced in Thailand that are covered by this certification were not manufactured using steel wire and/or wire bands produced in China, regardless of whether sourced directly from a Chinese producer or from a downstream supplier.

G. The collated staples covered by this certification are not covered by the antidumping duty or countervailing duty orders on collated staples from China.

H. This certification applies to the following entries (repeat this block as many times as necessary):

Entry Summary #:
Entry Summary Line Item #:
Foreign Seller:
Foreign Seller's Address:
Foreign Seller's Invoice #:
Foreign Seller's Invoice Line Item #:
Producer:
Producer's Address:

I. I understand that {NAME OF IMPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, product specification sheets, production records, invoices, mill certificates, *etc.*) until the later of: (1) the date that is five years after the latest entry date of the entries covered by the certification; or (2) the date that is three years after the conclusion of any litigation in United States courts regarding such entries.

J. I understand that {NAME OF IMPORTING COMPANY} is required to maintain a copy of the exporter's certification (attesting to information regarding the production and/or exportation of the imported merchandise identified above), and any supporting documentation provided to the importer by the exporter, until the later of: (1) the date that is five years after the latest entry date of the entries covered by the certification; or (2) the date that is three years after the conclusion of any litigation in United States courts regarding such entries.

K. I understand that {NAME OF IMPORTING COMPANY} is required to provide U.S. Customs and Border Protection (CBP) and/or the U.S. Department of Commerce (Commerce) with the importer certification, and any supporting documentation, and a copy of the exporter's certification, and any supporting documentation provided to the importer by the exporter, upon the request of either agency.

L. I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce.

M. I understand that failure to maintain the required certifications and supporting documentation, or failure to substantiate the claims made herein, or not allowing CBP and/or Commerce to verify the claims made herein, may result in a *de facto* determination that all entries to which this certification applies are entries of merchandise that is covered by the scope of the antidumping and countervailing duty orders on certain collated steel staples from China. I understand that such a finding will result in:

(i) suspension of liquidation of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met;

(ii) the importer being required to post the antidumping duty and countervailing duty cash deposits determined by Commerce; and

(iii) the importer no longer being allowed to participate in the certification process.

N. I understand that agents of the importer, such as brokers, are not permitted to make this certification.

O. This certification was completed and signed on, or prior to, the date of the entry summary if the entry date is more than 14 days after the date of publication of the notice of Commerce's preliminary determination of circumvention in the **Federal Register**. If the entry date is on or before the 14th day after the date of

publication of the notice of Commerce's preliminary determination of circumvention in the **Federal Register**, this certification was completed and signed by no later than 45 days after publication of the notice of Commerce's preliminary determination of circumvention in the **Federal Register**.

P. I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make materially false statements to the U.S. government.

Signature

{NAME OF COMPANY OFFICIAL}
{TITLE OF COMPANY OFFICIAL}
{DATE}

Exporter Certification

The party that made the sale to the United States should fill out the exporter certification.

I hereby certify that:

A. My name is {COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF EXPORTING COMPANY}, located at {ADDRESS OF EXPORTING COMPANY}.

B. I have direct personal knowledge of the facts regarding the production and exportation of the collated staples for which sales are identified below. ''Direct personal knowledge'' refers to facts the certifying party is expected to have in its own records. For example, an exporter should have direct personal knowledge of the producer's identity and location.

C. The collated staples covered by this certification were shipped to {NAME OF PARTY IN THE UNITED STATES TO WHOM MERCHANDISE WAS FIRST SHIPPED}, located at {U.S. ADDRESS TO WHICH MERCHANDISE WAS SHIPPED}.

D. The seller certifies that the collated staples produced in Thailand that are covered by this certification were not manufactured using steel wire and/or wire bands produced in China, regardless of whether sourced directly from a Chinese producer or from a downstream supplier.

E. The collated staples covered by this certification are not covered by the antidumping duty or countervailing duty orders on collated staples from China.

F. This certification applies to the following sales to {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER} (repeat this block as many times as necessary):

Foreign Seller's Invoice # to U.S. Customer:
Foreign Seller's Invoice to U.S. Customer Line Item #:
Producer Name:
Producer's Address:
Producer's Invoice # to the Foreign Seller: (*if the foreign seller and the producer are the same party, report ''NA'' here*)

G. I understand that {EXPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, product specification sheets, customer specification sheets, production records, invoices, mill certificates, *etc.*) until the later of: (1) the date that is five years after the latest entry date of the entries covered by the certification; or (2) the date that is three years after the conclusion of any litigation in United States courts regarding such entries.

H. I understand that {EXPORTING COMPANY}is required to provide the U.S. importer with a copy of this certification and is required to provide U.S. Customs and Border Protection (CBP) and/or the U.S. Department of Commerce (Commerce) with this certification, and any supporting documents, upon the request of either agency.

I. I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce.

J. I understand that failure to maintain the required certification and supporting documentation, or failure to substantiate the claims made herein, or not allowing CBP and/or Commerce to verify the claims made herein, may result in a *de facto* determination that all sales to which this certification applies are sales of merchandise that is covered by the scope of the antidumping and countervailing duty orders on collated staples from China. I understand that such a finding will result in:

(i) suspension of liquidation of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met;

(ii) the importer being required to post the antidumping and countervailing duty cash deposits determined by Commerce; and

(iii) the seller/exporter no longer being allowed to participate in the certification process.

K. I understand that agents of the seller/exporter, such as freight forwarding companies or brokers, are not permitted to make this certification.

L. This certification was completed and signed, and a copy of the certification was provided to the importer, on, or prior to, the date of shipment if the shipment date is after the date of publication of the notice of Commerce's preliminary determination of circumvention in the **Federal Register**. If the shipment date is on or before the date of publication of the notice of Commerce's preliminary determination of circumvention in the **Federal Register**, this certification was completed and signed, and a copy of the certification was provided to the importer, by no later than 45 days after publication of the notice of Commerce's preliminary determination of circumvention in the **Federal Register**.

M. I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make materially false statements to the U.S. government.

Signature

{NAME OF COMPANY OFFICIAL}
{TITLE OF COMPANY OFFICIAL}
{DATE}

APPENDIX IV

Certification Regarding Chinese Inputs (for Vietnam) Importer Certification

I hereby certify that:

A. My name is {IMPORTING COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF IMPORTING COMPANY}, located at {ADDRESS OF IMPORTING COMPANY}.

B. I have direct personal knowledge of the facts regarding the importation into the Customs territory of the United States of the certain collated steel staples (collated staples) from the People's Republic of China (China) completed in Vietnam that entered under the entry summary number(s), identified below, and are covered by this certification. ''Direct personal knowledge'' refers to the facts the certifying party is expected to have in its own records. For example, the importer should have direct personal knowledge of the exporter's and/or seller's identity and location.

C. If the importer is acting on behalf of the first U.S. customer, include the following sentence as paragraph C of this certification:

The collated staples covered by this certification were imported by {NAME OF IMPORTING COMPANY} on behalf of {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER}.

If the importer is not acting on behalf of the first U.S. customer, include the following sentence as paragraph C of this certification:

{NAME OF IMPORTING COMPANY} is not acting on behalf of the first U.S. customer.

D. The collated staples covered by this certification were shipped to {NAME OF PARTY IN THE UNITED STATES TO WHOM THE MERCHANDISE WAS FIRST SHIPPED}, located at {U.S. ADDRESS TO WHICH MERCHANDISE WAS SHIPPED}.

E. I have personal knowledge of the facts regarding the production of the imported products covered by this certification. ''Personal knowledge'' includes facts obtained from another party, (*e.g.,* correspondence received by the importer (or exporter) from the producer regarding the source of the inputs used to produce the imported products).

F. The importer certifies that the collated staples produced in Vietnam that are covered by this certification were not manufactured using steel wire and/or wire bands produced in China, regardless of whether sourced directly from a Chinese producer or from a downstream supplier.

G. The collated staples covered by this certification are not covered by the antidumping duty or countervailing duty orders on collated staples from China.

H. This certification applies to the following entries (repeat this block as many times as necessary):

Entry Summary #:
Entry Summary Line Item #:
Foreign Seller:
Foreign Seller's Address:
Foreign Seller's Invoice #:
Foreign Seller's Invoice Line Item #:
Producer:
Producer's Address:

I. I understand that {NAME OF IMPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, product specification sheets, production

records, invoices, mill certificates, *etc.*) until the later of: (1) the date that is five years after the latest entry date of the entries covered by the certification; or (2) the date that is three years after the conclusion of any litigation in United States courts regarding such entries.

J. I understand that {NAME OF IMPORTING COMPANY} is required to maintain a copy of the exporter's certification (attesting to information regarding the production and/or exportation of the imported merchandise identified above), and any supporting documentation provided to the importer by the exporter, until the later of: (1) the date that is five years after the latest entry date of the entries covered by the certification; or (2) the date that is three years after the conclusion of any litigation in United States courts regarding such entries.

K. I understand that {NAME OF IMPORTING COMPANY} is required to provide U.S. Customs and Border Protection (CBP) and/or the U.S. Department of Commerce (Commerce) with the importer certification, and any supporting documentation, and a copy of the exporter's certification, and any supporting documentation provided to the importer by the exporter, upon the request of either agency.

L. I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce.

M. I understand that failure to maintain the required certifications and supporting documentation, or failure to substantiate the claims made herein, or not allowing CBP and/or Commerce to verify the claims made herein, may result in a de facto determination that all entries to which this certification applies are entries of merchandise that is covered by the scope of the antidumping and countervailing duty orders on collated staples from China. I understand that such a finding will result in:

(i) suspension of liquidation of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met;

(ii) the importer being required to post the antidumping duty and countervailing duty cash deposits determined by Commerce; and

(iii) the importer no longer being allowed to participate in the certification process.

N. I understand that agents of the importer, such as brokers, are not permitted to make this certification.

O. This certification was completed and signed on, or prior to, the date of the entry summary if the entry date is more than 14 days after the date of publication of the notice of Commerce's preliminary determination of circumvention in the **Federal Register**. If the entry date is on or before the 14th day after the date of publication of the notice of Commerce's preliminary determination of circumvention in the **Federal Register**, this certification was completed and signed by no later than 45 days after publication of the notice of Commerce's preliminary determination of circumvention in the **Federal Register**.

P. I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make materially false statements to the U.S. government.

Signature

{NAME OF COMPANY OFFICIAL}
{TITLE OF COMPANY OFFICIAL}
{DATE}

Exporter Certification

The party that made the sale to the United States should fill out the exporter certification.

I hereby certify that:

A. My name is {COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF EXPORTING COMPANY}, located at {ADDRESS OF EXPORTING COMPANY}.

B. I have direct personal knowledge of the facts regarding the production and exportation of the collated staples for which sales are identified below. ''Direct personal knowledge'' refers to facts the certifying party is expected to have in its own records. For example, an exporter should have direct personal knowledge of the producer's identity and location.

C. The collated staples covered by this certification were shipped to {NAME OF PARTY IN THE UNITED STATES TO WHOM MERCHANDISE WAS FIRST SHIPPED}, located at {U.S. ADDRESS TO WHICH MERCHANDISE WAS SHIPPED}.

D. The seller certifies that the collated staples produced in Vietnam that are covered by this certification were not manufactured using steel wire and/or wire bands produced in China, regardless of whether sourced directly from a Chinese producer or from a downstream supplier.

E. The collated staples covered by this certification are not covered by the antidumping duty or countervailing duty orders on collated staples from China.

F. This certification applies to the following sales to {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER} (repeat this block as many times as necessary):

Foreign Seller's Invoice # to U.S. Customer:
Foreign Seller's Invoice to U.S. Customer Line Item #:
Producer Name:
Producer's Address:
Producer's Invoice # to the Foreign Seller: (if the foreign seller and the producer are the same party, report ''NA'' here)

G. I understand that {EXPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.,* documents maintained in the normal course of business, or documents obtained by the certifying party, for example, product specification sheets, customer specification sheets, production records, invoices, mill certificates, *etc.*) until the later of: (1) the date that is five years after the latest entry date of the entries covered by the certification; or (2) the date that is three years after the conclusion of any litigation in United States courts regarding such entries.

H. I understand that {EXPORTING COMPANY}is required to provide the U.S. importer with a copy of this certification and is required to provide U.S. Customs and Border Protection (CBP) and/or the U.S. Department of Commerce (Commerce) with this certification, and any supporting documents, upon the request of either agency.

I. I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce.

J. I understand that failure to maintain the required certification and supporting documentation, or failure to substantiate the claims made herein, or not allowing CBP and/or Commerce to verify the claims made herein, may result in a de facto determination that all sales to which this certification applies are sales of merchandise that is covered by the scope of the antidumping and countervailing duty orders on collated staples from China. I understand that such a finding will result in:

(i) suspension of liquidation of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met;

(ii) the importer being required to post the antidumping and countervailing duty cash deposits determined by Commerce; and

(iii) the seller/exporter no longer being allowed to participate in the certification process.

K. I understand that agents of the seller/exporter, such as freight forwarding companies or brokers, are not permitted to make this certification.

L. This certification was completed and signed, and a copy of the certification was provided to the importer, on, or prior to, the date of shipment if the shipment date is after the date of publication of the notice of Commerce's preliminary determination of circumvention in the **Federal Register**. If the shipment date is on or before the date of publication of the notice of Commerce's preliminary determination of circumvention in the **Federal Register**, this certification was completed and signed, and a copy of the certification was provided to the importer, by no later than 45 days after publication of the notice of Commerce's preliminary determination of circumvention in the **Federal Register**.

M. I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make materially false statements to the U.S. government.

Signature

{NAME OF COMPANY OFFICIAL}
{TITLE OF COMPANY OFFICIAL}
{DATE}

[FR Doc. 2024–01792 Filed 1–29–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–801]

Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Preliminary Results of New Shipper Review; 2022–2023

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

SUMMARY: The U.S. Department of Commerce (Commerce) is conducting a new shipper review (NSR) of Co May Import Export Company Limited (Co May) regarding the antidumping duty (AD) order on certain frozen fish fillets (fish fillets) from the Socialist Republic of Vietnam (Vietnam). The period of review (POR) is August 1, 2022, through January 31, 2023. We have preliminarily determined that Co May's sale was a *bona fide* transaction, and that the sale was not made below normal value (NV). Interested parties are invited to comment on these preliminary results.

DATES: Applicable January 30, 2024.

FOR FURTHER INFORMATION CONTACT: Javier Barrientos, Office V, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2243.

SUPPLEMENTARY INFORMATION:

Background

On August 12, 2003, Commerce published in the **Federal Register** the AD *Order* on fish fillets from Vietnam.[1] On March 23, 2023, we initiated an NSR based on a timely request from Co May.[2]

For a complete description of the events that followed the initiation of this NSR, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as the appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Order

The products covered by this order are fish fillets from Vietnam. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this NSR in accordance with section 751(a)(2)(B) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.214. Commerce calculated export price in accordance with section 772 of the Act. Because Vietnam is a non-market economy country within the meaning of section 771(18) of the Act, Commerce calculated NV in accordance with section 773(c) of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Preliminary Results

As a result of this NSR, Commerce preliminarily determines the following weighted-average dumping margin exists for the period, August 1, 2022, through January 31, 2023.

Exporter and producer	Weighted-average dumping margin (dollars per kilogram)
Co May Import Export Company Limited	$0.00

Verification

As provided in 19 CFR 351.307(b)(iv), Commerce intends to verify the information submitted by Co May in advance of the final results of the review.

Disclosure and Public Comment

Commerce intends to disclose the calculations performed in connection with these preliminary results to interested parties within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Interested parties will be notified of the deadline for the submission of case briefs at a later date.[4] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[5] Parties who submit case or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[6]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes.[7] In this NSR, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs. Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the Issues and Decision Memorandum that will accompany the final results of this NSR. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[8]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. Requests should contain the following information: (1) the party's name, address, and telephone number; (2) the number of participants, and whether any participant is a foreign national; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. An electronically-filed hearing request must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5:00 p.m. Eastern Time within 14 days after the date of publication of this notice.[9] If a request for a hearing is made, Commerce

[1] *See Notice of Antidumping Duty Order: Certain Frozen Fish Fillets from the Socialist Republic of Vietnam,* 68 FR 47909 (August 12, 2003) (*Order*).

[2] *See Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Initiation of Antidumping Duty New Shipper Review,* 88 FR 18520 (March 29, 2023).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of New Shipper Review of the Antidumping Duty Order on Certain Frozen Fish Fillets from the Socialist Republic of Vietnam; 2022–2023,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See* 19 CFR 351.309(c)(1)(ii).

[5] *See* 19 CFR 351.309(d)(1) and (2); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023) (*APO and Service Final Rule*).

[6] *See* 19 CFR 351.309(c)(2) and (d)(2).

[7] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[8] *See APO and Service Final Rule.*

[9] *See* 19 CFR 351.310(c).

intends to notify parties of the time and date for the hearing.

Commerce intends to issue the final results of this NSR, including the results of its analysis of issues raised in any written briefs, no later than 90 days after the date of issuance of this notice, unless extended, pursuant to section 751(a)(2)(B)(iii) of the Act.

Assessment Rates

Upon issuing the final results of this review, Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, ADs on all appropriate entries covered by this review.[10] If the respondent's weighted-average dumping margin is zero or *de minimis* in the final results of review, we will instruct CBP to liquidate the appropriate entries without regard to duties. If the respondent's weighted-average dumping margin is above *de minimis* in the final results of this review, we will calculate an importer-specific (or a customer-specific) per-unit assessment rate by dividing the amount of dumping for the reviewed sale to the importer or customer by the total sales quantity associated with the transaction(s). If an importer-specific rate is zero or *de minimis,* Commerce will instruct CBP to liquidate the appropriate entries without regard to ADs.

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

Cash Deposit Instructions

The following cash deposit requirements will be effective upon publication of the final results of this review for shipments of the subject merchandise from Vietnam entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) for subject merchandise produced and exported by Co May, the cash deposit rate will be the rate established for Co May in the final results of this NSR (except, if the rate is zero or *de minimis,* then no cash deposit will be required); (2) for subject merchandise exported by Co May, but not produced by Co May, the cash deposit rate will be the rate for the Vietnam-wide entity; and (3) for subject merchandise produced by Co May, but not exported by Co May, the cash deposit rate will be the rate applicable to the exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of ADs prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of ADs occurred and the subsequent assessment of double ADs.

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(2)(B) and 777(i)(1) of the Act, and 19 CFR 351.214.

Dated: January 17, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Discussion of Methodology
V. Recommendation

[FR Doc. 2024–01791 Filed 1–29–24; 8:45 am]

BILLING CODE 3510–DS–P

[10] *See* 19 CFR 351.212(b).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Protocol for Access to Tissue Specimen Samples From the National Marine Mammal Tissue Bank

AGENCY: National Oceanic & Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of Information Collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before April 1, 2024.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *NOAA.PRA@noaa.gov.* Please reference OMB Control Number 0648–0468 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Stephen Manley, NMFS Office of Protected Resources, 1315 East West Highway, #13604, Silver Spring, MD 20910, (301) 427–8476 or *stephen.manley@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This is a request for extension of an approved information collection. In 1989, the National Marine Mammal Tissue Bank (NMMTB) was established by the National Marine Fisheries Service (NMFS) Office of Protected Resources (OPR) in collaboration with the National Institute of Standards and Technology (NIST), Minerals Management Service (MMS), and the US Geological Survey/Biological Resources Division (USGS/BRD). The NMMTB provides protocols, techniques, and physical facilities for the long-term storage of tissues from marine mammals. Scientists can request tissues from this repository for retrospective analyses to determine environmental trends of contaminants and other substances of interest. Under 16 U.S.C. 1421f section 407(d)(1) of the Marine Mammal Protection Act, the NMFS must establish criteria for access to marine mammal tissues in the NMMTB and make those available for public comment and review. This was accomplished through the proposed rule RIN 0648–AQ51, published on 11/12/2002, and codified in 50 CFR 216.47.

The NMMTB collects, processes, and stores tissues from specific indicator species (*e.g.,* Atlantic bottlenose dolphins, Atlantic white sided dolphins, pilot whales, harbor porpoises), animals from mass standings, animals that have been obtained incidental to commercial fisheries, animals taken for subsistence purposes, biopsies, and animals from

unusual mortality events through two projects, the Marine Mammal Health and Stranding Response Program (MMHSRP) and the Alaska Marine Mammal Tissue Archival Project (AMMTAP).

The purposes of this collection of information are: (1) to enable NOAA to allow the scientific community the opportunity to request tissue specimen samples from the NMMTB and, (2) to enable the Marine Mammal Health and Stranding Response Program (MMHSRP) of NOAA to assemble information on all specimens submitted to the National Institute of Standards and Technology's Biorepository (NIST Biorepository), which includes the NMMTB. This request is for extension of a current information collection, with minor revisions. Most changes to the Access Policy were grammatical and minor. No changes have been made to the National Marine Mammal Tissue Bank Tissue Request Form or the NMMTB Field Data Sheet. Revisions were also made to The Examiner's Guide to the National Marine Mammal Tissue Bank which included minor grammatical corrections as well as an update to the species list and inventory of animals and tissues.

II. Method of Collection

Respondents must complete a specimen banking information sheet for every sample submitted to the Bank. Methods of submitting reports include internet, mail and facsimile transmission of paper forms. Those requesting samples send the information, and their research findings, mainly via email.

III. Data

OMB Control Number: 0648–0468.

Form Number(s): None.

Type of Review: Regular submission (extension of a current information collection)

Affected Public: Individuals or households; Business or other for-profit organizations; Not-for-profit institutions; State, Local, or Tribal government; Federal government.

Estimated Number of Respondents: 100 specimen submission forms (from ~20 different organizations); 5 requests for tissue samples.

Estimated Time per Response: Request for tissue sample, 2 hours. Specimen submission form, 45 minutes.

Estimated Total Annual Burden Hours: 85.

Estimated Total Annual Cost to Public: $152.00.

Respondent's Obligation: Mandatory.

Legal Authority: Under 16 U.S.C. 1421f section 407(d)(1) of the Marine Mammal Protection Act, the NMFS must establish criteria for access to marine mammal tissues in the NMMTB and make those available for public comment and review.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may 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.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–01827 Filed 1–29–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD629]

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of revised Letter of Authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA), as amended, its implementing regulations, and NMFS' MMPA Regulations for Taking Marine Mammals Incidental to Geophysical Surveys Related to Oil and Gas Activities in the Gulf of Mexico, notification is hereby given that NMFS has issued a revised Letter of Authorization (LOA) to WesternGeco, in place of TGS, for the take of marine mammals incidental to geophysical survey activity in the Gulf of Mexico.

DATES: The LOA is effective through September 28, 2024.

ADDRESSES: The LOA, original LOA request, request for transferal, and supporting documentation are available online at: *https://www.fisheries.noaa.gov/action/incidental-take-authorization-oil-and-gas-industry-geophysical-survey-activity-gulf-mexico.* In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Rachel Wachtendonk, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Except with respect to certain activities not pertinent here, the MMPA

defines ''harassment'' as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

On January 19, 2021, we issued a final rule with regulations to govern the unintentional taking of marine mammals incidental to geophysical survey activities conducted by oil and gas industry operators, and those persons authorized to conduct activities on their behalf (collectively ''industry operators''), in U.S. waters of the Gulf of Mexico (GOM) over the course of 5 years (86 FR 5322; January 19, 2021). The rule was based on our findings that the total taking from the specified activities over the 5-year period will have a negligible impact on the affected species or stock(s) of marine mammals and will not have an unmitigable adverse impact on the availability of those species or stocks for subsistence uses. The rule became effective on April 19, 2021.

Our regulations at 50 CFR 217.180 *et seq.* allow for the issuance of LOAs to industry operators for the incidental take of marine mammals during geophysical survey activities and prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat (often referred to as mitigation), as well as requirements pertaining to the monitoring and reporting of such taking. Under 50 CFR 217.186(e), issuance of an LOA shall be based on a determination that the level of taking will be consistent with the findings made for the total taking allowable under these regulations and a determination that the amount of take authorized under the LOA is of no more than small numbers.

Summary of Request

On September 27, 2023, NMFS issued an LOA to TGS (88 FR 68106, October 3, 2023) to take marine mammals incidental to a three-dimensional (3D) ocean bottom node (OBN) survey in the Green Canyon, Ewing Bank, and Atwater Valley protraction areas, including approximately 380 lease blocks. Approximate water depths of the survey area range from 150 to 2,000 meters (m). See section F of the LOA application for a map of the area. Additional description of the planned survey, as well as analysis related to the issuance of that LOA, is available in TGS' LOA application and the aforementioned **Federal Register** notice of issuance.

On December 20, 2023, TGS requested the transfer of the LOA to its partner in the planned survey effort (WesternGeco). WesternGeco confirmed to NMFS that it similarly requested transfer of the LOA. With the transfer of the LOA, WesternGeco agrees to comply with the associated terms, conditions, stipulations, and restrictions of the original LOA. No other changes were requested. The revised LOA remains effective through September 28, 2024.

The revised LOA sets forth only a change in the LOA holder's name. There are no other changes to the LOA as described in the October 3, 2023, **Federal Register** notice of issuance (88 FR 68106): the specified activity; estimated take by incidental harassment; and small numbers analysis and determination; and the period of effectiveness remain unchanged and are herein incorporated by reference.

Authorization

NMFS is changing the name of the holder of the LOA from ''TGS'' to ''WesternGeco''.

Dated: January 24, 2024.

Catherine Marzin,

Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2024–01743 Filed 1–29–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD639]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Pacific Gas & Electric Sediment Remediation Project, San Francisco Bay

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an incidental harassment authorization (IHA) to Pacific Gas & Electric (PG&E) to incidentally harass marine mammals during construction activities associated with a sediment remediation project in San Francisco Bay.

DATES: The authorization is effective from May 1, 2024 to April 30, 2025.

ADDRESSES: Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/action/incidental-take-authorization-pacific-gas-electric-sediment-remediation-project-san.* In case of problems accessing these documents, please call the contact listed below.

FOR FURTHER INFORMATION CONTACT: Kristy Jacobus, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed IHA is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as ''mitigation''); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

Summary of Request

On May 4, 2023, NMFS received a request from PG&E for an IHA to take marine mammals incidental to a Sediment Remediation Project in Remedial Response Areas A and B, Piers

39 to 43½, San Francisco Bay. Following NMFS' review of the application, PG&E submitted additional information on July 25, 2023 and September 26, 2023 and subsequently submitted a revised application on November 16, 2023, which was deemed adequate and complete. PG&E's request is for take of seven species (eight stocks) of marine mammals by Level B harassment only. Neither PG&E nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate. There are no changes from the proposed IHA to the final IHA.

This IHA will cover 1 year of a larger project for which PG&E intends to request take authorization for subsequent facets of the project if necessary. The larger 5 to 7 year project involves construction to remediate contaminated sediment.

Description of Activity

Overview

PG&E is remediating sediments impacted with polycyclic aromatic hydrocarbons (PAHs) in San Francisco Bay around the area offshore of Pier 43½ to the east of Pier 45 and offshore area of Pier 43. The Project is expected to occur over a period of 5 to 7 years, and this IHA will authorize take associated with Year 1 only. PG&E expects that Year 1 will include installation of hydroacoustic data collection piles; installation of piles to attach a turbidity curtain; dredging of impacted sediment; installation of sediment pins to promote slope stability; capping of impacted sediment to be left in place; placement of armoring as needed; and temporary relocation of the Red and White Fleet (RWF). The project's planned activities that have the potential to take marine mammals, by Level B only, include impact installation and vibratory removal of composite piles; vibratory installation and removal of H-piles or steel shell piles less than or equal to 24 inches (61 cm) in diameter; vibratory installation and removal of 36-inch steel guide piles; vibratory and impact installation of 24-inch steel fender piles; vibratory removal of the 24-inch fender piles; and vibratory and impact installation of timber piles. In-water construction is expected to occur over 50 non-consecutive days over 1 year.

A detailed description of the planned construction project is provided in the **Federal Register** noticed for the proposed IHA (88 FR 82836, November 27, 2023). Since that time, no changes have been made to the planned activities. Therefore, a detailed description is not provided here. Please refer to that **Federal Register** notice for the description of the specific activity.

Comments and Responses

A notice of NMFS' proposal to issue an IHA to PG&E was published in the **Federal Register** on November 27, 2023 (88 FR 82836). That notice described, in detail, PG&E's activity, the marine mammal species that may be affected by the activity, and the anticipated effects on marine mammals. In that notice, we requested public input on the request for authorization described therein, our analyses, the proposed authorization, and any other aspect of the notice of proposed IHA, and requested that interested persons submit relevant information, suggestions, and comments.

During the 30-day public comment period, NMFS received comments from Turtle Island Restoration Network (TIRN) and a letter from the U.S. Geological Survey stating that they had no comments. In addition, a comment was received from a private citizen expressing general opposition to PG&E, which is not related to NMFS' proposed action. All relevant, substantive comments, and NMFS' responses, are provided below. The comments and recommendations are available online at: *https://www.fisheries.noaa.gov/action/incidental-take-authorization-pacific-gas-electric-sediment-remediation-project-san.* Please see the comment submission for full details regarding the recommendations and supporting rationale.

Comment 1: TIRN asserts that NMFS failed to adequately consider the potential for delayed mortality of marine mammals or the potential long-term impacts of underwater noise on the ecosystem as a whole, and states that NMFS ''must require PG&E to submit a request for authorization of incidental Level A harassment takes of marine mammals.''

Response: We first note that TIRN conflates take by Level A harassment and mortality and serious injury. As defined by the MMPA, Level A harassment means ''any act of pursuit, torment, or annoyance which has the potential to injure a marine mammal or marine mammal stock in the wild'' (16 U.S.C. 1362(18)(A)). Serious injury is defined as ''any injury that will likely result in mortality'' under NMFS' MMPA implementing regulations (50 CFR 216.3). Level A harassment does not include serious injury or mortality, and serious injury or mortality cannot be authorized through an IHA.

NMFS acknowledges that pile driving can impact marine mammals' ability to detect prey and can impact marine mammal prey in the vicinity of the project area, as discussed in the **Federal Register** notice for the proposed IHA (88 FR 82836, November 27, 2023). However, NMFS expects these effects to be temporary and disagrees that these impacts are likely to result in long-term disruption or result in delayed mortality. TIRN suggests, without evidence, that the specified activity is likely to reduce the ability for marine mammals to hunt to the extent that such behavioral effects may lead to delayed mortality. Any effects to marine mammals' ability to hunt or detect prey are expected to be temporary, *e.g.,* on the order of minutes to hours, due to marine mammals' transient nature, likelihood to avoid disturbance, the short duration of construction, and the mitigation used which will reduce marine mammals' exposure to pile driving noise. Mortality can result if marine mammal foraging behavior is impeded, but such an extreme result would require complete cessation of foraging over an extended period of time. There is no potential for such impacts to result from this activity given the short durations over which bouts of activity will occur and unimpeded access to other areas of equal foraging value. The most likely impact to fishes from pile driving are expected to be temporary behavioral avoidance, and any behavioral avoidance by fish of the disturbed area would still leave significantly large potential areas in the nearby vicinity for marine mammals to forage. Further discussion of the expected short-term impacts to marine mammals and prey can be found in the Potential Effects of Specified Activities on Marine Mammals and Their Habitat in the **Federal Register** notice for the proposed IHA (88 FR 82836, November 27, 2023).

NMFS disagrees that long-term disruptions and delayed mortality of marine mammals are likely to occur as a result of PG&E's project and, therefore, authorization of Level A harassment or serious injury or mortality is not appropriate.

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS'

Stock Assessment Reports (SARs; *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS' website (*https://www.fisheries.noaa.gov/find-species*).

Table 1 lists all species or stocks for which take is expected and authorized for this activity, and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS' SARs). While no serious injury or mortality is anticipated or authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species or stocks and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS' stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS' U.S. Pacific and Alaska SARs. All values presented in table 1 are the most recent available at the time of publication and are available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.*

TABLE 1—MARINE MAMMAL SPECIES LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES [1]

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) [2]	Stock abundance (CV, N_{min}, most recent abundance survey) [3]	PBR	Annual M/SI [4]
Family Delphinidae:						
Bottlenose dolphin	*Tursiops truncatus*	Coastal California	-,-,N	453 (0.06, 346, 2011)	2.7	≥2.0
Family Phocoenidae (porpoises):						
Harbor porpoise	*Phocoena phocoena*	San Francisco-Russian River	-,-,N	7,777 (0.62, 4811, 2017)	73	≥0.4
Order Carnivora—Pinnipedia						
Family Otariidae (eared seals and sea lions):						
California Sea Lion	*Zalophus californianus*	United States	-,-,N	257,606 (N/A, 233,515, 2014)	14,011	≥321
Northern Fur Seal	*Callorhinus ursinus*	California	-,-,N	14,050 (0.03, 7,524, 2013)	451	1.8
Northern Fur Seal	*Callorhinus ursinus*	Eastern North Pacific	-, D, Y	626,618 (0.2, 530,376, 2021)	11,403	373
Steller Sea Lion	*Eumetopias jubatus*	Eastern North Pacific	-,-,N	43,201 (N/A, 43,201, 2017)	2,592	112
Family Phocidae (earless seals):						
Harbor Seal	*Phoca vitulina*	California	-,-,N	30,968 (N/A, 27,348, 2014)	1,641	43
Northern Elephant Seal	*Mirounga angustirostris*	California Breeding	-,-,N	187,386 (N/A, 85,369, 2013)	5,122	13.7

[1] Information on the classification of marine mammal species can be found on the web page for The Society for Marine Mammalogy's Committee on Taxonomy (*https://marinemammalscience.org/science-and-publications/list-marine-mammal-species-subspecies/;* Committee on Taxonomy (2022)).

[2] Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[3] NMFS marine mammal stock assessment reports online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports.* CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance.

[4] These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (*e.g.,* commercial fisheries, vessel strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range.

As indicated above, all seven species (with eight managed stocks) in table 1 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur. Gray whales and humpback whales rarely enter the Bay but may occasionally pass offshore of the Project Area. However, if either of these species are to approach the Level B harassment zone construction will be shutdown. Therefore, no take is expected of these species, and these species will not be discussed further.

A detailed description of the of the species likely to be affected by the sediment remediation project, including brief introductions to the species and relevant stocks as well as available information regarding population trends and threats, and information regarding local occurrence, were provided in the **Federal Register** notice for the proposed IHA (88 FR 82836, November 27, 2023); since that time, we are not aware of any changes in the status of these species and stocks; therefore, detailed descriptions are not provided here. Please refer to that **Federal Register** notice for these descriptions. Please also refer to NMFS' website (*https://www.fisheries.noaa.gov/find-species*) for generalized species accounts.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007, 2019) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical modeling, *etc.*). Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized

composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in table 2.

TABLE 2—MARINE MAMMAL HEARING GROUPS

[NMFS, 2018]

Hearing group	Generalized hearing range *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, *Kogia,* river dolphins, Cephalorhynchid, *Lagenorhynchus cruciger* & *L. australis*).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.,* all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.* 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth and Holt, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

The effects of underwater noise from PG&E's sediment remediation activities have the potential to result in behavioral harassment of marine mammals in the vicinity of the project area. The notice of proposed IHA (88 FR 82836, November 27, 2023) included a discussion of the effects of anthropogenic noise on marine mammals and the potential effects of underwater noise from PG&E's construction on marine mammals and their habitat. That information and analysis is incorporated by reference into this final IHA determination and is not repeated here; please refer to the notice of proposed IHA (88 FR 82836, November 27, 2023).

Estimated Take of Marine Mammals

This section provides an estimate of the number of incidental takes authorized through the IHA, which will inform both NMFS' consideration of ''small numbers,'' and the negligible impact determinations.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes will be by Level B harassment only, in the form of disruption of behavioral patterns and/or temporary threshold shift (TTS) for individual marine mammals resulting from exposure to vibratory and impact pile driving. Based on the nature of the activity and the anticipated effectiveness of the mitigation measures (*i.e.,* shutdown) discussed in detail below in the Mitigation section, Level A harassment is neither anticipated nor authorized.

As described previously, no serious injury or mortality is anticipated or authorized for this activity. Below we describe how the take numbers are estimated.

For acoustic impacts, generally speaking, we estimate take by considering: (1) acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.,* previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the take estimates.

Acoustic Thresholds

NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur permanent threshold shift (PTS) of some degree (equated to Level A harassment).

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (*e.g.,* frequency, predictability, duty cycle, duration of the exposure, signal-to-noise ratio, distance to the source), the environment (*e.g.,* bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage, depth) and can be difficult to predict (*e.g.,* Southall *et al.,* 2007, 2021; Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above root-mean-squared pressure received levels (RMS SPL) of 120 dB (referenced to 1 micropascal (re 1 µPa)) for continuous (*e.g.,* vibratory pile driving, drilling) and above RMS SPL 160 dB re 1 µPa for non-explosive impulsive (*e.g.,* seismic

airguns) or intermittent (*e.g.,* scientific sonar) sources. Generally speaking, Level B harassment take estimates based on these behavioral harassment thresholds are expected to include any likely takes by TTS as, in most cases, the likelihood of TTS occurs at distances from the source less than those at which behavioral harassment is likely. TTS of a sufficient degree can manifest as behavioral harassment, as reduced hearing sensitivity and the potential reduced opportunities to detect important signals (conspecific communication, predators, prey) may result in changes in behavior patterns that would not otherwise occur.

PG&E's activity includes the use of continuous (vibratory pile driving) and impulsive (impact pile driving) sources, and therefore the RMS SPL thresholds of 120 and 160 dB re 1 µPa are applicable.

Level A Harassment—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0) (Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). PG&E's activity includes the use of impulsive (impact pile driving) and non-impulsive (vibratory pile driving) sources.

These thresholds are provided in the table below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS' 2018 Technical Guidance, which may be accessed at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 3—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

Hearing group	PTS onset acoustic thresholds * (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	*Cell 1:* $L_{pk,flat}$: 219 dB; $L_{E,LF,24h}$: 183 dB	*Cell 2:* $L_{E,LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	*Cell 3:* $L_{pk,flat}$: 230 dB; $L_{E,MF,24h}$: 185 dB	*Cell 4:* $L_{E,MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	*Cell 5:* $L_{pk,flat}$: 202 dB; $L_{E,HF,24h}$: 155 dB	*Cell 6:* $L_{E,HF,24h}$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	*Cell 7:* $L_{pk,flat}$: 218 dB; $L_{E,PW,24h}$: 185 dB	*Cell 8:* $L_{E,PW,24h}$: 201 dB.
Otariid Pinnipeds (OW) (Underwater)	*Cell 9:* $L_{pk,flat}$: 232 dB; $L_{E,OW,24h}$: 203 dB	*Cell 10:* $L_{E,OW,24h}$: 219 dB.

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 µPa, and cumulative sound exposure level (L_E) has a reference value of 1µPa^{2}s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript "flat" is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that are used in estimating the area ensonified above the acoustic thresholds, including source levels and transmission loss coefficient.

The sound field in the project area is the existing background noise plus additional construction noise from the project. Marine mammals are expected to be affected via sound generated by the primary components of the project (*i.e.,* pile driving and removal).

The project includes vibratory pile installation and removal and impact pile driving. Source levels for these activities are based on reviews of measurements of the same or similar types and dimensions of piles available in the literature. Source levels for each pile size and activity are presented in table 4. Source levels for vibratory installation and removal of piles of the same diameter are conservatively assumed to be the same.

The majority of source levels were selected from a single source, as shown in table 4 below. For the vibratory installation of 36-inch steel shell piles and vibratory installation of timber piles, NMFS determined it appropriate to use an average of source levels. NMFS reviewed all available monitoring reports of vibratory driving of 36-inch steel piles in San Francisco Bay (Gast &Associated Environmental Consultants, 2021, 2023; Illingworth & Rodkin, 2018, 2020). Averaging of sound levels was performed by first converting from dB to linear units of pressure (Pascals [Pa]), averaging, and converting back to dB. The mean RMS level at 10 meters (m) for San Francisco Bay was approximately 168 dB re 1 µPa RMS. Therefore, NMFS has selected this average value as the most appropriate value for vibratory driving of 36-inch steel pipe piles during the project. With regard to vibratory installation of timber piles, there are limited data available, and none from San Francisco Bay. Therefore, NMFS evaluated all available timber pile data (three projects from Puget Sound, WA, and one project from Norfolk, VA) (Greenbusch Group, 2018; Illingworth and Rodkin, 2017; Laughlin, 2011; U.S. Navy, 2016) and calculated the mean and maximum RMS values for each project and for all projects together. The overall mean RMS value was approximately 158 dB re 1 µPa RMS. NMFS therefore selected this as an appropriate proxy value for vibratory driving of timber piles during the project.

TABLE 4—SOUND SOURCE LEVELS FOR PILE DRIVING ACTIVITIES [1]

Pile type	Method	Peak sound pressure (dB re 1 µPa)	RMS (dB re 1 µPa)	SEL (dB re 1 µPa2 sec)	Source
Hydroacoustic Data Collection					
18-inch composite/plastic	Impact Install	185	160	150	Caltrans, 2020; extrapolated from 13-inch composite.

TABLE 4—SOUND SOURCE LEVELS FOR PILE DRIVING ACTIVITIES [1]—Continued

Pile type	Method	Peak sound pressure (dB re 1 μPa)	RMS (dB re 1 μPa)	SEL (dB re 1 μPa2 sec)	Source
18-inch composite/plastic	Vibratory Removal	N/A	152	N/A	WSDOT, 2012; 13-inch composite used as proxy.
Turbidity Curtain					
Steel H-Pile	Vibratory Install and Removal	N/A	143	N/A	Caltrans, 2020.
Steel Shell Pile ≤24-inches	Vibratory Install and Removal	N/A	153	N/A	Caltrans, 2020; 24-inch pipe pile used as proxy.
RWF Relocation					
24-inch steel shell	Vibratory Installation and Removal	N/A	153	N/A	Caltrans, 2020.
24-inch steel shell	Impact Installation [2]	208	193	178	Illingworth & Rodkin, Inc. 2014.
36-inch steel shell	Vibratory Installation and Removal	N/A	168	N/A	Gast & Associated Environmental Consultants, 2021, 2023; Illingworth and Rodkin, 2018, 2020. See explanation above.
Slope Stabilization					
14 to 16 inch Timber	Vibratory	N/A	158	N/A	Greenbusch Group, 2018; Illingworth and Rodkin, 2017; Laughlin, 2011; U.S. Navy 2016. See explanation above.
14 to 16 inch Timber	Impact	184	157	145	Caltrans, 2020.
14 to 16-inch Composite	Vibratory	N/A	152	N/A	WSDOT, 2012. 13-inch composite used as proxy.
14 to 16-inch Composite	Impact	177	153	145	Caltrans, 2020.

[1] All values are at 10 m from the source.
[2] PG&E will use a bubble curtain attenuation system for impact pile driving of the RWF 24-inch steel shell piles, and we conservatively assumes a 5 dB reduction in source level from those presented here due to use of the attenuation system.

Level B Harassment Zones—Transmission loss (TL) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition topography. The general formula for underwater TL is:

$TL = B * Log10 (R_1/R_2)$,

where
TL = transmission loss in dB;
B = transmission loss coefficient;
R_1 = the distance of the modeled SPL from the driven pile; and
R_2 = the distance from the driven pile of the initial measurement.

The recommended TL coefficient for most nearshore environments is the practical spreading value of 15. This value results in an expected propagation environment that would lie between spherical and cylindrical spreading loss conditions, known as practical spreading. As is common practice in coastal waters, here we assume practical spreading (4.5 dB reduction in sound level for each doubling of distance) for all impact and vibratory installation and removal of piles with the exception of vibratory installation and removal of the 36-inch steel pipe piles in the RWF Relocation. Illingworth & Rodkin conducted hydro-acoustic monitoring for the 2017 WETA Downtown San Francisco Ferry Terminal Expansion Project and calculated a TL coefficient of 18.7 for vibratory installation of 36-inch steel shell piles (Illingworth & Rodkin, 2018). Given the proximity to the project area, PG&E determined that 18.7 was an appropriate transmission coefficient to use for the vibratory installation of the 36-inch steel shell pile, and NMFS concurs.

The ensonified area associated with Level A harassment is more technically challenging to predict due to the need to account for a duration component. Therefore, NMFS developed an optional User Spreadsheet tool to accompany the Technical Guidance that can be used to relatively simply predict an isopleth distance for use in conjunction with marine mammal density or occurrence to help predict potential takes. We note that because of some of the assumptions included in the methods underlying this optional tool, we anticipate that the resulting isopleth estimates are typically going to be overestimates of some degree, which may result in an overestimate of potential take by Level A harassment. However, this optional tool offers the best way to estimate isopleth distances when more sophisticated modeling methods are not available or practical. For stationary sources such as pile driving, the optional User Spreadsheet tool predicts the distance at which, if a marine mammal remained at that distance for the duration of the activity, it would be expected to incur PTS. Source levels are provided above in table 4. Inputs used in the optional User Spreadsheet tool are provided below in table 5. Resulting estimated Level A and B harassment isopleths are provided in table 6.

TABLE 5—USER SPREADSHEET INPUTS (SOURCE LEVELS PROVIDED IN TABLE 4)

Pile type	Method	Duration	Piles/day
Hydroacoustic Data Collection			
18-inch composite/plastic	Impact Install	400 strikes/pile	10
18-inch composite/plastic	Vibratory Removal	20 minutes	10

TABLE 5—USER SPREADSHEET INPUTS (SOURCE LEVELS PROVIDED IN TABLE 4)—Continued

Pile type	Method	Duration	Piles/day
Turbidity Curtain			
Steel H-Pile	Vibratory	10 minutes	4
Steel Shell Pile ≤24-inches	Vibratory	10 minutes	4
RWF Relocation			
24-inch steel shell	Vibratory	10 minutes	4
24-inch steel shell	Impact	400 strikes/pile	4
36-inch steel shell	Vibratory	20 minutes	4
Sediment Pin Installation			
Timber	Vibratory	20 minutes	20
Timber	Impact	400 strikes/pile	20
14 to16-inch Composite	Vibratory	20 minutes	10
14 to 16-inch Composite	Impact	400 strikes/pile	10

TABLE 6—LEVEL A HARASSMENT AND LEVEL B HARASSMENT ISOPLETHS FROM VIBRATORY AND IMPACT PILE DRIVING

Pile type & method	Level A/PTS isopleth (m)					Level B Isopleth (m)	Level B area of ensonification (km^2)
	Hearing groups						
	Cetaceans			Pinnipeds			
	LF	MF	HF	Phocids	Otariids		
Hydroacoustic Data Collection Piles							
18-inch composite (Impact)	16	<1	19	9	<1	10	<0.01
18-inch Composite (Vibratory)	4	<1	6	3	<1	1,360	3.58
Turbidity Curtain							
Steel H-Pile (Vibratory)	<1	0	<1	<1	<1	341	0.29
Steel Shell Pile ≤ 24-inches (Vibratory)	2	<1	4	2	<1	1,585	4.61
RWF Temporary Relocation Piles							
24-inch Steel Shell Pile (Vibratory)	2	<1	4	2	<1	1,585	4.54
24-inch Steel Shell Pile (Impact, Attenuated)*	294	11	351	158	12	736	1.06
36-inch Steel Shell Pile (Vibratory)	20	3	28	14	2	3,688	23.46
Sediment Pins							
14 to 16-inch Timber Pile (Vibratory)	16	2	23	10	1	3,415	19.17
14 to 16-inch Timber Pile (Impact)	12	<1	14	6	<1	6	<0.01
14 to 16-inch Composite Pile (Vibratory)	4	<1	6	3	<1	1,360	3.2
14 to 16-Inch Composite Pile (Impact)	7	<1	9	4	<1	3.4	<0.01

*5 dB reduction in sound due to use of bubble curtain assumed.

Marine Mammal Occurrence

In this section we provide information about the occurrence of marine mammals, including density or other relevant information which will inform the take calculations.

Because reliable marine mammal density information is not available for the San Francisco Bay, several datasets were used to attain estimates of the abundance of marine mammals in the Bay. Datasets used included 5 years of sighting and stranding data from The Marine Mammal Center (TMMC) (NMFS, 2021a); 5 years of sighting and stranding data from the California Academy of Sciences (CAS) (NMFS, 2021b); citizen-reported live sightings from *iNaturalist.org;* 5 days of sighting data during sediment investigation in 2020 during the initial phase of the project (Haase, 2021); and counts from haulouts. Data from all sources, when available, were considered. Depending on the distribution of sightings and granularity of data, different sources have been used to estimate the number of individuals of each species with the potential to occur in vicinity of the project. The largest ensonified area is during vibratory installation of 36-inch steel shell piles, which results in a 3,688 m isopleth and 23.46 kilometers squared (km^2) area of ensonification.

Harbor Seal

Harbor seals in the Bay forage mainly within 7.0 miles (mi; (11.3 km)) of their primary haulout site (Grigg *et al.* 2012), and often within just 1 to 3 miles (1 to 5 km) (Torok, 1994). The only harbor seal haulout within 7 miles (11.3 km) of the project site is Yerba Buena Island (YBI), which is 3.1 mi (5 km) to the east of the Project Area. Noise from the project is not expected to reach the haulout, however, harbor seals that use this haulout are likely to forage within ensonified areas from the project. Harbor seal take estimates were based on observations conducted by Marine Mammal Observers (MMOs) over a 5 day period in 2020, during sediment investigation in the initial phase of the project, within remedial response areas A, B, and C (See Haase, 2021). A maximum of 20 harbor seals were observed per day. PG&E therefore estimates 20 harbor seals per day within

the project area per day. NMFS concurs with this assumption.

Northern Elephant Seal

TMMC recorded 903 elephant seals in the Bay from 2016 to 2021 (NMFS, 2021a). The CAS reported an additional 6 for a total of 909 over 5 years in the Bay from 2016 to 2021 (NMFS, 2021b), yielding an average of 0.5 elephant seals per day. To ensure sufficient authorization of take of northern elephant seals, PG&E assumed 0.5 elephant seals will occur in the area per day (*i.e.,* one elephant seal every 2 days). NMFS concurs with this assumption.

California Sea Lion

The Pier 39 K-Dock haulout is the only regularly used California Sea Lion haulout in the vicinity of the Project Area, adjacent to Area C. The Sea Lion Center at Pier 39 regularly counted the sea lions at K-Dock from 1991 through 2018. From 2016 through 2018, the yearly average ranged from 89 to 229 animals per day. The average per day over all 3 years was 191 sea lions (Pacific Gas & Electric, 2023). Although there are times of the year when the K-dock is unoccupied or there are few individuals present, it is difficult to predict abundance based on time of year. In order to ensure sufficient authorization of sea lions, PG&E is assuming a local abundance estimate of 191 sea lions per day within the estimated harassment area, and NMFS concurs.

Northern Fur Seal

TMMC recorded 44 northern fur seals in the Bay from 2016 to 2021 (NMFS, 2021a). CAS recorded an additional 3 for a total of 47 over 5 years (NMFS, 2021b), yielding 0.03 per day, or approximately 10 per year. In the fall and winter, northern fur seals occasionally strand on YBI and Treasure Island (Pacific Gas & Electric, 2023), approximately 2.0 mi (3.2 km) from the project area. Using PG&E's assumption of approximately 0.03 fur seals per day over the course of 50 days of pile driving plus known fur seal strandings near the project area, NMFS has determined it appropriate to assume five fur seals in the project area during the project time period.

Steller Sea Lion

Steller sea lions are rare in San Francisco Bay. TMMC recorded four Steller sea lions in the Bay from 2016 to 2021 (NMFS, 2021a), while CAS reported no Steller sea lions during this time (NMFS, 2021b). In 2020 and 2021, *INaturalist.org* recorded four Steller sea lions in the Bay. On rare occasions, Steller sea lions are seen on the Pier 39 K-dock haulout. An adult male was spotted there in May 2023 (Segura, 2023) and in previous years a single male Steller sea lion had been observed using the Pier 39 K-dock haulout intermittently during July and August and occasionally September (Pacific Gas & Electric, 2023). Given these known occasional occurrences of the Steller sea lion at Pier 39, PG&E feels it is appropriate to assume five Steller sea lions in the project area during the time period of the project, and NMFS concurs.

Bottlenose Dolphins

Historically, observations of bottlenose dolphins have occurred west of Treasure Island and were concentrated in the Project vicinity along the nearshore area of San Francisco south to Redwood City. Since 2016, one individual has been regularly seen near the former Alameda Air Station and five animals were regularly seen in the summer and fall of 2018 in the same location (Pacific Gas & Electric, 2023). A recent study reports that dolphins have been sighted in the vicinity of the Golden Gate Bridge, around Yerba Buena and Angel Islands, and in the central Bay (Keener *et al.,* 2023). PG&E is assuming that one group of bottlenose dolphins will enter into the project isopleth per month of pile driving, and NMFS concurs. A group size is estimated to be five animals based on sightings of bottlenose dolphins in the Bay (Pacific Gas & Electric, 2023).

Harbor Porpoise

Harbor porpoises are primarily seen near the Golden Gate Bridge, Marin County, and the city of San Francisco on the northwest side of the Bay (Keener *et al.,* 2012; Stern *et al.,* 2017), in the vicinity of the project area. Limited data exists on the abundance of harbor porpoises in the Bay, and therefore data from MMOs in 2020 was used (see Haase 2021). An individual harbor porpoise was seen in the project zone on 2 of the 5 days, and a group of two individuals was reported on a separate day of the 5 day observation period (Haase, 2021). To ensure sufficient authorization of take of harbor porpoise, it is estimated that two harbor porpoises will occur within the estimated harassment area per day.

Take Estimation

Here we describe how the information provided above is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and is authorized.

Take estimate calculations vary by species. To calculate take by Level B harassment for harbor seals, California sea lions, northern elephant seals, and harbor porpoises, NMFS multiplied the daily occurrence estimates described in the *Marine Mammal Occurrence* section by the number of project days (table 7).

For northern fur seals, PG&E is assuming a total of five animals in the area of the project during the duration of the project, based on sightings in the Bay and known strandings on YBI (see *Marine Mammal Occurrence* above), and is therefore requesting, and NMFS has authorized, take of five northern fur seals by Level B harassment (table 7).

Although Steller sea lions are rare in San Francisco Bay, based on sighting data and known occurrence of Steller sea lions on the Pier 39 K-dock haulout (PG&E, 2023; Segura, 2023), PG&E is conservatively requesting five takes by Level B harassment of Steller sea lions during the time period of the project, and NMFS concurs (table 7).

For bottlenose dolphins, PG&E estimates that one group of five bottlenose dolphins may be taken by Level B harassment per month of pile driving. Based on 5 months of pile driving, NMFS has authorized 25 takes by Level B harassment of bottlenose dolphins.

TABLE 7—AUTHORIZED TAKE BY LEVEL B HARASSMENT AUTHORIZED AND ESTIMATED TAKE AS A PERCENTAGE OF THE POPULATION

Species	Stock	Expected occurrence	Estimated Level B take	Stock abundance *	Percent of stock
Pacific Harbor Seal	California	20 seals per day	1000	30,968	3.2
Northern Elephant Seal ...	California Breeding	0.5 seals per day	25	187,386	0.01
California Sea Lion	United States	191 sea lions per day	9,550	257,606	3.7

TABLE 7—AUTHORIZED TAKE BY LEVEL B HARASSMENT AUTHORIZED AND ESTIMATED TAKE AS A PERCENTAGE OF THE POPULATION—Continued

Species	Stock	Expected occurrence	Estimated Level B take	Stock abundance *	Percent of stock
Northern Fur Seal	California; Eastern North Pacific.	5 seals over project duration.	5	14,050; 626,618	0.04; 0.001
Steller sea lion	Eastern United States	5 sea lions over project duration.	5	43,201	0.01
Bottlenose dolphin	Coastal California	5 dolphins per month of project.	25	453	5.5
Harbor Porpoise	San Francisco-Russian River.	2 porpoises per day	100	7,777	1.3

* NMFS marine mammal stock assessment reports online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports.*

Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned), and;

(2) The practicability of the measures for applicant implementation, which may consider such things as cost and impact on operations.

PG&E must follow mitigation measures as specified below.

PG&E must ensure that construction supervisors and crews, the monitoring team, and relevant PG&E staff are trained prior to the start of all pile driving activities, so that responsibilities, communication procedures, monitoring protocols, and operational procedures are clearly understood. New personnel joining during the project must be trained prior to commencing work.

Shutdown Zones

PG&E must establish shutdown zones and Level B monitoring zones for all pile driving activities. The purpose of a shutdown zone is generally to define an area within which shutdown of the activity will occur upon sighting of a marine animal (or in anticipation of an animal entering the defined area). Shutdown zones are based on the largest Level A harassment zone for each pile size/type and driving method, and behavioral monitoring zones are meant to encompass Level B harassment zones for each pile size/type and driving method, as shown in table 6. A minimum shutdown zone of 10 m will be required for all in-water construction activities to avoid physical interaction with marine mammals, and the radii of the shutdown zones are rounded to the next largest 10 m interval in comparison to the Level zone for each activity type. Marine mammal monitoring will be conducted during all pile driving activities to ensure that marine mammals do not enter Level A shutdown zones, that marine mammal presence in the isopleth does not exceed authorized take, and to prevent take of the humpback and gray whale. Shutdown zones for each activity type are shown in table 8.

Prior to pile driving, shutdown zones and monitoring zones will be established based on zones represented in table 8. Observers will survey the shutdown zones for at least 30 minutes before pile driving activities start. If marine mammals are found within the shutdown zone, pile driving will be delayed until the animal has moved out of the shutdown zone, either verified by an observer or by waiting until 15 minutes has elapsed without a sighting. If a marine mammal approaches or enters the shutdown zone during pile driving, the activity will be halted. Pile driving may resume after the animal has moved out of and is moving away from the shutdown zone or after at least 15 minutes has passed since the last observation of the animal.

All marine mammals will be monitored in the Level B harassment zones and throughout the area as far as visual monitoring can take place. If a marine mammal enters the Level B harassment zone, in-water activities will continue and PSOs will document the animal's presence within the estimated harassment zone.

If a species for which authorization has not been granted (*i.e.,* gray whale or humpback whale), or a species which has been granted but the authorized takes are met, is observed approaching or within the Level B monitoring zone, pile driving activities will be shutdown immediately. Activities will not resume until the animal has been confirmed to have left the area or 15 minutes has elapsed with no sighting of the animal.

TABLE 8—SHUTDOWN ZONES AND LEVEL B MONITORING ZONES BY ACTIVITY

Pile type and method	Shutdown zone for all species (m)	Monitoring zone (m)
Hydroacoustic Data Collection Piles		
18-inch Composite/Plastic (impact)	20	10
18-Inch Composite/Plastic (vibratory removal)	10	1,360
Turbidity Curtain		
Steel H-Pile (Vibratory Install and Removal)	10	341
24-inch steel shell pile (Vibratory install and removal)	10	1,585
RWF Relocation Piles		
24-inch steel shell pile (Vibratory install and removal)	10	1,585
24-inch steel shell pile (impact-attenuated)	360	736
36-inch steel shell pile (vibratory)	30	3,688
Sediment Pins		
14 to 16-inch timber (Vibratory)	30	3,415
14 to 16-inch timber (impact)	20	10
14 to 16-inch composite (impact)	10	10
14 to 16-inch composite (vibratory install)	20	1,360

Protected Species Observers (PSOs)

The placement of PSOs during all pile driving activities (described in the Monitoring and Reporting section) will ensure that the entire shutdown zone is visible. Should environmental conditions deteriorate such that the entire shutdown zone will not be visible (*e.g.,* fog, heavy rain), pile driving will be delayed until the PSO is confident marine mammals within the shutdown zone could be detected.

PSOs will monitor the full shutdown zones and as much of the Level B harassment zones as possible. Monitoring zones provide utility for observing by establishing monitoring protocols for areas adjacent to the shutdown zones. Monitoring zones enable observers to be aware of and communicate the presence of marine mammals in the project areas outside the shutdown zones and thus prepare for a potential cessation of activity should the animal enter the shutdown zone.

Pre- and Post-Activity Monitoring

Monitoring must take place from 30 minutes prior to initiation of pile driving activities (*i.e.,* pre-clearance monitoring) through 30 minutes post-completion of pile driving. Prior to the start of daily in-water construction activity, or whenever a break in pile driving of 30 minutes or longer occurs, PSOs will observe the shutdown and monitoring zones for a period of 30 minutes. The shutdown zone will be considered cleared when a marine mammal has not been observed within the zone for a 30-minute period. If a marine mammal is observed within the shutdown zones, pile driving activity will be delayed or halted. If work ceases for more than 30 minutes, the pre-activity monitoring of the shutdown zones will commence. A determination that the shutdown zone is clear must be made during a period of good visibility (*i.e.,* the entire shutdown zone and surrounding waters must be visible to the naked eye).

Soft-Start Procedures

Soft-start procedures are used to provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the hammer operating at full capacity. For impact pile driving, contractors will be required to provide an initial set of three strikes from the hammer at reduced energy, followed by a 30-second waiting period, then two subsequent reduced-energy strike sets. Soft start will be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30 minutes or longer.

Bubble Curtain

A bubble curtain must be employed during all impact pile installation of steel piles less than 24 inches in diameter to interrupt the acoustic pressure and reduce impact on marine mammals. Impact pile driving will not be allowed for 36-inch steel shell piles. The bubble curtain must distribute air bubbles around 100 percent of the piling circumference for the full depth of the water column. The lowest bubble ring must be in contact with the mudline for the full circumference of the ring. The weights attached to the bottom ring must ensure 100 percent substrate contact. No parts of the ring or other objects may prevent full substrate contact. Air flow to the bubblers must be balanced around the circumference of the pile.

Based on our evaluation of the applicant's measures, NMFS has determined that the mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present while conducting the activities. Effective reporting is critical both to compliance as well as ensuring that the

most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the activity; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and,
- Mitigation and monitoring effectiveness.

Visual Monitoring

Marine mammal monitoring must be conducted in accordance with the conditions in this section and the IHA. Marine mammal monitoring during pile driving activities will be conducted by PSO's meeting NMFS' standards and in a manner consistent with the following:

- PSOs must be independent of the activity contractor (for example, employed by a subcontractor) and have no other assigned tasks during monitoring periods;
- At least one PSO will have prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued incidental take authorization;
- Other PSOs may substitute education (degree in biological science or related field) or training for experience;
- Where a team of three or more PSOs is required, a lead observer or monitoring coordinator will be designated. The lead observer will be required to have prior experience working as a marine mammal observer during construction;
- PSOs will submit PSO resumes for approval by NMFS 30 days prior to the onset of pile driving; and,
- PSOs must be approved by NMFS prior to beginning any activity subject to the IHA.

PSOs should have the following additional qualifications:

- Ability to conduct field observations and collect data according to assigned protocols;
- Experience or training in the field identification of marine mammals, including the identification of behaviors;
- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates, times, and reason for implementation of mitigation (or why mitigation was not implemented when required); and marine mammal behavior; and
- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

PG&E will have between one and three PSOs on site at all times during pile driving activities. One PSO will be designated as the Lead PSO and will receive updates from other PSOs. The Lead PSO will be stationed at the active pile driving rig or at the best vantage point practicable to monitor the shutdown zones and implement shutdown and delay procedures. The other PSOs will be stationed at the best vantage points practicable to observe the monitoring zones. Exact locations will be determined in the field based on the pile driving site, field conditions, and in coordination with contractors, but may include docks, barges, and tower structures. PSOs will be equipped with high quality binoculars or spotting scopes for monitoring and radios and cell phones for maintaining contact with other observers and work crew. Monitoring will be conducted 30 minutes before, during, and 30 minutes after all in-water construction activities. PSOs will record all incidents of marine mammal occurrence, regardless of distance from activity, and will document any behavioral reactions in concert with distance from piles being driven or removed. Pile driving activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than 30 minutes.

Data Collection

PSOs will use approved data forms to record the following information:

- Dates and times (beginning and end) of all marine mammal monitoring;
- PSO locations during marine mammal monitoring;
- Construction activities occurring during each daily observation period, including how many and what type of piles were driven or removed and by what method (*i.e.,* impact or vibratory);
- Weather parameters and water conditions;
- The number of marine mammals observed, by species, relative to the pile location and if pile driving or removal was occurring at time of sighting;
- Distance and bearings of each marine mammal observed to the pile being driven or removed;
- Description of marine mammal behavior patterns, including direction of travel;
- Age and sex class, if possible, of all marine mammals observed; and,
- Detailed information about implementation of any mitigation triggered (such as shutdowns and delays), a description of specific actions that ensued, and resulting behavior of the animal if any.

Reporting

PG&E must submit a draft marine mammal monitoring report to NMFS within 90 days after the completion of pile driving activities, or 60 days prior to the requested issuance of any future IHAs for the project, or other projects at the same location, whichever comes first. A final report must be prepared and submitted within 30 calendar days following receipt of any NMFS comments on the draft report. If no comments are received from NMFS within 30 calendar days of receipt of the draft report, the report shall be considered final. The marine mammal report will include an overall description of work completed, a narrative regarding marine mammal sightings, and associated PSO data sheets and/or raw sighting data. Specifically, the report will include:

- Dates and times (beginning and end) of all marine mammal monitoring;
- Construction activities occurring during each daily observation period including: (a) the number and types of piles driven and the method; and (b) total duration of driving time for each pile (vibratory driving) and number of strikes for each pile (impact driving);

- PSO locations during marine mammal monitoring;
- Environmental conditions during monitoring periods (at beginning and end of PSO shift and whenever conditions change significantly), including Beaufort sea state and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon, and estimated observable distance;
- For each observation of a marine mammal the following must be recorded: (a) Name of PSO who sighted the animal(s) and PSO location and activity at time of sighting; (b) time of sighting; (c) identification of the animal(s) (*e.g.* genus/species, lowest possible taxonomic level, or unidentified), PSO confidence in identification, and the composition of the group if there is a mix of species; (d) distance and location of each observed marine mammal relative to pile being driven or removed for each sighting; (e) estimated number of animals (min/max/best estimate); (f) estimated number of animals by cohort (adults, juveniles, neonates, group composition, *etc.*); (g) animal's closest point of approach and estimated time spent within the harassment zone; (h) description of any marine mammal behavioral observations (*e.g.* observed behaviors such as feeding or traveling), including an assessment of behavioral responses thought to have resulted from the activity (*e.g.* no response or changes in behavioral state such as ceasing feeding, changing direction, flushing, or breaching);
- Number of marine mammals detected within the harassment zones, by species; and,
- Detailed information about implementation of any mitigation (*e.g.* shutdowns and delays), a description of specific actions that ensued, and resulting changes in behavior of the animal(s), if any.

Reporting Injured or Dead Marine Mammals

In the event that personnel involved in the construction activities discover an injured or dead marine mammal, PG&E will report the incident to the Office of Protected Resources (OPR) (*PR.ITP.MonitoringReports@noaa.gov*), NMFS and to the West Coast regional stranding network (866–767–6114) as soon as feasible. If the death or injury was clearly caused by the specified activity, PG&E will immediately cease the specified activities until NMFS is able to review the circumstances of the incident and determine what, if any, additional measures are appropriate to ensure compliance with the terms of the IHAs. PG&E will not resume their activities until notified by NMFS. The report will include the following:

- Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and,
- General circumstances under which the animal was discovered.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.,* intensity, duration), the context of any impacts or responses (*e.g.,* critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, the discussion of our analysis applies to all the species listed in table 1, given that the anticipated effects of this activity on these different marine mammal stocks are expected to be similar. There is little information about the nature or severity of the impacts, or the size, status, or structure of any of these species or stocks that would lead to a different analysis for this activity.

Level A harassment is extremely unlikely given the small size of the Level A harassment isopleths and the required mitigation measures designed to minimize the possibility of injury to marine mammals. No serious injury or mortality is anticipated given the nature of the activity.

Pile driving activities have the potential to disturb or displace marine mammals. Specifically, the project activities may result in take, in the form of Level B harassment from underwater sounds generated from impact and vibratory pile driving activities. Potential takes could occur if individuals move into the ensonified zones when these activities are underway.

The takes by Level B harassment will be due to potential behavioral disturbances. The potential for harassment is minimized through construction methods and the implementation of planned mitigation strategies (see Mitigation section).

Behavioral responses of marine mammals to pile driving at the project site, if any, are expected to be mild and temporary. Marine mammals within the Level B harassment zone may not show any visual cues they are disturbed by activities or could become alert, avoid the area, leave the area, or display other mild responses that are not observable such as changes in vocalization patterns. Given the short duration of noise-generating activities per day and that pile driving and removal will occur over approximately 50 days during a span of 5 months, any harassment will be temporary. There are no other areas or times of known biological importance for any of the affected species.

Take will occur within a limited, confined area of each stock's range. Further, the amount of take authorized is extremely small when compared to stock abundance.

No marine mammal stocks for which incidental take authorization are listed as threatened or endangered under the ESA. Only one stock, the Eastern North Pacific Stock of the northern fur seal, is listed as depleted under the MMPA. However, we do not expect the authorizations in this action to affect the stock. No injury or mortality is authorized, take by Level B harassment is limited (five takes over the duration of the project), and the action should have no effect on the reproduction of this species. In addition, the five authorized takes for the northern fur seal include both the depleted Eastern

North Pacific Stock and the California stock, which is not depleted.

The relatively low marine mammal occurrences in the area, shutdown zones, and planned monitoring make injury takes of marine mammals unlikely. The shutdown zones will be thoroughly monitored before the pile driving activities begin, and activities will be postponed if a marine mammal is sighted within the shutdown zone. There is a high likelihood that marine mammals will be detected by trained observers under environmental conditions described for the project. Limiting construction activities to daylight hours will also increase detectability of marine mammals in the area. Therefore, the mitigation and monitoring measures are expected to eliminate the potential for injury and Level A harassment as well as reduce the amount and intensity of Level B behavioral harassment. Furthermore, the pile driving activities analyzed here are similar to, or less impactful than, numerous construction activities conducted in other similar locations which have occurred with no reported injuries or mortality to marine mammals, and no known long-term adverse consequences from behavioral harassment.

The project is not expected to have significant adverse effects on marine mammal habitat. There are no known Biologically Important Areas (BIAs) or ESA-designated critical habitat within the project area, and the activities will not permanently modify existing marine mammal habitat.

In summary and as described above, the following factors primarily support our determination that the impacts resulting from this activity are not expected to adversely affect any of the species or stocks through effects on annual rates of recruitment or survival:

- No serious injury, mortality, or Level A harassment is anticipated or authorized;
- The specified activities and associated ensonified areas are very small relative to the overall habitat ranges of all species;
- The project area does not overlap known BIAs or ESA-designated critical habitat;
- The lack of anticipated significant or long-term effects or marine mammal habitat; and,
- The presumed efficacy of the mitigation measures in reducing the effects of the specified activity.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the monitoring and mitigation measures, NMFS finds that the total marine mammal take from the activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted previously, only take of small numbers of marine mammals may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

The amount of take NMFS has authorized is below one-third of the estimated stock abundances for stocks (See table 7). These are all likely conservative estimates because they assume all takes are of different individual animals which is likely not the case. Some individuals may return multiple times in a day, but PSOs will count them as separate takes if they cannot be individually identified.

Based on the analysis contained herein of the activity (including the mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks will not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species.

No incidental take of ESA-listed species is authorized or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our action (*i.e.,* the issuance of an IHA) and alternatives with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NAO 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has determined that the issuance of this IHA qualifies to be categorically excluded from further NEPA review.

Authorization

NMFS has issued an IHA to PG&E for the potential harassment of small numbers of seven marine mammal species incidental to the sediment remediation project in San Francisco Bay, that includes the previously explained mitigation, monitoring, and reporting requirements.

Dated: January 25, 2024.

Catherine G. Marzin,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2024–01790 Filed 1–29–24; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities Under OMB Review

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995

(PRA), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Information and Regulatory Affairs (OIRA), of the Office of Management and Budget (OMB), for review and comment. The ICR describes the nature of the information collection and its expected costs and burden.

DATES: Comments must be submitted on or before before February 29, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be submitted within 30 days of this notice's publication to OIRA, at *https://www.reginfo.gov/public/do/PRAMain.* Please find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the website's search function. Comments can be entered electronically by clicking on the ''comment'' button next to the information collection on the ''OIRA Information Collections Under Review'' page, or the ''View ICR—Agency Submission'' page. A copy of the supporting statement for the collection of information discussed herein may be obtained by visiting *https://www.reginfo.gov/public/do/PRAMain.*

In addition to the submission of comments to *https://Reginfo.gov* as indicated above, a copy of all comments submitted to OIRA may also be submitted to the Commodity Futures Trading Commission (the ''Commission'' or ''CFTC'') by clicking on the ''Submit Comment'' box next to the descriptive entry for OMB Control No. 3038–0015, at *https://comments.cftc.gov/FederalRegister/PublicInfo.aspx.*

Or by either of the following methods:

- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail above.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments submitted to the Commission should include only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[1] The Commission reserves the right, but shall have no obligation, to review, prescreen, filter, redact, refuse or remove any or all of your submission from *https://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the ICR will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Carrie Kennedy, Division of Enforcement, U.S. Commodity Futures Trading Commission, 290 Broadway, New York, NY 10007; (646) 746–9780; email: *ckennedy@cftc.gov* and refer to OMB Control No. 3038–0015.

SUPPLEMENTARY INFORMATION:

Title: ''Copies of Crop and Market Information Reports,'' OMB Control No. 3038–0015. This is a request for an extension of a currently approved information collection.

Abstract: The information collected pursuant to this rule, 17 CFR 1.40, is in the public interest and is necessary for market surveillance. Manipulation of commodity futures prices is a violation of the Commodity Exchange Act (Act). Section 9(a)(2) of the Act (7 U.S.C. 13(a)(2)) prohibits the dissemination of false or misleading or knowingly inaccurate reports that affect or tend to affect the prices of commodities. In order to facilitate the enforcement of this provision, Commission regulation 1.40 requires that members of an exchange and FCMs provide upon request copies of any report published or given general circulation which concerns crop or market information that affects or tends to affect the price of any commodity.

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.[2] On November 20, 2023, the Commission published in the **Federal Register** notice of the proposed extension of this information collection and provided 60 days for public comment on the proposed extension, 88 FR 80696 (''60-Day Notice''). The Commission did not receive any comments on the 60-Day Notice.

Burden Statement: The respondents' burden for this collection is estimated to be as follows:

Estimated Number of Respondents: 10.

Estimated Average Burden Hours per Respondent: 0.17.

Estimated Total Annual Burden Hours: 1.7 hours.[3]

Frequency of Collection: On occasion.

There are no capital costs or operating and maintenance costs associated with this collection.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: January 24, 2024.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2024–01745 Filed 1–29–24; 8:45 am]

BILLING CODE 6351–01–P

[1] 17 CFR 145.9.

[2] 44 U.S.C. 3512, 5 CFR 1320.5(b)(2)(i) and 1320.8(b)(3)(vi). *See also* 46 FR 63035 (Dec. 30, 1981).

[3] The estimated total annual burden hours remain unchanged from the 2018 and 2021 renewals.

COUNCIL OF THE INSPECTORS GENERAL ON INTEGRITY AND EFFICIENCY

Senior Executive Service Performance Review Board Membership

AGENCY: Council of the Inspectors General on Integrity and Efficiency.

ACTION: Notice.

DATES: Applicable October 1, 2023.

FOR FURTHER INFORMATION CONTACT: Doug Holt, CIGIE Executive Director, (202) 292–2600. Individual Offices of Inspectors General at the telephone numbers listed below.

SUPPLEMENTARY INFORMATION:

I. Background:

The Inspector General Act of 1978, as amended, created the Offices of Inspectors General as independent and objective units to conduct and supervise audits and investigations relating to Federal programs and operations. The Inspector General Reform Act of 2008 established the Council of the Inspectors General on Integrity and Efficiency (CIGIE) to address integrity, economy, and effectiveness issues that transcend individual Government agencies; and increase the professionalism and effectiveness of personnel by developing policies, standards, and approaches to aid in the establishment of a well-trained and highly skilled workforce in the Offices of Inspectors General. CIGIE is an interagency council whose executive chair is the Deputy Director for Management, Office of Management and Budget, and is comprised principally of the 75 Inspectors General (IGs).

II. CIGIE Performance Review Board

Under 5 U.S.C. 4314(c)(1)–(5), and in accordance with regulations prescribed

by the Office of Personnel Management, each agency is required to establish one or more Senior Executive Service (SES) performance review boards. The purpose of these boards is to review and evaluate the initial appraisal of a senior executive's performance by the supervisor, along with any recommendations to the appointing authority relative to the performance of the senior executive. The current members of the Council of the Inspectors General on Integrity and Efficiency Performance Review Board, as of October 1, 2023, are as follows:

Agency for International Development

Phone Number: (202) 712–1150

CIGIE Liaison—Nicole Angarella and Ashley Obando (202) 712–4630

- Nicole Angarella—Acting Deputy Inspector General, Performing the Duties of the Inspector General.
- Marc Meyer—Assistant Inspector General for Investigations.
- Alvin A. Brown—Deputy Assistant Inspector General for Audit.
- Toayoa Aldridge—Deputy Assistant Inspector General for Audit.
- Van Nguyen—Assistant Inspector General for Audit, Inspections and Evaluations.
- Ashley Obando—Acting Chief of Staff.
- Adam Kaplan—Acting General Counsel.

Department of Agriculture

Phone Number: (202) 720–8001

CIGIE Liaison—Angel N. Bethea (202) 720–8001

- Ann M. Coffey—Deputy Inspector General.
- Christy A. Slamowitz—Counsel to the Inspector General.
- Janet Sorensen—Assistant Inspector General for Audit.
- Steven H. Rickrode, Jr.—Deputy Assistant Inspector General for Audit.
- Yarisis Rivera Rojas—Deputy Assistant Inspector General for Audit.
- Nicole Gardner—Deputy Assistant Inspector General for Investigations.
- Mily Le—Assistant Inspector General for Management.

Department of Commerce

Phone Number: (202) 578–3324

CIGIE Liaison—Melina Avakian (202) 578–3324

- Roderick M. Anderson—Deputy Inspector General.
- Richard L. Bachman—Assistant Inspector General for Audit and Evaluation.
- E. Wade Green—Counsel to the Inspector General.
- Robert O. Johnston, Jr.—Chief of Staff.
- Scott M. Kieffer—Assistant Inspector General for Investigations.
- Frederick J. Meny—Assistant Inspector General for Audit & Evaluation.
- Arthur L. Scott, Jr.—Assistant Inspector General for Audit and Evaluation.
- Mark H. Zabarsky—Principle Assistant Inspector General for Audit and Evaluation.

Council of the Inspectors General on Integrity and Efficiency

Phone Number: (202) 292–2600

CIGIE Liaison—Denise Mangra (202) 292–2604

- Andrew Cannarsa—Executive Director.
- Douglas Holt—Executive Director CIGIE Training Institute.

Department of Defense

Phone Number: (703) 604–8324

CIGIE Liaison—Darcell E. Wilder (703) 699–7495

- Jaryd M. Bern—Assistant Inspector General for Legislative Affairs & Communications.
- David A. Core—Principal Deputy General Counsel.
- Leo J. FitzHarris IV—Deputy Inspector General for Misson Support
- Marguerite C. Garrison—Deputy Inspector General for Administrative Investigations.
- Carol N. Gorman—Assistant Inspector General for Readiness and Cyber Operations.
- Paul Hadjiyane—General Counsel.
- James R. Ives—Principal Deputy Director Defense Criminal Investigative Service.
- Carmen J. Malone—Assistant Inspector General for Acquisition, Contracting, and Sustainment.
- Brett A. Mansfield—Deputy Inspector General for Audit.
- Kelly P. Mayo—Deputy Inspector General for Investigations.
- Troy M. Meyer—Deputy Inspector General for Overseas Contingency Operations.
- Harris S. Quddos—Chief Information Officer.
- Michael J. Roark—Deputy Inspector General for Evaluations.
- Steven A. Stebbins—Principal Deputy Inspector General.
- Randolph R. Stone—Assistant Inspector General for Space, Intelligence, Engineering and Oversight.
- Richard B. Vasquez—Assistant Inspector General for Readiness and Global Operations.
- Lorin T. Venable—Assistant Inspector General for Financial Management and Reporting.
- David G. Yacobucci—Assistant Inspector General for Data Analytics.
- Willie L. Young—Principal Assistant Inspector General for Mission Support.

Department of Education

Phone Number: (202) 245–6900

CIGIE Liaison—Joy Stith (202) 245–6435

- Vacant—Deputy Inspector General.
- Bryon Gordon—Assistant Inspector General for Audit.
- Sean Dawson—Deputy Assistant Inspector General for Audit.
- Theresa Perolini—Deputy Assistant Inspector General for Audit Services.
- Robert Mancuso—Assistant Inspector General for Investigations.
- Jason Williams—Deputy Assistant Inspector General for Investigations.
- Kevin Young—Assistant Inspector General for Technology Services.
- Antonio Murray—Deputy Assistant Inspector General for Technology Services.
- Antigone Potamianos—Counsel to the Inspector General.

Department of Energy

Phone Number: (202) 586–4393

CIGIE Liaison—Ryan Cocolin (202) 586–8672

- Jennifer Quinones—Deputy Inspector General.
- Travis Farris—Chief Counsel to the Inspector General.
- Charles Sabatos—Assistant Inspector General for Management and Administration.
- Lewe Sessions—Assistant Inspector General for Investigations.
- Kenneth Dieffenbach—Deputy Inspector General for Investigations.
- Kshemendra Paul—Assistant Inspector General for Cyber Assessments and Data Analytics
- Todd Wisniewski—Deputy Assistant Inspector General for Cyber Assessments and Data Analytics
- Earl Omer—Assistant Inspector General for Audits.
- John McCoy II—Deputy Assistant Inspector General for Audits.
- Anthony Cruz—Assistant Inspector General for Inspections, Intelligence Oversight, and Special Projects.
- Debbie Thomas—Deputy Assistant Inspector General for Inspections, Intelligence Oversight, and Special Projects.
- Jonathan Black—Chief Advisor for Strategic Planning and Program Oversight.

Environmental Protection Agency

CIGIE Liaison—Jee Kim (202) 566–1429

- Kellie J. Walker—Chief of Staff.
- M. Benjamin May—Counsel of the Inspector General.
- Mary Katherine Trimble—Assistant Inspector General for Audit.
- Paul Bergstrand—Assistant Inspector General for Special Review and Evaluation.
- Jason Abend—Assistant Inspector General for Investigations.
- Michael Zola—Assistant Inspector General for Congressional and Public Affairs.
- Stephanie Wright—Chief Technology Officer.

Equal Employment Opportunity Commission

Phone Number: 1–800–849–4230

CIGIE Liaison—Joyce T. Willoughby (202) 921–3138

- Milton A. Mayo, Jr.—Inspector General.

Federal Labor Relations Authority

Phone Number: (202) 218–7744

CIGIE Liaison—Dana Rooney (202) 218–7744

- Dana Rooney—Inspector General.

Federal Maritime Commission

Phone Number: (202) 523–5863

CIGIE Liaison—Jon Hatfield (202) 523–5863

- Jon Hatfield—Inspector General.

Federal Trade Commission

Phone Number: (202) 326–2355

CIGIE Liaison—Andrew Katsaros (202) 326–2355

- Andrew Katsaros—Inspector General.

General Services Administration

Phone Number: (202) 501–0450

CIGIE Liaison—Sarah Breen (202) 273–7284

- Robert C. Erickson—Deputy Inspector General.
- Edward Martin—Counsel to the Inspector General.
- R. Nicholas Goco—Assistant Inspector General for Audits.
- Barbara Bouldin—Deputy Assistant Inspector General for Acquisition Program Audits.
- Brian Gibson—Deputy Assistant Inspector General for Real Property Audits.
- James E. Adams—Assistant Inspector General for Investigations.
- Jason Suffredini—Deputy Assistant Inspector General for Inspections.
- Patricia D. Sheehan—Assistant Inspector General for Inspections.
- Kristine Preece—Assistant Inspector General for Administration.

Department of Health and Human Services

Phone Number: (202) 619–3148

CIGIE Liaison—Steven Driscoll (202) 860–4777

- Juliet Hodgkins—Principal Deputy Inspector General.
- Megan Tinker—Chief of Staff.
- Robert Owens, Jr.—Deputy Inspector General for Management and Policy.
- Christian Schrank—Assistant Inspector General for Investigations.
- Adam Globerman—Assistant Inspector General for Investigations.
- Ann Maxwell—Deputy Inspector General for Evaluation and Inspections.
- Erin Bliss—Assistant Inspector General for Evaluation and Inspections.
- Robert DeConti—Chief Counsel to the Inspector General.
- Lisa Re—Assistant Inspector General for Legal Affairs.
- Amy Frontz—Deputy Inspector General for Audit Services.
- Tamara Lilly—Assistant Inspector General for Audit Services.
- Carla Lewis—Assistant Inspector General for Audit Services.
- John Hagg—Assistant Inspector General for Audit Services.

Department of Homeland Security

Phone Number: (202) 981–6000

CIGIE Liaison—Lyvette Wallace (202) 369–3675

- Maureen Duddy—Assistant Inspector General for Audits, Financial Acquisitions and Emerging Threats.
- Erika Lang—Assistant Inspector General for Inspections and Evaluations.

Department of Housing and Urban Development

Phone Number: (202) 708–0430

CIGIE Liaison—Fara Damelin (2020) 680–2088

- Charles Jones—Senior Advisor for External Affairs.
- Fara Damelin—Chief of Staff.
- Kilah White—Assistant Inspector General for Audit.
- Kimberly Randall—Deputy Assistant Inspector General for Audit.
- Ryan McGonagle—Deputy Assistant Inspector General for Audit.
- Sarah Sequeira—Deputy Assistant Inspector General for Audit.
- Kudawashe Ushe—Chief Information Officer.
- Maura Malone—Counsel to the Inspector General.
- Brian Pattison—Assistant Inspector General for Evaluation.
- Matthew Harris—Assistant Inspector General for Investigation
- Audra Dortch—Deputy Assistant Inspector General for Investigation.
- Stephen Begg—Deputy Inspector General.

International Development Finance Corporation

Phone Number: (202) 361–8609

CIGIE Liaison—Gladis Griffith (202) 977–5893

- Anthony Zakel—Inspector General (SL).
- Gladis Griffith—Deputy Inspector General & General Counsel (SL).
- Darrell Benjamin—Assistant Inspector General of Audits (SL).
- John Warren—Assistant Inspector General of Investigations (SL).

Department of the Interior

Phone Number: (202) 208–5635

CIGIE Liaison—Karen Edwards (202) 208–5635

- Caryl Brzymialkiewicz—Deputy Inspector General.
- Jill Baisinger—Chief of Staff.
- Matthew Elliott—Assistant Inspector General for Investigations.
- Edward ''Ted'' Baugh—Deputy Assistant Inspector General for Investigations.
- Justin Martell—General Counsel.
- Kathleeen Sedney—Assistant Inspector General for Audit.
- Nicole Miller—Deputy Inspector General for Audit.
- Jorge Christian—Assistant Inspector General for Management.
- Michael O'Rourke—Assistant Inspector General for Strategy, Data, and Innovation.

Department of Justice

Phone Number: (202) 514–3435

CIGIE Liaison—John Lavinsky (202) 514–3435

- William M. Blier—Deputy Inspector General.
- Jonathan M. Malis—General Counsel.
- Michael Sean O'Neill—Assistant Inspector General for Oversight and Review.
- Patricia A. Sumner—Deputy Assistant Inspector General for Oversight and Review.
- Jason R. Malmstrom—Assistant Inspector General for Audit.
- Carol S. Taraszka—Deputy Assistant Inspector General for Audit.

• Kevin M. Strung—Assistant Inspector General for Audit, Office of Data Analytics.
• Sarah E. Lake—Assistant Inspector General for Investigations.
• Sandra D. Barnes—Deputy Assistant Inspector General for Investigations
• Sanjay Arnold—Assistant Inspector General for Information Technology Division.
• Rene L. Lee—Assistant Inspector General for Evaluation and Inspections.
• Allison E. Russo—Deputy Assistant Inspector General Evaluation and Inspections.
• Mark L. Hayes—Assistant Inspector General for Management and Planning.
• Nancy L. House—Deputy Assistant Inspector General for Management and Planning.

Department of Labor

Phone Number: (202) 693–5100

CIGIE Liaison—Erin Zickafoose (202) 693–7062

• Luiz A. Santos—Deputy Inspector General.
• Delores ''Dee'' Thompson—Counsel to the Inspector General.
• Carolyn Ramona Hantz—Assistant Inspector General for Audit.
• Laura Nicolosi—Deputy Assistant Inspector General for Audit.
• Tawanda Holmes—Deputy Assistant Inspector General for Audit.
• Michael C. Mikulka—Assistant Inspector General for Investigations—Labor Racketeering and Fraud.
• Suzann K. Gallagher—Deputy Assistant Inspector General for Investigations—Labor Racketeering and Fraud.
• Christopher T. Cooper—Deputy Assistant Inspector General for Investigations—Labor Racketeering and Fraud.
• Tara A. Porter—Assistant Inspector General for Management and Policy.
• Claudette L. Fogg-Castillo—Deputy Assistant Inspector General for Management and Policy.
• Jessica Southwell—Chief Performance and Risk Management Officer.

National Aeronautics and Space Administration

Phone Number: (202) 358–1220

CIGIE Liaison—Renee Juhans (202) 358–1712

• George A. Scott—Deputy Inspector General
• Robert H. Steinau—Assistant Inspector General for Investigation.
• Frank LaRocca—Counsel to the Inspector General.
• Kimberly F. Benoit—Assistant Inspector General for Audits.
• Robert H. Steinau—(Acting) Assistant Inspector General for Management Planning

National Archives and Records Administration

Phone Number: (301) 837–3000

CIGIE Liaison—John Simms (301) 837–3000

• Brett Baker—Inspector General.

National Labor Relations Board

Phone Number: (202) 273–1960

CIGIE Liaison—Robert Brennan (202) 273–1960

• David P. Berry—Inspector General.

National Science Foundation

Phone Number: (703) 292–7100

CIGIE Liaison—Lisa Vonder Haar (703) 292–2989

• Megan Wallace—Assistant Inspector General for Investigations.
• Ken Chason—Counsel to the Inspector General.
• Javier E. Inclán—Assistant Inspector General for Management and CIO.

Nuclear Regulatory Commission

Phone Number: (301) 415–5930

CIGIE Liaison—Christine Arroyo (301) 415–0526

• Ziad Buhaissi—Deputy Inspector General.
• Malion Bartley—Assistant Inspector General for Investigations.
• Hruta Virkar—Assistant Inspector General for Audits.

Office of Personnel Management

Phone Number: (202) 606–1200

CIGIE Liaison—Faiza Mathon-Mathieu (202) 606–2236

• Krista A. Boyd—Inspector General.
• Norbert E. Vint—Deputy Inspector General.
• Michael R. Esser—Assistant Inspector General for Audits.
• Melissa D. Brown—Deputy Assistant Inspector General for Audits.
• Lewis F. Parker, Jr.—Deputy Assistant Inspector General for Audits.
• Drew M. Grimm—Assistant Inspector General for Investigations.
• Conrad Quarles—Deputy Assistant Inspector General for Investigations.
• Nicholas E. Hoyle—Assistant Inspector General for Management.
• Robin A. Thottungal—Deputy Assistant Inspector General for Management/Chief Information Technology Officer.
• Monyca W. Peyton—Deputy Assistant Inspector General for Management.
• Paul St. Hillaire—Assistant Inspector General for Legal and Legislative Affairs.
• Faiza Mathon-Mathieu—Deputy Assistant Inspector General for Legal and Legislative Affairs.

Special Inspector General for Pandemic Recovery

Phone Number: (202) 923–7782

CIGIE Liaison—Geoffrey A. Cherrington (202) 713–8437

• Barbara Bruin—Deputy Special Inspector General.
• Theodore R. Stehney—Assistant Inspector General for Audits.
• Erica M. Kavanagh—Assistant Inspector General for Administration.
• Geoffrey A. Cherrington—Assistant Inspector General for External Affairs.
• Christopher Cherry—Deputy Assistant Inspector General for Investigations.
• Jean Saint Elin—Deputy Assistant Inspector General for Audits.
• James A. Nussbaumer—Deputy Assistant Inspector General for Administration.
• David C. Woll, Jr.—Deputy General Counsel.
• Pamela Satterfield—Deputy General Counsel.

United States Postal Service

Phone Number: (703) 248–2100

CIGIE Liaison—Agapi Doulaveris (703) 248–2286

• Elizabeth Martin—Deputy Inspector General/Chief Diversity Officer.
• Julius Rothstein—Deputy Inspector General/Attorney.
• Robert Kwalwasser—Assistant Inspector General for Investigations.

Railroad Retirement Board

Phone Number: (312) 751–4690

CIGIE Liaison—Jill Roellig (312) 751–4993

• Patricia A. Marshall—Deputy Inspector General and Counsel to the Inspector General.

Small Business Administration

Phone Number: (202) 401–0753

CIGIE Liaison—Mary Kazarian (202) 205–6586

• Sheldon Shoemaker—Deputy Inspector General.
• Shafee Carnegie—Assistant Inspector General for Investigations.
• Andrea Deadwyler—Assistant Inspector General for Audits.

• Francine Hines—Assistant Inspector General for Management and Operations.

Social Security Administration

Phone Number: (410) 966–8385

CIGIE Liaison—Craig Meklir (443) 316–7922

• Michelle L.H. Anderson—Assistant Inspector General for Audit.
• Mike Arbuco—Chief Operating Officer.
• Jeffery Brown—Deputy Assistant Inspector General for Audit.
• B. Chad Bungard—Chief Strategy Officer.
• Mark Franco—Deputy Assistant Inspector General for Investigations.
• Joscelyn Funnié—Assistant Inspector General for Workforce Performance and Development.
• Kevin Huse—Deputy Assistant Inspector General for Investigations.
• Donald Jefferson—Assistant Inspector General for Investigations.
• Adriana Menchaca-Gendron—Assistant Inspector General for Resource Management.
• Michelle M. Murray—Chief Counsel to the Inspector General.
• Ted Planzos—Chief Investigative Counsel.
• Adam Schneider—Deputy Assistant Inspector General for Investigations.
• Mark Searight—Deputy Assistant Inspector General for Audit.

Special Inspector General for the Troubled Asset Relief Program

Phone Number: (202) 622–1419

CIGIE Liaison—Melissa Bruce (202) 617–4238

• Melissa Bruce—Principal Deputy Special Inspector General.
• Thomas Jankowski—Deputy Inspector General for Investigations.
• Sidney Rocke—General Counsel.

Department of State and the U.S. Agency for Global Media

Phone Number: (571) 348–3804

CIGIE Liaison—Mark Huffman (571) 348–4881

• Diana R. Shaw—Deputy Inspector General.
• Nicole Matthis—Acting Chief of Staff and Deputy Assistant Inspector General for Evaluations and Special Projects.
• Norman P. Brown—Assistant Inspector General for Audits.
• Sandra J. Lewis—Acting Deputy Inspector General for Internal Operations and Mission Support.
• Justin Brown (SL)—Senior Advisor to the Inspector General.
• Matthew Tuchow—General Counsel.
• Kevin S. Donohue—Deputy General Counsel.
• Gayle L. Voshell—Deputy Assistant Inspector General for Audits.
• Beverly J.C. O'Neill—Deputy Assistant Inspector General for Audits, Middle East Region Operations.
• Arne Baker—Acting Assistant Inspector General for Inspections.
• Lisa R. Rodely—Deputy Assistant Inspector General for Inspections.
• Robert J. Smolich—Assistant Inspector General for Investigations.
• Jason Loeffler—Deputy Assistant Inspector General for Investigations.
• Andrew Chiu—Assistant Inspector General for Administration/Director of the Office of the Executive Director.
• Jeffrey McDermott—Assistant Inspector General for Evaluations and Special Projects.
• Brian Sano (SL)—Director of Organizational Health.

Department of Transportation

Phone Number: (202) 366–1959

CIGIE Liaison—Nathan P. Richmond: (202) 493–0422

• Mitchell L. Behm—Deputy Inspector General.
• M. Elise Chawaga—Principal Assistant Inspector General for Investigations.
• Susan Ocampo—Deputy Assistant Inspector General for Investigations.
• Charles A. (Chuck) Ward—Principal Assistant Inspector General for Auditing and Evaluation.
• Tiffany Mostert—Assistant Inspector General for Audit Operations and Special Reviews.
• Nelda Z. Smith—Assistant Inspector General for Aviation Audits.
• Dory Dillard-Christian—Assistant Inspector General for Financial Audits.
• David Pouliott—Assistant Inspector General for Surface Transportation Audits.
• Carolyn Hicks—Assistant Inspector General for Acquisition and Procurement Audits.
• Kevin Dorsey—Assistant Inspector General for Information Technology Audits.
• Omer Poirier—Chief Counsel.
• Andrea Nossaman—Assistant Inspector General for Strategic Communications and Programs.

Department of the Treasury

Phone Number: (202) 622–1090

CIGIE Liaison—Rich Delmar (202) 927–3973

• Richard K. Delmar—Deputy Inspector General.
• Jeffrey Lawrence—Assistant Inspector General for Management.
• Sally Luttrell—Assistant Inspector General for Investigations.
• Sean McDowell—Deputy Assistant Inspector General for Investigations.
• Deborah L. Harker—Assistant Inspector General for Audit.
• Pauletta Battle—Deputy Assistant Inspector General for Financial Management & Transparency Audit.
• Susan Barron—Deputy Assistant Inspector General for Financial Sector Audits.
• Marla Freedman—Executive Advisor for Audit.
• Robert Taylor, Jr.—Executive Advisor for Audit.
• Lisa DeAngelis—Deputy Assistant Inspector General for Coronavirus Relief Fund & Air Carriers Audit (Limited Term SES).

Treasury Inspector General for Tax Administration/Department of the Treasury

Phone Number: (202) 622–6500

CIGIE Liaison—LaToya George (404) 831–8075

• Gladys Hernandez—Chief Counsel.
• Lori Creswell—Deputy Chief Counsel.
• Mervin Hyndman—Deputy Inspector General for Mission Support/Chief Financial Officer.
• Richard Varn II—Chief Information Officer.
• Trevor Nelson—Acting Deputy Inspector General for Investigations.
• Heather Hill—Deputy Inspector General for Inspections and Evaluations.
• Nancy LaManna—Assistant Inspector General for Audit, Management, Planning, and Workforce Development.
• Diana Tengesdal—Assistant Inspector General for Audit, Returns Processing and Account Services.
• Bryce Kisler—Assistant Inspector General for Audit, Management Services and Exempt Organizations.
• Russell Martin—Assistant Inspector General for Audit, Returns Processing, and Accounting Services.
• Danny Verneuille—Assistant Inspector General for Audit, Security, and Information Technology Services.
• Matthew Weir—Assistant Inspector General for Audit, Compliance, and Enforcement Operations.
• Edward Currie—Acting Assistant Inspector General for Investigations—Special Investigations and Support Directorate.
• Dale Forrester—Assistant Inspector General for Investigations—Strategic Enforcement Directorate.

• Derek Anderson—Deputy Assistant Inspector General for Investigations—Field Operations.
• John Kirk—Assistant Inspector General for Investigations—Wester Field Region.

Department of Veterans Affairs

Phone Number: (202) 461–4603

CIGIE Liaison—Brady Beckham (202) 264–9376

• David Case—Deputy Inspector General.
• John D. Daigh—Assistant Inspector General for Healthcare Inspections.
• Michael Goduti—Deputy Assistant Inspector General for Management and Administration.
• David Johnson—Assistant Inspector General for Investigations.
• Julie Kroviak—Principal Deputy Assistant Inspector General for Healthcare Inspections.
• Brent Penny—Assistant Inspector General for Management and Administration.
• Larry Reinkemeyer—Assistant Inspector General for Audits and Evaluations.
• Gopala Seelamneni—Deputy Assistant Inspector General for Management and Administration/Chief Technology.
• Chris Wilber—Counselor to the Inspector General.

Douglas Holt,

Executive Director, Training Institute, Council of the Inspectors General on Integrity and Efficiency

[FR Doc. 2024–01763 Filed 1–29–24; 8:45 am]

BILLING CODE 6820–C9–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Oak Ridge

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces an in-person/virtual hybrid meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Oak Ridge. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, March 13, 2024; 6 p.m.–8 p.m. ET

ADDRESSES: This hybrid meeting will be in-person at the Department of Energy (DOE) Information Center (address below) and virtually via Zoom. To attend virtually or to register for in-person attendance, please send an email to: *orssab@orem.doe.gov* by 5 p.m. ET on Wednesday, March 6, 2024.

DOE Information Center, Office of Science and Technical Information, 1 Science.gov Way, Oak Ridge, Tennessee 37831.

FOR FURTHER INFORMATION CONTACT: Melyssa P. Noe, Deputy Designated Federal Officer, U.S. Department of Energy, Oak Ridge Office of Environmental Management (OREM), P.O. Box 2001, EM–942, Oak Ridge, TN 37831; Phone (865) 241–3315; or E-Mail: *Melyssa.Noe@orem.doe.gov.* Or visit the website at *www.energy.gov/orssab.*

SUPPLEMENTARY INFORMATION: *Purpose of the Board:* The purpose of the Board is to provide advice and recommendations concerning the following EM site-specific issues: clean-up activities and environmental restoration; waste and nuclear materials management and disposition; excess facilities; future land use and long-term stewardship. The Board may also be asked to provide advice and recommendations on any EM program components.

Tentative Agenda:

• OREM Presentation
• Discussion
• Public Comment Period
• Board Business

Public Participation: This meeting is open to the public. The EM SSAB, Oak Ridge, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Melyssa P. Noe at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed with the Board via email either before or after the meeting. Public comments received by no later than 5:00 p.m. ET on Wednesday, March 6, 2024, will be read aloud during the meeting.

Comments will be accepted after the meeting, by no later than 5:00 p.m. ET on Monday, March 18, 2024. Please submit comments to *orssab@orem.doe.gov.* Please put ''Public Comment'' in the subject line. Individuals who wish to make oral statements should contact Melyssa P. Noe at the email address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to submit written public comments should email them as directed above. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by emailing or calling Melyssa P. Noe at the email address and telephone number listed above. Minutes will also be available at the following website: *https://www.energy.gov/orem/listings/oak-ridge-site-specific-advisory-board-meetings.*

Signing Authority: This document of the Department of Energy was signed on January 25, 2024, by David Borak, Deputy Committee Management Officer, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on January 25, 2024.

Treena V. Garrett,

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

[FR Doc. 2024–01809 Filed 1–29–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Idaho Cleanup Project

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces an in-person/virtual hybrid meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Idaho Cleanup Project (ICP). The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Thursday, February 22, 2024; 9 a.m.–12:45 p.m. MST.

An opportunity for public comment will be at 11:30 a.m. MST.

These times are subject to change; please contact the ICP Citizens Advisory Board (CAB) Administrator (below) for confirmation of times prior to the meeting.

ADDRESSES: This meeting will be open to the public in-person at the Residence Inn (address below) or virtually via Zoom. To attend virtually, please contact Mariah Porter, ICP CAB Administrator, by email *mariah.porter@em.doe.gov* or phone (208) 557–7857, no later than 5:00 p.m. MST on Tuesday, February 20, 2024.

Board members, Department of Energy (DOE) representatives, agency liaisons, and Board support staff will participate in-person at: Residence Inn, 635 West Broadway Street, Idaho Falls, ID 83404.

FOR FURTHER INFORMATION CONTACT: Mariah Porter, ICP CAB Administrator, by phone (208) 557–7857 or email *mariah.porter@em.doe.gov* or visit the Board's internet homepage at *https://energy.gov/em/icpcab.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to provide advice and recommendations concerning the following EM site-specific issues: clean-up activities and environmental restoration; waste and nuclear materials management and disposition; excess facilities; future land use and long-term stewardship. The Board may also be asked to provide advice and recommendations on any EM program components.

Tentative Agenda (agenda topics may change up to the day of the meeting; please contact Mariah Porter for the most current agenda):

1. Recent Public Outreach
2. ICP Overview
3. Program Presentation
4. Budget Update on Fiscal Year 2024 Appropriation and Fiscal Year 2026 Budget Priorities
5. Federal Advisory Committee Act Discussion
6. Program Presentation

Public Participation: The in-person/online virtual hybrid meeting is open to the public either in-person at the Residence Inn or via Zoom. To sign-up for public comment, please contact the ICP CAB Administrator (above) no later than 5 p.m. MST on Tuesday, February 20, 2024. In addition to participation in the live public comment sessions identified above, written statements may be filed with the Board either five days before or five days after the meeting by sending them to the ICP CAB Administrator at the aforementioned email address. Written public comment received prior to the meeting will be read into the record. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Mariah Porter, ICP CAB Administrator, phone (208) 557–7857 or email *mariah.porter@em.doe.gov.* Minutes will also be available at the following website: *https://www.energy.gov/em/icpcab/listings/cab-meetings.*

Signing Authority: This document of the Department of Energy was signed on January 24, 2024, by David Borak, Deputy Committee Management Officer, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on January 25, 2024.

Treena V. Garrett,

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

[FR Doc. 2024–01769 Filed 1–29–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER24–966–000]

Eleven Mile Solar Center, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Eleven Mile Solar Center, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is February 12, 2024.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and

assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: January 23, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–01732 Filed 1–29–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15307–000]

Premium Energy Holdings, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Application

On March 17, 2023, Premium Energy Holdings, LLC, filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the to be located 10 miles south of the of the unincorporated community of Olancha in Inyo County, California. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would be a closed-loop pumped storage hydropower facility. The applicant proposes three alternative upper reservoirs: McCloud Reservoir, Little Cactus Reservoir, or Haiwee Canyon Reservoir. The proposed North Haiwee 2 Reservoir would be the lower reservoir for each alternative.

Upper Reservoir Alternative 1: McCloud Reservoir

The McCloud Reservoir alternative consists of: (1) a 504-acre upper reservoir having a total storage capacity of 44,554 acre-feet at a normal maximum operating elevation of 5,260 feet mean sea level (msl); (2) a 175-foot-high, 3,068-foot-long roller compacted concrete upper reservoir dam; (3) a 2.41-mile-long, 39-foot-diameter concrete-lined headrace tunnel; (4) a 0.2-mile-long, 35-foot-diameter concrete-lined vertical shaft; (5) a 5.6-mile-long, 35-foot-diameter concrete-lined horizontal tunnel; (6) six 0.78-mile-long, 22-foot-diameter steel penstocks; (7) a 585-foot-long, 90-foot-wide, 165-foot-high concrete-lined powerhouse located in an underground cavern, housing five pump-turbine generator-motor units rated for 400 megawatts (MW) each; and (8) a 0.68-mile-long, 42-foot-diameter concrete-lined tailrace tunnel discharging into the proposed North Haiwee 2 Reservoir.

Upper Reservoir Alternative 2: Little Cactus Reservoir

The Little Cactus Reservoir alternative consists of: (1) a 499-acre upper reservoir having a total storage capacity of 47,021 acre-feet at a normal maximum operating elevation of 4,980 feet msl; (2) a 235-foot-high, 2,836-foot-long roller compacted concrete upper reservoir dam; (3) a 1.06-mile-long, 39-foot-diameter concrete-lined headrace tunnel; (4) a 0.16-mile-long, 35-foot-diameter concrete-lined vertical shaft; (5) a 4-mile-long, 35-foot-diameter concrete-lined horizontal tunnel; (6) six 0.7-mile-long, 22-foot-diameter steel penstocks; (7) a 585-foot-long, 90-foot-wide, 165-foot-high concrete-lined powerhouse located in an underground cavern, housing five pump-turbine generator-motor units rated for 400 MW each; and (8) a 0.78-mile-long, 42-foot-diameter concrete-lined tailrace tunnel discharging into the proposed North Haiwee 2 Reservoir.

Upper Reservoir Alternative 3: Haiwee Canyon Reservoir

The Haiwee Canyon Reservoir alternative consists of: (1) a 138-acre upper reservoir having a total storage capacity of 28,620 acre-feet at a normal maximum operating elevation of 6,160 feet msl; (2) a 595-foot-high, 2,256-foot-long roller compacted concrete upper reservoir dam; (3) a 1.64-mile-long, 31-foot-diameter concrete-lined headrace tunnel; (4) a 0.32-mile-long, 28-foot-diameter concrete-lined vertical shaft; (5) a 5.2-mile-long, 28-foot-diameter concrete-lined horizontal tunnel; (6) six 0.54-mile-long, 18-foot-diameter steel penstocks; (7) a 585-foot-long, 90-foot-wide, 165-foot-high concrete-lined powerhouse located in an underground cavern, housing five pump-turbine generator-motor units rated for 400 MW each; and (8) a 0.8-mile-long, 33-foot-diameter concrete-lined tailrace tunnel discharging into the proposed North Haiwee 2 Reservoir.

Lower Reservoir: North Haiwee 2 Reservoir

The proposed North Haiwee 2 Reservoir would consist of: (1) a 320-acre lower reservoir having a total storage capacity 38,350 acre-feet at a normal maximum operating elevation of 3,770 feet msl; and (2) a 160-foot-high, 7,090-foot-long roller compacted concrete lower reservoir dam.

Interconnection

For each upper reservoir alternative, project power would be transmitted to the grid via: (1) a new, 2.5-mile-long, 500 kilovolt (kV) underground transmission line extending from the powerhouse to the proposed North Haiwee switchyard (the point of interconnection); and (2) appurtenant facilities. The estimated annual generation of the Haiwee Project under each of the alternatives would be 6,900 gigawatt-hours.

Applicant Contact: Mr. Victor Rojas, Premium Energy Holdings, LLC, 355 South Lemon Ave., Suite A, Walnut, CA 91789; *victor.rojas@pehllc.net;* phone: (909) 595–5314.

FERC Contact: Everard Baker; email: *everard.baker@ferc.gov;* phone: (202) 502–8554.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members, and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.* Comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications should be submitted within 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne Reese, Acting Secretary Federal Energy

Regulatory Commission, 888 First Street NE, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–15307–000.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's website at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–15307) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: January 23, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–01730 Filed 1–29–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Institution of Section 206 Proceedings and Refund Effective Date

	Docket Nos.
Calpine Bethlehem LLC	EL24–28–000
Calpine Mid-Atlantic Generation, LLC.	EL24–29–000
Calpine Mid Merit, LLC	EL24–30–000
Calpine Mid-Merit II, LLC	EL24–31–000
Calpine New Jersey Generation, LLC.	EL24–32–000
Zion Energy LLC	EL24–33–000

On January 22, 2024, the Commission issued an order in Docket Nos. EL24–28–000, EL24–29–000, EL24–30–000, EL24–31–000, EL24–32–000, and EL24–33–000 pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e, instituting an investigation to determine whether the revenue requirements set forth in Calpine Reactive Suppliers' [1] Rate Schedules are unjust, unreasonable, unduly discriminatory or preferential, or otherwise unlawful. *Calpine Bethlehem LLC,* 186 FERC ¶ 61,061 (2024).

The refund effective date in Docket Nos. EL24–28–000, EL24–29–000, EL24–30–000, EL24–31–000, EL24–32–000, and EL24–33–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

[1] Calpine Reactive Suppliers include: Calpine Bethlehem, LLC; Calpine Mid-Atlantic Generation, LLC; Calpine Mid Merit, LLC; Calpine Mid-Merit II, LLC; Calpine New Jersey Generation, LLC; and Zion Energy LLC.

Any interested person desiring to be heard in Docket Nos. EL24–28–000, EL24–29–000, EL24–30–000, EL24–31–000, EL24–32–000, and EL24–33–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214 (2022), within 21 days of the date of issuance of the order.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field. User assistance is available for eLibrary and the FERC's website during normal business hours from FERC Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFile'' link at *http://www.ferc.gov.* In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: January 23, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–01733 Filed 1–29–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC24–44–000.

Applicants: Blackwater Solar, LLC, Wolfskin Solar, LLC, Bird Dog Solar, LLC, Hobnail Solar, LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Blackwater Solar, LLC, et al.

Filed Date: 1/19/24.

Accession Number: 20240119–5284.

Comment Date: 5 p.m. ET 2/9/24.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG24–92–000.

Applicants: Wadley Solar, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Wadley Solar, LLC.

Filed Date: 1/23/24.

Accession Number: 20240123–5054.

Comment Date: 5 p.m. ET 2/13/24.

Docket Numbers: EG24–93–000.

Applicants: AE-Telview ESS, LLC.

Description: AE-Telview ESS, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 1/23/24.

Accession Number: 20240123–5114.

Comment Date: 5 p.m. ET 2/13/24.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL24–54–000.

Applicants: Karen Schedler, Jeremy Helms, and Vote Solar.

Description: First Amended Petition for Enforcement Pursuant to (Section 210(H) of the Public Utility Regulatory Policies Act of 1978 or applicable Policy) of Solar United Neighbors.

Filed Date: 1/22/24.

Accession Number: 20240122–5099.

Comment Date: 5 p.m. ET 2/12/24.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1276–018; ER10–1287–017; ER10–1292–016; ER10–1303–016; ER10–1319–018; ER10–1353–018; ER18–1183–009; ER18–1184–009; ER23–1411–003.

Applicants: Newport Solar LLC, Delta Solar Power II, LLC, Delta Solar Power I, LLC, Dearborn Industrial Generation, L.L.C., CMS Generation Michigan Power, LLC, Genesee Power Station Limited Partnership, CMS Energy Resource Management Company, Grayling Generation Station Limited Partnership, Consumers Energy Company.

Description: Notice of Change in Status of Consumers Energy Company, et al.

Filed Date: 1/22/24.

Accession Number: 20240122–5262.

Comment Date: 5 p.m. ET 2/12/24.

Docket Numbers: ER12–2178–018; ER10–2178–043; ER10–2192–043; ER13–1536–027.

Applicants: Exelon Generation Company, LLC, Constellation Energy Commodities Group Maine, LLC, Constellation NewEnergy, Inc., AV Solar Ranch 1, LLC.

Description: Notice of Change in Status of AV Solar Ranch 1, LLC, et al.

Filed Date: 1/19/24.

Accession Number: 20240119–5283.

Comment Date: 5 p.m. ET 2/9/24.

Docket Numbers: ER17–1609–007.

Applicants: Carroll County Energy LLC.

Description: Notice of Change in Status of Carroll County Energy LLC.

Filed Date: 1/19/24.

Accession Number: 20240119–5282.

Comment Date: 5 p.m. ET 2/9/24.

Docket Numbers: ER22–2931–000; EL24–26–000.

Applicants: PJM Interconnection, L.L.C., PJM Interconnection, L.L.C.

Description: Answer of PJM Interconnection, L.L.C. to the December 20, 2023, Show Cause Order and Motion to Hold Proceedings in Abeyance and for Expedited Consideration and Shortened Comment Period.

Filed Date: 1/19/24.

Accession Number: 20240119–5185.

Comment Date: 5 p.m. ET 1/26/24.

Docket Numbers: ER23–1123–003.

Applicants: Portland General Electric Company.

Description: Compliance filing: Amend Compliance Filing Revising PGE OATT Attachment P JAN24 to be effective 4/16/2023.

Filed Date: 1/23/24.

Accession Number: 20240123–5068.

Comment Date: 5 p.m. ET 2/13/24.

Docket Numbers: ER23–1816–003.

Applicants: New York Independent System Operator, Inc., New York State Electric & Gas Corporation.

Description: Compliance filing: New York State Electric & Gas Corporation submits tariff filing per 35: NYSEG Compliance: Rate Schedule 19 Formula Rate Template to be effective 7/3/2023.

Filed Date: 1/23/24.

Accession Number: 20240123–5075.

Comment Date: 5 p.m. ET 2/13/24.

Docket Numbers: ER23–1817–003.

Applicants: New York Independent System Operator, Inc., New York State Electric & Gas Corporation, Rochester Gas and Electric Corporation.

Description: Compliance filing: Rochester Gas and Electric Corporation submits tariff filing per 35: RG&E Compliance: Rate Schedule 19 Formula Rate Template to be effective 7/3/2023.

Filed Date: 1/23/24.

Accession Number: 20240123–5069.

Comment Date: 5 p.m. ET 2/13/24.

Docket Numbers: ER23–2541–002.

Applicants: Nevada Cogeneration Associates #2.

Description: Tariff Amendment: Deficiency Ltr2 Resp to be effective 10/1/2023.

Filed Date: 1/22/24.

Accession Number: 20240122–5225.

Comment Date: 5 p.m. ET 2/12/24.

Docket Numbers: ER24–561–000.

Applicants: VESI 23 LLC.

Description: Supplement to December 6, 2023 VESI 23 LLC tariff filing.

Filed Date: 1/17/24.

Accession Number: 20240117–5196.

Comment Date: 5 p.m. ET 1/29/24.

Docket Numbers: ER24–973–000.

Applicants: Evergy Kansas Central, Inc.

Description: § 205(d) Rate Filing: Revisions to Rate Schedule FERC No. 327 to be effective 4/1/2023.

Filed Date: 1/23/24.

Accession Number: 20240123–5042.

Comment Date: 5 p.m. ET 2/13/24.

Docket Numbers: ER24–974–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2024–01–23_SA 4083 Duke Energy-Emerald Green 1st Rev GIA (J1481) to be effective 1/12/2024.

Filed Date: 1/23/24.

Accession Number: 20240123–5043.

Comment Date: 5 p.m. ET 2/13/24.

Docket Numbers: ER24–975–000.

Applicants: MS Solar 6, LLC.

Description: Compliance filing: MS Solar 6, LLC Change in Status Filing to be effective 3/24/2024.

Filed Date: 1/23/24.

Accession Number: 20240123–5087.

Comment Date: 5 p.m. ET 2/13/24.

Docket Numbers: ER24–976–000.

Applicants: Prairie Creek Wind, LLC.

Description: Request for Limited Waiver of Prairie Creek Wind, LLC.

Filed Date: 1/18/24.

Accession Number: 20240118–5229.

Comment Date: 5 p.m. ET 2/8/24.

Docket Numbers: ER24–977–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to WMPA, SA No. 6980; Queue No. AF2–060 (amend) to be effective 3/24/2024.

Filed Date: 1/23/24.

Accession Number: 20240123–5097.

Comment Date: 5 p.m. ET 2/13/24.

Take notice that the Commission received the following public utility holding company filings:

Docket Numbers: PH24–5–000.

Applicants: Axium Infrastructure Inc.

Description: Axium Infrastructure Inc. submits FERC 65–B Notice of Change in Fact to Waiver Notification.

Filed Date: 1/22/24.

Accession Number: 20240122–5264.

Comment Date: 5 p.m. ET 2/12/24.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: January 23, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–01735 Filed 1–29–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: PR24–42–000.
Applicants: Rocky Mountain Natural Gas LLC.
Description: § 284.123 Rate Filing: RMNG Revised SOC Filing to be effective 1/1/2024.
Filed Date: 1/23/24.
Accession Number: 20240123–5022.
Comment Date: 5 p.m. ET 2/13/24.
Docket Numbers: RP24–332–000.
Applicants: Golden Triangle Storage, LLC.
Description: Compliance filing: Compliance Notice of Non-Material Change to be effective N/A.
Filed Date: 1/22/24.
Accession Number: 20240122–5136.
Comment Date: 5 p.m. ET 2/5/24.
Docket Numbers: RP24–333–000.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: § 4(d) Rate Filing: Implementation of Period 1 Settlement Rates on an Interim Basis to be effective 1/1/2024.
Filed Date: 1/23/24.
Accession Number: 20240123–5038.
Comment Date: 5 p.m. ET 2/5/24.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: January 23, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–01734 Filed 1–29–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2452–236]

Consumers Energy Company; Notice of Intent To Prepare an Environmental Assessment

On September 2, 2022, and supplemented on November 8, 2022, March 17, 2023, and August 8, 2023, Consumers Energy Company (licensee), licensee for the Hardy Hydroelectric Project No. 2452 (project) filed an application for a non-capacity license amendment. The project is located on the Muskegon River in Newago and Mecosta counties, Michigan and does not occupy federal lands.

In collaboration with the Commission's Division of Dam Safety and Inspections, the licensee proposes to construct several modifications to the auxiliary spillway to increase its capacity and repair and upgrade the spillway discharge channel to improve stability and safety. In addition to the auxiliary spillway modifications, the licensee proposes to upgrade the dam crest to improve transportation infrastructure by replacing and widening the road on the dam crest, which would also require replacement of the access bridge to the intake tower and replacement of the existing splash wall. A Notice of Application Accepted for Filing and Soliciting Comments, Motions to Intervene, and Protest was issued on October 12, 2022. No comments were received.

This notice identifies Commission staff's intention to prepare an environmental assessment (EA) for the proposed action. The planned schedule for the completion of the EA is March 2024.[1] Revisions to the schedule may be made as appropriate. The EA will be issued and made available for review by all interested parties. All comments filed on the EA will be reviewed by staff and considered in the Commission's final decision on the proceeding.

With this notice, the Commission is inviting federal, state, local, and Tribal agencies with jurisdiction and/or special expertise with respect to environmental issues affected by the proposal to cooperate in the preparation of the EA planned to be issued March 2024. Agencies wishing to cooperate, or further discuss the benefits, responsibilities, and obligations of the cooperating agency role, should contact staff listed at the bottom of this notice by February 13, 2024. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of any environmental document cannot also intervene. *See* 94 FERC ¶ 61,076 (2001).

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members, and others to access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Any questions regarding this notice may be directed to David Rudisail at 202–502–6376 or *David.rudisail@ferc.gov.*

Dated: January 23, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–01731 Filed 1–29–24; 8:45 am]

BILLING CODE 6717–01–P

[1] 42 U.S.C. 4336a(g)(1)(B) requires lead federal agencies to complete EAs within 1 year of the agency's decision to prepare an EA.

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2013–0691; FRL–11707]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Implementation of the Fine Particulate Matter ($PM_{2.5}$) National Ambient Air Quality Standards (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an

information collection request (ICR), Implementation of the Fine Particulate Matter ($PM_{2.5}$) National Ambient Air Quality Standards (EPA ICR Number 2258.06; OMB Control Number 2060–0611) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through January 31, 2024. Public comments were previously requested via the **Federal Register** on August 15, 2023, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before February 29, 2024.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2013–069, to EPA online using *www.regulations.gov* (our preferred method), by email to *a-and-r-docket@epa.gov* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Ms. Leigh Herrington, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mailcode C539–01, Post Office Box 12055, Research Triangle Park, NC 27711; telephone number: (919) 541–0882; fax number: (919) 541–2225; email address: *herrington.leigh@epa.gov.*

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through January 31, 2024. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Public comments were previously requested via the **Federal Register** on August 15, 2023, during a 60-day comment period (88 FR 55453). This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is (202) 566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: The $PM_{2.5}$ NAAQS State Implementation Plan (SIP) Requirements Rule ($PM_{2.5}$ SIP Requirements Rule) was effective on October 24, 2016 (81 FR 58010, August 24, 2016). This rule provides the framework of Clean Air Act (CAA) requirements for air agencies to develop state implementation plans to attain and maintain the $PM_{2.5}$ NAAQS. States have applied this framework to develop attainment plans and redesignation requests and maintenance plans for areas designated nonattainment for the 1997 $PM_{2.5}$ NAAQS, the 2006 $PM_{2.5}$ NAAQS, and the 2012 $PM_{2.5}$ NAAQS. This proposed ICR renewal covers the period February 1, 2024–January 31, 2027.

The initial ICR finalized with the $PM_{2.5}$ NAAQS SIP Requirements Rule estimated, for the 3 years following the ICR approval date, the burden associated with plan development and plan revisions related to ongoing implementation efforts in 31 areas designated nonattainment for the 1997, 2006 and/or 2012 $PM_{2.5}$ NAAQS. The estimates included the burden to develop and submit, and the burden to the EPA to review and to approve or disapprove, attainment plans to meet the requirements prescribed in CAA sections 110 and part D, subparts 1 and 4 of title I. A $PM_{2.5}$ NAAQS attainment plan contains rules and other measures designed to improve air quality and achieve the NAAQS by the deadlines established under the CAA. It also must address several additional CAA requirements related to demonstrating timely attainment and must contain contingency measures in the event the nonattainment area does not achieve reasonable further progress throughout the attainment period or in the event the area does not attain the NAAQS by its attainment date. States that have attained by the applicable attainment date may be eligible to submit a redesignation request and maintenance plan to receive a redesignation from ''nonattainment'' to ''attainment.'' After a state submits an attainment or maintenance plan, the CAA requires the EPA to take action on the plan. Tribes located within the geographic boundary of a nonattainment area may develop or submit attainment plans, but they are not required to do so.

This ICR supersedes the existing ICR—for which the EPA is proposing renewal in this action—for purposes of $PM_{2.5}$ NAAQS implementation.

Form Numbers: None.

Respondents/affected entities: State and local governments.

Respondent's obligation to respond: Mandatory.

Estimated number of respondents: 12.

Frequency of response: Once per triggering event (*i.e.,* an air agency is required to revise and submit a SIP revision when the area is initially designated as nonattainment, reclassified to a higher classification, when an areas fails to achieve reasonable further progress, when a Serious nonattainment area fails to timely attain, and/or when a state requests redesignation for a $PM_{2.5}$ nonattainment area that attains the NAAQS).

Total estimated burden: 24,900 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $1.76M (present value per year), which includes $0 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is a decrease of 1800 hours of total estimated respondent burden compared with the ICR currently approved by OMB. This decrease is due to the reduction in nonattainment areas from 18 to 12. While the hours decreased due to the fewer number of respondents, there is a present-day value increase in estimated costs due to the increase in labor rates and the need for several areas to continue to develop plans to help address complex air quality issues.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2024–01806 Filed 1–29–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2004–0500; FRL–11705–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; EPA's ENERGY STAR Program in the Residential Sector (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), EPA's ENERGY STAR Program in the Residential Sector (EPA ICR Number 2193.05, OMB Control Number 2060–0586) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through January 30, 2024. Public comments were previously requested via the **Federal Register** on April 18, 2023, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before February 29, 2024.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OAR–2004–0500 to EPA online using *www.regulations.gov* (our preferred method), by email to *a-and-r-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Zachary Shadid, Energy Star Residential Branch, Mail code 6202A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 343–9058; fax number: (202) 343–2204; email address: *shadid.zachary@epa.gov.*

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through January 31, 2024. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Public comments were previously requested via the **Federal Register** on April 18, 2023 during a 60-day comment period (88 FR 23671). This notice allows for an additional 30 days for public comments. Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: ENERGY STAR® is a voluntary energy efficiency labeling and public outreach program aimed at forming public-private partnerships that prevent air pollution rather than control it after its creation. This ICR covers information collection activities under the ENERGY STAR program within the new residential construction and existing residential construction markets. ENERGY STAR promotes energy efficient new home construction and cost-effective energy efficiency improvements in existing homes.

Form Numbers: 5900–188, 5900–266, 5900–268, 5900–269, 5900–270, 5900–420, 5900–421, 5900–422, 5900–423, 5900– 424, 5900– 425, 5900–426, 5900–427, 5900–428, 5900–429, 5900–446, 5900–447.

Respondents/affected entities: Respondents in this ICR include ENERGY STAR partners, including home builders, multifamily high rise developers, manufactured home plants, verification organizations, and energy efficiency program sponsors. Also included are oversight organizations and HVAC contractors.

Respondent's obligation to respond: Voluntary.

Estimated number of respondents: 1,256 (total).

Frequency of response: Once, quarterly, annually, and on occasion.

Total estimated burden: 208,824 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $20,656,339 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is an increase of 30,976 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is due to increasing energy codes and a shift to more individually verified homes. EPA updated program technical specifications to be more rigorous in the verification process while trying to reduce the number of items required to verify homes for the ENERGY STAR label. Additionally, a natural market shift occurred, resulting in an increase in individually verified homes and a reduction in sampled homes. The sampling protocol enables partners to test one in seven homes in what is termed a 'sample set.' ENERGY STAR partners have a choice when verifying homes to use a sampling or individually verified protocol. Due to various market forces, ENERGY STAR partners increasingly choose to individually verify homes instead of using the sampling protocol. EPA expects this trend to continue as ENERGY STAR partners become more Environmental, Social and Governance (ESG) and data-driven-focused.

Courtney Kerwin,

Director, Information Engagement Division.

[FR Doc. 2024–01805 Filed 1–29–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2018–0638; FRL–11710–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Waiver From Tier 4 Emission Standards for Marine Diesel Engines (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Waiver from Tier 4 Emission Standards for Marine Diesel Engines (EPA ICR Number 2602.03, OMB Control Number 2060–0726) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through January 31,

2024. Public comments were previously requested via the **Federal Register** on June 7, 2023 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments must be submitted on or before April 1, 2024.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2018–0638 to EPA online using *www.regulations.gov* (our preferred method), by email to *a-and-r-Docket@epa.gov* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Maria Lennox, Assessment and Standards Division, Office of Transportation and Air Quality, Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: (734) 214–4025; email address: *lennox.maria@epa.gov.*

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through January 31, 2024. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Public comments were previously requested via the **Federal Register** on June 7, 2023 during a 60-day comment period (88 FR 37241). This notice allows 60 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: EPA adopted the Tier 4 marine diesel engine standards in June 2008, under the authority of the Clean Air Act (73 FR 37096). The Tier 4 standards were phased in, with an effective date beginning in 2016 through 2018 for most engines. In August 2020, EPA amended those regulations in response to industry concerns about the availability of suitable Tier 4 certified engines for installation in certain kinds of high-speed vessels. The amendments provided focused relief for qualifying engines and vessels in two phases, depending on engine and vessel size. Builders of qualifying vessels were required to submit to EPA information describing their need for regulatory relief and demonstrating that their vessels met the size and power conditions.

- Phase One was available through 2021 and was limited to propulsion engines with maximum power output up to 1,400 kW and power density of at least 27.0 kW per liter displacement. Additionally, the relief is limited to vessels up to 65 feet waterline length with total nameplate propulsion power at or below 2,800 kW. This includes vessels such as lobster fishing boats, pilot boats, and some research boats.
- Phase Two is available through 2023 and is limited to vessels with a single propulsion engine with maximum power output up to 1,000 kW and power density of at least 35.0 kW per liter displacement, where the vessel is made with a nonmetal hull and has a maximum length of 50 feet. These vessels are expected to be primarily lobster or other fishing boats. EPA also adopted a waiver provision that can be applied for, if necessary, beginning in 2024, if suitable engines continue to be unavailable; this waiver requires the vessel builder to submit an application which would be reviewed by EPA before issuing the waiver.

This information collection request renewal covers the reporting burden associated with applying for the waiver for vessels meeting the criteria for Phase 2 relief. EPA will use the information requested under this collection to determine if a boat builder qualifies for a regulatory waiver from the marine diesel Tier 4 standards, allowing that manufacturer to install Tier 3 engines on a qualifying vessel. It will be collected electronically and used to evaluate whether companies qualify for using engines meeting less stringent standards. Manufacturers may assert a claim of confidentiality in accordance with the Freedom of Information Act (FOIA) and EPA regulations at 40 CFR part 2. We will release this information only as permitted or required under the FOIA and EPA regulations at 40 CFR part 2 and part 1068. Non-confidential portions of the information submitted to CD are available to trade associations, importers, environmental groups, members of the public, and state and local government organizations.

Form Numbers: None.

Respondents/affected entities: Manufacturers that sell or import into the United States (USA) new marine diesel engines and manufacturers that produce for sale in the USA certain high-speed marine vessels.

Respondent's obligation to respond: Required to obtain or retain a benefit.

Estimated number of respondents: 20 (total).

Frequency of response: On occasion: as necessary to obtain Tier 4 waivers for a specific vessel or vessels.

Total estimated burden: 380 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $39,707 (per year), which includes $0 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is an increase of 380 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is due to the end of the automatic delay for application of the Tier 4 standards to affected boats and the need to request a waiver from EPA to allow use of a Tier 3 engine if a suitable Tier 4 engine continues to be unavailable.

Courtney Kerwin,

Director, Information Engagement Division.

[FR Doc. 2024–01808 Filed 1–29–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2007–0358; FRL–11709–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Responsible Appliance Disposal Program (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR),

Responsible Appliance Disposal Program (EPA ICR Number 2254.04, OMB Control Number 2060–0703) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through January 31, 2024. Public comments were previously requested via the **Federal Register** on June 6, 2023, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before February 29, 2024.

ADDRESSES: Submit your comments to EPA, referencing Docket ID Number EPA–HQ–OAR–2007–0358, online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sally Hamlin, Stratospheric Protection Division, Office of Air and Radiation, 6205A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–343–9711; email address: *Hamlin.sally@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: The Responsible Appliance Disposal program (RAD) is a voluntary partnership program sponsored by the Environmental Protection Agency (EPA) that encourages Partners to reduce emissions of ozone-depleting substances (ODS) and their alternatives (*e.g.,* hydrofluorocarbons (HFCs)) that can be attributed to improper disposal of appliances. Appliances may contain ODS or HFC refrigerants and foams as well as universal wastes such as mercury, used oil, and polychlorinated biphenyls (PCBs). Federal law requires refrigerant recovery and proper management of universal waste but does not require the recovery of appliance foam. The RAD Program works with utilities, retailers, manufacturers, federal agencies/states/municipalities, waste removal service providers, affiliates, and others to dispose of appliances using best environmental practices.

To encourage reductions in emissions associated with appliance disposal in the United States, EPA launched the RAD Program. The RAD Program supports Section 608 of the Clean Air Act (CAA) and is an important component of EPA's mission to protect the ozone layer by reducing emissions of ODS. These efforts also support the American Innovation and Manufacturing (AIM) Act. RAD Program Partners reduce emissions of ODS and HFCs and realize other benefits through recovery and destruction/reclamation of refrigerants and foam blowing agents—the latter of which is not covered under existing Federal regulations—and by ensuring that all other hazardous and recyclable materials are handled using best environmental practices. Greenhouse gas (GHG) emissions are avoided through recovery of both ODS, HFCs, and other foam blowing agents. Additionally, through the RAD Program, EPA is partnering with utilities, retailers, manufacturers, federal agencies/state/municipalities, waste removal service providers, and others to promote the retirement of old appliances and permanently remove energy inefficient units from the electricity grid, providing energy savings to consumers.

Participation in the Program begins with completion of a mutually agreed upon Partnership Agreement that outlines mutual responsibilities for participation in the RAD Program. By voluntarily joining the Program, a Partner agrees to complete an annual reporting form identifying the number and types of appliances handled and the fates of their individual components. The electronic reporting form automatically generates feedback for the user on the results of their participation in terms of emissions avoided, quantity of used oil/PCBs/mercury destroyed or recycled, energy savings achieved, and consumer savings realized. An annual report provides Partners with information on their progress towards achieving emissions reductions and information about developments in the latest recycling technologies and practices. Through recognition of Partner efforts, and the Program's promotion of recycling best practices through webinars, web updates, fact sheets, and presentations, non-Partners become aware of recycling best practices and can evaluate what best practices could work for them. The RAD Program largely serves to disseminate information on recycling best practices and creates a platform for information sharing on recycling and waste management practices. The data collected are used as an indicator of whether industry is reducing emissions from end-of-life appliances.

Form Numbers: Partnership agreement forms, partnership reporting forms.

Respondents/affected entities: Utilities, manufacturers, retailers, Federal and State agencies, municipalities and waste removal companies.

Respondent's obligation to respond: Voluntary.

Estimated number of respondents: 52 (total over 3 years).

Frequency of response: Annual and when desired.

Total estimated burden: 292 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $43,702 (per year), includes $00 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is no change to the total estimated respondent burden compared with the 292 hours for the ICR currently approved by OMB. While the total number of respondents increased, the number of expected new Partners decreased. Therefore, the increase in burden associated with existing Partner activities is offset by the decrease in burden associated with new Partner activities.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2024–01799 Filed 1–29–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL—11696–01–OA]

Meeting of the Local Government Advisory Committee's Small Communities Advisory Subcommittee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), EPA hereby provides notice of a meeting of the Local Government Advisory Committee (LGAC) and its Small Community Advisory Subcommittee (SCAS) on the dates and times described below. These meetings will be open to the public. For information on public attendance and participation, please see the registration information under **SUPPLEMENTARY INFORMATION.**

DATES: The SCAS will meet virtually February 9th, 2024, starting at 1 p.m. through 2 p.m. Eastern Standard Time. The LGAC will have a virtual meeting February 15th, from 2:30–4 p.m. Eastern Standard Time.

FOR FURTHER INFORMATION CONTACT: Paige Lieberman, Designated Federal Officer (DFO) of the Local Government Advisory Committee, at *LGAC@epa.gov* or 202–564–9957 or Lynzi Barnes, DFO of the Small Community Advisory Subcommittee, at *barnes.edlynzia@epa.gov* or (773) 638–9158.

Information on Accessibility: For information on access or services for individuals requiring accessibility accommodations, please send an email to *LGAC@epa.gov.* To request accommodation, please do so five (5) business days prior to the meeting, to give EPA as much time as possible to process your request.

SUPPLEMENTARY INFORMATION: *Content:* The SCAS will review draft recommendations from the LGAC involving the Lead and Copper Rule Improvements. The SCAS will deliberate and provide additional feedback to the LGAC recommendations before they are finalized. The LGAC will discuss recommendations on the Lead and Copper Rule Improvements with a goal to finalize and send to the EPA Administrator. The LGAC will also receive a new charge from EPA's Office of Environmental Justice and External Civil Rights. Meeting materials and recommendations will be posted online closer to the meeting dates.

Registration: Both meetings will be held virtually through Microsoft Teams. Members of the public who wish to participate should register by contacting Paige Lieberman, Designated Federal Officer (DFO) of the Local Government Advisory Committee, at *LGAC@epa.gov* or 202–564–9957 or Lynzi Barnes, DFO of the Small Community Advisory Subcommittee, at *barnes.edlynzia@epa.gov* or (773) 638–9158 within 24 hours of the meeting start time. The agenda and other supportive meeting materials will be available online at *https://www.epa.gov/ocir/*local-government-advisory-committee-lgac and can be obtained by written request to the DFO. In the event of cancellation for unforeseen circumstances, please contact the DFO or check the website above for reschedule information.

Edlynzia Barnes,

Designated Federal Officer, Office of Congressional and Intergovernmental Relations.

[FR Doc. 2024–01779 Filed 1–29–24; 8:45 am]

BILLING CODE 6560–50–P

FARM CREDIT SYSTEM INSURANCE CORPORATION

Board of Directors Meeting

SUMMARY: Notice of the forthcoming regular meeting of the Board of Directors of the Farm Credit System Insurance Corporation (FCSIC), is hereby given in accordance with the provisions of the Bylaws of the FCSIC.

DATES: 10 a.m., Wednesday, February 7, 2024.

ADDRESSES: You may observe the open portions of this meeting in person at 1501 Farm Credit Drive, McLean, Virginia 22102–5090, or virtually. If you would like to virtually attend, at least 24 hours in advance, visit *FCSIC.gov,* select ''News & Events,'' then select ''Board Meetings.'' From there, access the linked ''Instructions for board meeting visitors'' and complete the described registration process.

FOR FURTHER INFORMATION CONTACT: If you need more information or assistance for accessibility reasons, or have questions, contact Ashley Waldron, Secretary to the Board. Telephone: 703–883–4009. TTY: 703–883–4056.

SUPPLEMENTARY INFORMATION: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public. The following matters will be considered:

Portions Open to the Public

- Approval of Minutes for December 13, 2023.
- Review and Setting of Insurance Premium Accrual Rates.

Portions Closed to the Public

- Annual Report on Contracts.
- Annual Report on Whistleblower Activity.

Ashley Waldron,

Secretary to the Board.

[FR Doc. 2024–01772 Filed 1–29–24; 8:45 am]

BILLING CODE 6705–01–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Notice of Board Meeting

DATES: February 2, 2024, at 11:00 a.m.

ADDRESSES: 77 K Street NE, Washington, DC 20002.

STATUS: Closed to the public.

FOR FURTHER INFORMATION CONTACT: Kimberly Weaver, Director, Office of External Affairs, (202) 942–1640.

SUPPLEMENTARY INFORMATION:

Board Meeting Agenda

Closed Session

1. Information covered under 5 U.S.C. 552b(c)(9)(B).

Authority: 5 U.S.C. 552b(e)(1).

Dated: January 25, 2024.

Dharmesh Vashee,

General Counsel, Federal Retirement Thrift Investment Board.

[FR Doc. 2024–01784 Filed 1–29–24; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; New Collection

AGENCY: Federal Trade Commission (''FTC'' or ''Commission'').

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (''PRA''), the Federal Trade Commission (''FTC'' or ''Commission'') is submitting to the Office of Management and Budget (''OMB'') its proposal to seek OMB clearance for information collection requirements contained in the Federal Cigarette Labeling and Advertising Act (''FCLAA''). The FCLAA requires the FTC to review plans for the rotation of health warnings on cigarette packaging and advertising. The current provisional clearance expires on January 31, 2024, and the FTC intends to seek OMB renewal for three years.

DATES: Comments must be received on or before February 29, 2024.

ADDRESSES: Interested parties may file a comment online or on paper, by

following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Shira Modell, General Attorney, Division of Advertising Practices, Bureau of Consumer Protection, (202) 725–2162, *smodell@ftc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

The Federal Cigarette Labeling and Advertising Act, 15 U.S.C. 1331 *et seq.* (2006 ed.) (''FCLAA'') tasks the FTC with reviewing the rotation of statutorily-prescribed Surgeon General's health warnings on cigarette packaging and in advertisements, and requires the FTC to collect certain information from manufacturers, packagers, and importers importing for sale, distributing, or advertising cigarettes in the United States.

Because this information collection requirement is statutorily prescribed, OMB clearance was not required for the requirement to submit information to be effective.[1] Nonetheless, the FTC recently decided to obtain OMB clearance for this statutorily mandated information collection. Accordingly, on July 28, 2023, the FTC obtained from OMB (i) approval of an expedited provisional clearance for this information collection (OMB Control Number: 3084–0175, Title: Information Collection under the Federal Cigarette Labeling and Advertising Act), and (ii) a waiver under 5 CFR 1320.13(d) of the requirement to publish a notice of the emergency clearance request. On September 6, 2023, the FTC published a **Federal Register** notice with a 60-day comment period soliciting comments from the public concerning the proposed collections of information (hereinafter, ''**Federal Register** Notice''). *See* 88 FR 60941 (September 6, 2023). In response to this **Federal Register** Notice, the FTC received four responsive, non-duplicative comments.[2]

B. Comments

Three of the four comments express the commenters' strong support for the information collection, noting that the collection of the information is useful and necessary for the purpose of the promotion of public health.[3] One of the four comments expresses concerns pertaining to the information collection.[4] In the remainder of this section, the Commission provides summaries of the four comments and the Commission's responses to the comments.

I. Individual Commenters

Comments: Two of the four comments the Commission received express strong support for the information collection, and explain that the commenters had personally witnessed the effects of tobacco addiction on others.[5]

Response: The Commission shares the commenters' concern about the importance of informing consumers about the health risks associated with cigarette smoking through display of the Surgeon General's health warnings on cigarette packaging and advertising.

II. Comment by State Attorneys General

Comment: The Offices of the Attorneys General for the States of Maryland, Arizona, Arkansas, California, Colorado, Connecticut, Hawaii, Illinois, Montana, Missouri, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, and Washington (hereinafter, collectively referred to as ''State AGOs'') submitted a joint comment, noting that the information collection (''FCLAA information collection'') is useful and necessary for the purpose of the promotion of public health, and aids State governments in their regulation of cigarette manufacturers seeking to sell cigarettes in the States.[6] The State AGOs note that most States publish a directory of cigarette brands that have been approved for sale in their respective States, and require manufacturers to submit certain information, including approval letters from the FTC showing that the manufacturers have submitted plans that the FTC found to be compliant with the FCLAA.[7] According to the State AGOs, the submission of the approval letters (1) promotes public health by ensuring that cigarette brands a manufacturer seeks to sell in the State will bear required health warnings that alert consumers to the risks cigarettes pose to the smoker's health and the health of people nearby; (2) informs States about the cigarette brands a manufacturer intends to sell during the upcoming year; (3) serves as a tool for States to verify that cigarettes listed on their directory of approved brands are, in fact, legal for sale in the United States; and (4) provides a level of assurance to the reviewing States that a manufacturer is a business that is in good standing, capable of meeting its regulatory obligations with different government agencies, and committed to operating legally.

Response: The FTC appreciates the comment, which underscores the necessity of this information collection.

I. Comment by ITG Brands, LLC, and Commonwealth Brands, LLC

Comment: ITG Brands, LLC, submitted a public comment on behalf of itself and its affiliate, Commonwealth Brands, LLC, voicing the following concerns pertaining to this information collection.

First, the two cigarette companies assert that the Notice's apparent position that rotation plans must identify brand styles by name exceeds FTC's statutory authority and is unnecessary. According to the two cigarette companies, the text of 15 U.S.C. 1333© only requires that rotation plans sufficiently explain how cigarette manufacturers will comply with their quarterly or simultaneous rotation obligations. The two cigarette companies assert that because the text of 15 U.S.C. 1333(c)(1) does not employ the term ''brand style,'' the statute does not suggest that any element of a rotation plan must be brand-specific. In support of this argument, they note that, in 1985, the FTC approved a number of rotation plans that include language continuing to permit those cigarette

[1] An agency not having obtained OMB clearance for a statutorily-mandated information collection requirement does not excuse a respondent's failure to comply with the requirement. *U.S.* v. *Ionia Management S.A.,* 498 F. Supp. 2d 477, 489 (D. Conn. 2007); *accord* 5 CFR 1320.6(e) (where information collection requirements are imposed by statute, an agency's not having complied with the requirements of the PRA is not a defense against the assessment of a penalty).

[2] *See Comment FTC–2023–0056–0007, https://www.regulations.gov/comment/FTC-2023-0056-0007* (Sept. 27, 2023) [hereinafter *Comment from Anonymous*]; *Comment FTC–2023–0056–0009, https://www.regulations.gov/comment/FTC-2023-0056-0009* (Nov. 6, 2023) [hereinafter *State AGO Comment*]; *Comment FTC–2023–0056–0006, https://www.regulations.gov/comment/FTC-2023-0056-0006* (Sept. 23, 2023) [hereinafter *JD Comment*]; *Comment FTC–2023–0056–0010, https://www.regulations.gov/comment/FTC-2023-0056-0010* (Nov. 6, 2023) [hereinafter *ITG Brands & Commonwealth Brands Comment*].

[3] *See State AGO Comment; see also JD Comment; Comment from Anonymous.*

[4] *See ITG Brands & Commonwealth Brands Comment.*

[5] *See JD Comment; Comment from Anonymous.*

[6] *See State AGO Comment.*

[7] *State AGO Comment* (citing Md. Code Ann., Bus. Reg. sections 16–501 to –508; Ohio Rev. Code Ann. section 1346.05 *et seq.*; 35 Pa. Stat. Ann. sections 5702.101 *et seq.*; S.C. Code Ann. sections 11–48–30; Tenn. Code Ann. sections 67–4–2601 *et seq.*).

manufacturers to introduce new brands and brand styles without having to seek prior approval or submit sample packaging.

Second, the two cigarette companies argue that the **Federal Register** Notice's apparent position that cigarette manufacturers must submit packaging for new brands and brand styles and packaging changes for existing brand styles, exceeds the FTC's statutory authority and is unnecessary. Noting that 15 U.S.C. 1333(c) does not specify that cigarette manufacturers must submit ''packages'' to the FTC for approval, the two cigarette companies contend that Congress would have expressly required cigarette manufacturers to submit ''packages,'' if it had intended them to do so. The two companies assert that FTC appears to be using the rotation plan requirement of 15 U.S.C. 1333(c) to enforce the warning label requirements of paragraphs (a) and (b) of 15 U.S.C. 1333, although 15 U.S.C. 1333(c) only requires manufacturers to submit a plan ensuring compliance with the subsection's rotation requirements. According to the two cigarette companies, 15 U.S.C. 1333(c) does not require the plan to cover the manufacturer's compliance with paragraphs (a) and (b) of 15 U.S.C. 1333. The two cigarette companies argue that ''the FTC seems to recognize this by its treatment of the major tobacco companies, as on information and belief the FTC has not required them to submit sample packaging before implementing packaging changes since 1985.''

Third, the two cigarette companies assert that the information collection imposes a substantial burden on cigarette manufacturers beyond the burden stated in the **Federal Register** Notice. The two companies contend that the Commission's analysis fails to account for the costs cigarette manufacturers incur as a result of submitting packaging for the agency's review and that even the collection activities accounted for in the burden analysis are drastically underestimated.

For example, the two cigarette companies assert that the submission of ''revised packaging and plan documents involves . . . far more than the 8 hours that the FTC estimates, with a more accurate estimate based on ITG and Commonwealth's experience requiring up to 20 to 40 hours per submission.'' The companies' estimate includes, among other things, the time spent making printing arrangements for packaging samples and addressing any changes requested by the FTC.

The two companies also assert that, due to the fact that the FTC requires cigarette manufacturers to submit actual packaging samples, rather than PDFs of packaging samples, the introduction of new brand styles requires a special print run from an outside printing company. According to the two companies, samples of actual packaging for new products are often not available until shortly before the intended launch of such products and require up to three months of lead time for printing ''and additional expense for printing a complete sample set from $8,000 to $25,000 per variant.'' The two cigarette companies state that the aggregate burden in time and expense resulting from this is substantial when cigarette companies introduce several new brand styles a year. Moreover, the companies assert that, since the plans of Philip Morris and RJR/Lorillard permit those manufacturers to introduce new brands and brand styles without having to seek prior approval or submit sample packaging, other cigarette companies—such as ITG Brands, LLC, and Commonwealth Brands, LLC—experience a substantial competitive burden as a result of this delay.

Fourth, the two cigarette companies argue that the FTC should minimize these burdens by (1) allowing all manufacturers to adopt rotation plans that permit the introduction of new brands or brand styles without further submission to the Commission as long as the rotation plan explains how the warnings on such new products will be appropriately rotated, and (2) no longer requiring manufacturers to submit ''every packaging change [to the FTC] for review and approval.'' The two cigarette companies contend that doing so would be consistent with the regulations the U.S. Food and Drug Administration (''FDA'') has issued in light of the pending transfer of statutory authority concerning the display of health warnings. The two companies claim that in a final rule, titled ''Tobacco Products; Required Warnings for Cigarette Packages and Advertisements,'' the FDA took the position that, ''in lieu of a supplement to an approved plan for a new brand, manufacturers may reference in their initial plan 'all brands' in their product listing(s) . . . and incorporate any new brands into their approved plan, so long as no other changes are made to the plan.'' [8]

Response: The two companies are correct that section 1333(c)(1) does not explicitly mention brand styles. However, section 1333(b)(1), which addresses the format of packaging warnings, specifically states that the health warning statements must be in ''conspicuous and legible type in contrast by typography, layout, or color with all other printed material on the package.'' Accordingly, to ensure that the Surgeon General's health warnings on cigarette packs and cartons are conspicuous, since at least 1991, the Commission has required manufacturers and importers to submit health warning plans for all new cigarette brands and brand styles, and has reviewed the packaging submitted with those plans by the manufacturers and importers before that packaging is sent out into the marketplace. As a practical matter, no other system would efficiently effectuate Congress's intent that the warnings be conspicuous on cigarette packaging.

Moreover, section 1333(c)(2) of the FCLAA does expressly use the term ''brand style'' with respect to a manufacturer or importer that is applying for permission to use the alternative to quarterly rotation. Section 1333(c)(2)(A) sets forth the requirements that must be met to qualify for the alternative ''with respect to a brand style of cigarettes,'' [9] including that the number of cigarettes ''of such brand style'' sold in the previous fiscal year is less than one-quarter of 1 percent of all cigarettes sold in the U.S. that year.

The Commission believes it has the authority under FCLAA to review the format of packaging warnings in order to ensure that the Act's statutory requirements are satisfied. Paragraph (a)(1) of section 1333 sets forth the requisite wording of the four packaging warnings, and paragraph (b)(1) of section 1333 sets forth the aforementioned format requirements applicable to the ''label statements'' required by paragraph (a)(1). Paragraph (c)(1) of section 1333 then refers to the ''label statements'' specified in paragraph (a)(1), and provides that the label statements are required to be rotated ''on packages of each brand of cigarettes manufactured by the manufacture or importer'' in accordance with a plan approved by the Commission that ensures ''that all of the labels required . . . will be displayed by the manufacturer or importer.'' [10] Read together, these provisions provide the basis for the Commission to require that manufacturers and importers submit packaging samples to ensure that the rotation plan meets the statutorily prescribed rotation and formatting requirements. In order to do so for new brands and brand styles, the Commission must have the ability to

[8] *ITG Brands* & *Commonwealth Brands Comment* (citing 85 FR 15638 (Mar. 18, 2020)).

[9] 15 U.S.C. 1333(c)(2)(A) (emphasis added).

[10] *See* 15 U.S.C. 1333(c)(1) (emphasis added).

require cigarette manufacturers and importers to submit updated rotation plans and packaging samples.

With regard to the companies' argument that the information collection imposes a substantial burden on cigarette manufacturers beyond the burden stated in the **Federal Register** Notice, the Commission notes the following. First, ''[s]amples of products or of any other physical objects,'' which, by definition, includes packaging samples, do not constitute ''information'' for purposes of the PRA,[11] and any costs related to the preparation and submission of any such samples should not be included in a burden analysis prepared for purposes of the PRA.[12]

Second, the companies' estimate that, in the context of the introduction of new brands and brand styles, the preparation and submission of an amended plan takes approximately 20 to 40 hours—*i.e.,* up to a full workweek—is likely not reflective of the industry average. The amendment of an existing rotation plan to add a new brand or brand style is generally relatively quick and simple, and cigarette manufacturers can use their existing approved rotation plans as templates. A company with an approved plan for rotating the warnings quarterly on its packaging must merely identify the new brand style being added to that plan and submit the packaging for that new brand style; [13] if the company wishes to add a new brand to its plan, it must also identify the warning that will be assigned to that brand during each quarter of the year. If the company wishes to use the option provided by section 1333(c)(2) and display the four warnings an equal number of times during the year on the packaging of certain brand styles, it must provide information sufficient to show that its sales satisfy both of the criteria in 15 U.S.C. 1333(c)(2)(A), provide packaging, and explain—again, as it has done previously—how it will ensure that all four warnings will be equally displayed during the one-year period beginning on the date the plan is approved (for example, by using printing plates that produce an even number of all four warnings simultaneously on each print run).

Third, the two cigarette companies' estimate includes activities that do not result from a collection of information. Specifically, because, as indicated above, the submission of the samples does not constitute a collection of information for purposes of the PRA,[14] the two cigarette companies' estimate erroneously includes time spent making printing arrangements.[15] Furthermore, when a plan submitted to the Commission cannot be approved in its original form, FTC staff usually provides the cigarette manufacturer with specific, individualized guidance as to the changes necessary for Commission approval. As the PRA exempts ''request[s] for facts or opinions addressed to a single person'' and ''[f]acts or opinions obtained or solicited through nonstandardized follow-up questions designed to clarify responses to approved collections of information,'' [16] the time spent incorporating requested changes into the companies' proposals should not be reflected in the burden estimate for this information collection.[17]

Fourth, the Commission questions the companies' assertion that the preparation of their plans requires the assistance of outside counsel. For the years 2017 through 2021—the most recent years for which the two companies' plans are on the public record—their plans were all signed by in-house counsel. Although some manufacturers and importers do use outside counsel to file their plans, they presumably do so because it makes more sense from a business perspective than using in-house personnel.

The companies also fail to explain why the submission to the Commission of the packaging that they intend to use for new products requires a significant lead time for printing that would not otherwise be incurred. Even if the Commission were to allow manufacturers to adopt rotation plans that permit the introduction of new brands or brand styles without further submission to the Commission, manufacturers and importers would nonetheless have to create, print, and then review any packaging for new varieties or redesigned packaging for existing varieties for compliance with the FCLAA's format requirements.[18] The two companies also fail to explain why the expense associated with the preparation of sample packaging by an outside printing company would not still be incurred if the companies were to review their own new packaging for compliance with FCLAA (rather than submit them to the Commission for approval).

The companies also argue that the fact that they are required to seek Commission approval prior to the introduction of new brand styles or packaging causes them to suffer a ''substantial competitive burden.'' However, consideration of whether the requirement imposes a competitive burden is beyond the scope of a burden analysis under the PRA, which defines the term ''burden'' more narrowly.[19] Furthermore, the two companies' final argument—that is, that requiring Commission approval for the introduction of new brand styles is inconsistent with the approach that the FDA proposed in light of the pending transfer of statutory authority concerning the display of health warnings [20]—is equally beyond the scope of this notice. The FDA's proposed approach is based on the Family Smoking Prevention and Tobacco Control Act, Public Law 111–31, tit. II, sec. 201 (June 22, 2009) (hereinafter, ''FSPTCA''), which differs from the FCLAA in significant aspects.[21]

Accordingly, as the Commission does not find the two companies' arguments to be convincing, the Commission declines to adjust the estimates that were included in its expedited provisional clearance request and approved by OMB on July 28, 2023.

C. Overview of Information Collection

Title of Collection: Information Collection under the Federal Cigarette Labeling and Advertising Act.

OMB Control Number: 3084–0175.

Type of Review: Extension without change of currently approved collection.

[11] *See* 5 CFR 1320.3(c) (''Collection of information means . . . the obtaining, causing to be obtained, soliciting, or requiring the disclosure to an agency, third parties or the public *of information* by or for an agency. . . .'') (emphasis omitted) (emphasis added), CFR 1320.3(h)(2) (' 'Information' does not generally include . . . [s]amples of products or of any other physical objects.'').

[12] *See* 5 CFR 1320.3(b)(1) (defining the term ''burden'' as ''the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide *information* to or for a Federal agency'') (emphasis added).

[13] The Commission's insistence on actual packaging, rather than just artwork, reflects its experience that colors can be different in artwork than in final packaging, and that those differences can affect whether the warnings are conspicuous.

[14] *See supra* note 13.

[15] *See supra* note 15.

[16] *See* 5 CFR 1320.3(h)(6), (9).

[17] *See supra* note 15.

[18] As noted *supra* note 13, the preparation and submission of packaging samples does not constitute a collection of information for purposes of the PRA, and, thus, should be disregarded for purposes of this burden analysis.

[19] For a definition of the term ''burden,'' see 44 U.S.C. 3502(2) and 5 CFR 1320.3(b)(1).

[20] *ITG Brands* & *Commonwealth Brands Comment* (citing 85 FR 15638 (Mar. 18, 2020)).

[21] For example, the FSPTCA provides precise details as to the size, font, location, and color of the nine warning statements that will ultimately replace the current four Surgeon General's warnings. *See* 15 U.S.C. 1333(a)(2) (2009 ed.). Additionally, only the FCLAA specifically requires the annual submission of information demonstrating that the manufacturer or importer continues to qualify for equalization of the health warnings.

Abstract: The Federal Cigarette Labeling and Advertising Act, 15 U.S.C. 1331 *et seq.* (2006 ed.) (''FCLAA''), requires cigarette manufacturers, packagers, and importers to place one of four statutorily-prescribed Surgeon General's health warnings on cigarette packaging and in advertisements, on a rotational basis in accordance with plans reviewed and approved by the FTC. Each manufacturer, packager, and importer (hereinafter, also referred to as ''respondents'') wishing to import for sale or distribute cigarettes in the United States is required to submit a plan to the FTC that (1) explains how the respondent intends to comply with the statutory requirement to display the statutorily-prescribed health warnings on its packaging, (2) identifies each of the respondent's brands and brand styles, (3) includes a schedule (or other explanation) showing the warnings that will be assigned to each brand during each quarter of the year, and (4) specifies when in the manufacturing process the respondent will consult its rotation schedule for that particular brand in order to assign the appropriate quarterly warning. Respondents wishing to engage in advertising of cigarettes in the United States are required to submit to the FTC a plan that (1) includes a rotation schedule for the four statutorily-prescribed health warnings for each brand the respondent intends to advertise, (2) specifies how the respondent will determine which health warnings will appear on different kinds of advertisements, and (3) specifies how the respondent will handle advertisements that feature more than one of the respondent's brands.

The FCLAA also provides for an alternative method for displaying the required health warnings on packaging—that is, equalization. Specifically, manufacturers, packagers, and importers may seek the FTC's approval to display the health warnings on a particular cigarette brand style an equal number of times. In order to obtain approval for equalization, respondents must submit an additional plan to the FTC that establishes (1) that their sales satisfy the statutory-prescribed requirements for equalization, and (2) how the respondent will ensure that all four health warnings will be equally displayed during the one-year period following the plan's approval (*e.g.,* by using printing plates that produce an even number of all four warnings simultaneously on each print run). Respondents seeking to equalize must submit new plans annually to demonstrate that their sales continue to qualify for equalization.

The Commission uses the information to assess—as it is required to do under the FCLAA—whether a manufacturer or importer will display the Surgeon General's health warnings in compliance with the governing statutory provisions in the FCLAA.

Affected Public: Private Sector: Businesses and other for-profit entities.

Estimated Annual Burden Hours: 328.

Estimated Annual Labor Costs: $16,695.

Estimated Annual Non-Labor Costs: $0.

D. Request for Comment

Pursuant to OMB regulations, 5 CFR part 1320, which implement the PRA, 44 U.S.C. 3501 *et seq.,* the FTC is providing this second opportunity for public comment while submitting to OMB its request for clearance for the information collection requirements contained in the FCLAA. For more details about the requirements and the basis for the calculations summarized above, see 88 FR 60941.

Your comment—including your name and your state—will be placed on the public record of this proceeding. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as anyone's Social Security number; date of birth; driver's license number or other state identification number or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for ensuring that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''[t]rade secret or any commercial or financial information which is . . . privileged or confidential''—as provided in Section 6(f) of the FTC Act 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including, in particular, competitively sensitive information, such as costs, sales statistics, inventories, formulas, patterns devices, manufacturing processes, or customer names.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

[FR Doc. 2024–01798 Filed 1–29–24; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9145–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—October Through December 2023

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published in the 3-month period, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone No.
I. CMS Manual Instructions	Ismael Torres	(410) 786–1864
II. Regulation Documents Published in the **Federal Register**	Terri Plumb	(410) 786–4481
III. CMS Rulings	Tiffany Lafferty	(410) 786–7548
IV. Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786–7491
V. FDA-Approved Category B IDEs	John Manlove	(410) 786–6877
VI. Collections of Information	William Parham	(410) 786–4669
VII. Medicare-Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786–2749
VIII. American College of Cardiology—National Cardiovascular Data Registry Sites.	Sarah Fulton, MHS	(410) 786–2749
IX. Medicare's Active Coverage-Related Guidance Documents	Lori Ashby, MA	(410) 786–6322
X. One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786–7205

Addenda	Contact	Phone No.
XI. National Oncologic Positron Emission Tomography Registry Sites	David Dolan, MBA	(410) 786–3365
XII. Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	David Dolan, MBA	(410) 786–3365
XIII. Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786–2749
XIV. Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786–2749
XV. Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	David Dolan, MBA	(410) 786–3365
All Other Information	Annette Brewer	(410) 786–6580

SUPPLEMENTARY INFORMATION:

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and ''real time'' accessibility. In addition, many of the websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website proves to be difficult, the contact person listed can provide information.

III. How To Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at *http://www.cms.gov/manuals.*

The Director of the Office of Strategic Operations and Regulatory Affairs of the Centers for Medicare & Medicaid Services (CMS), Kathleen Cantwell, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Trenesha Fultz-Mimms,

Federal Register Liaison, Department of Health and Human Services.

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: February 1, 2023 (88 FR 6729), May 12, 2023 (88 FR 30752), August 4, 2023 (88 FR 51814) and October 26, 2023 (88 FR 73591). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (October Through December 2023)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How To Obtain Manuals

The internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the internet-only manual (IOM) or retired. Pub 15–1, Pub 15–2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703–605–6050). You can download copies of the listed material free of charge at: *http://cms.gov/manuals.*

How To Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at *http://www.gpo.gov/libraries/.*

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual Updates to Medicare Benefit Policy Manual and Medicare Claims Processing Manual for Opioid Treatment Programs (OTPs) (CMS-Pub. 100–02) Transmittal No. 12418.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual.

Fee-For Service Transmittal Numbers

Please Note: Beginning Friday, March 20, 2020, there will be the following change regarding the Advance Notice of Instructions due to a CMS internal process change. Fee-For Service Transmittal Numbers will no longer be determined by Publication. The Transmittal numbers will be issued by a single numerical sequence beginning with Transmittal Number 10000.

For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at *www.cms.gov/Manuals.*

Transmittal No.	Manual/subject/publication No.
	Medicare General Information (CMS-Pub. 100–01)
12037	Update to Medicare Deductible, Coinsurance and Premium Rates for Calendar Year (CY) 2024.
12341	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12425	Enforcing Billing Requirements for Intensive Outpatient Program (IOP) Services with New Condition Code 92—Additional Publication Update.
	Medicare Benefit Policy (CMS-Pub. 100–02)
12283	Internet Only Manual Updates to Pub. 100–02 and 100–04 to Implement Consolidated Appropriations Act 2023 Changes for Skilled Nursing Facility (SNF).
12291	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
12299	An Omnibus CR to Implement Policy Updates in the CY 2023 PFS Final Rule, Including (1) Removal of Selected NCDs (NCD 160.22 Ambulatory EEG Monitoring), and, (2) Expanding Coverage of Colorectal Cancer Screening—Full Agile Pilot CR.
12385	Hospice Benefit Policy Manual Updates Related to the Addition of Marriage and Family Therapists (MFTs) or Mental Health Counselors (MHCs) to the Hospice Interdisciplinary Team.
12400	Hospice Benefit Policy Manual Updates Related to the Addition of Marriage and Family Therapists (MFTs) or Mental Health Counselors (MHCs) to the Hospice Interdisciplinary Team.
12418	Updates to Medicare Benefit Policy Manual and Medicare Claims Processing Manual for Opioid Treatment Programs (OTPs).
12421	January 2024 Update of the Hospital Outpatient Prospective Payment System (OPPS).
12425	Enforcing Billing Requirements for Intensive Outpatient Program (IOP) Services with New Condition Code 92—Additional Publication Update.
	Medicare National Coverage Determination (CMS-Pub. 100–03)
12299	An Omnibus CR to Implement Policy Updates in the CY 2023 PFS Final Rule, Including (1) Removal of Selected NCDs (NCD 160.22 Ambulatory EEG Monitoring), and, (2) Expanding Coverage of Colorectal Cancer Screening—Full Agile Pilot CR.
12352	Manual Updates for Coverage of Intravenous Immune Globulin (IVIG) For Treatment of Primary Immune Deficiency Diseases in the Home.
	Medicare Claims Processing (CMS-Pub. 100–04)
12283	Internet Only Manual Updates to Pub. 100–02 and 100–04 to Implement Consolidated Appropriations Act 2023 Changes for Skilled Nursing Facility (SNF) Physician's Services and Other Professional Services Excluded From Part A PPS Payment and the Consolidated Billing Requirement.
12284	Deleting Internet Only Manuals (IOM) Pub. 100–04, Chapter 4, Section 190, Payer Only Codes Utilized by Medicare Payer Only Codes Utilized by Medicare.
12287	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12288	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
12289	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12290	Diagnosis Code Update for Add-on Payments for Blood Clotting Factor Administered to Hemophilia Inpatients Payment for Blood Clotting Factor Administered to Hemophilia Inpatients.
12291	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
12298	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
12299	An Omnibus CR to Implement Policy Updates in the CY 2023 PFS Final Rule, Including (1) Removal of Selected NCDs (NCD 160.22 Ambulatory EEG Monitoring), and, (2) Expanding Coverage of Colorectal Cancer Screening—Full Agile Pilot CR.
12301	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12305	Calendar Year (CY) 2024 Participation Enrollment and Medicare Participating Physicians and Suppliers Directory (MEDPARD) Procedures.
12306	Processing Claims When the Dates of Service Are Beyond the Time Limit for the Patient Assessment Actions When a Claim Does Not Match the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI) Payment Adjustments—Applying OASIS Assessment Items to Determine HIPPS Codes.
12315	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.

Transmittal No.	Manual/subject/publication No.
12316	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12321	Implementation of Rural Emergency Hospital (REH) Provider Type.
12322	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12325	Update to the Internet Only Manual (IOM) Publication (Pub.) 100–04, Chapter 18 Section 50.3–50.4, To Remove 0359U Per The International Classification of Diseases, 10th Revision (ICD–10) and Other Coding Revisions to National Coverage Determinations (NCDs)—October 2023.
12326	Internet-Only Manual Update, Pub. 100–04, Chapter 23 (Fee Schedule Administration and Coding Requirements), Section 50.6.
12337	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12339	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
12342	April 2024 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder.
12343	Quarterly Update to Home Health (HH) Grouper.
12344	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions.
12347	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12354	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12357	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12359	Implementation of New Benefit Category for Lymphedema Compression Treatment Items.
12360	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12361	Updates to Chapter 1 of the Medicare Claims Processing Manual (Publication (Pub.) 100–04) to Include Newly Created and Utilized Payer Only Codes.
12364	NCD 220.6.20—Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease.
12369	Implementation of Rural Emergency Hospital (REH) Provider Type.
12375	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
12389	Calendar Year (CY) 2024 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment.
12391	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12396	Update to the Internet Only Manual (IOM) Publication (Pub.) 100–04, Chapter 32 Sections 320.3.3 and 370.1 for Coding Revisions to the National Coverage Determinations (NCDs)—April 2024 Change Request (CR) 13390.
12398	Calendar Year 2024 Update for Durable Medical Equipment, Orthotics and Supplies (DMEPOS) Fee Schedule.
12399	April 2024 Bi-Annual Update of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM).
12401	Instructions for Retrieving the 2024 Pricing and Healthcare Common Procedure Coding System (HCPCS) Data Files through CMS' Mainframe Telecommunications Systems.
12402	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
12403	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
12404	Instructions for Downloading the Medicare ZIP Code File for April 2024 Files.
12406	CY 2024 Home Infusion Therapy (HIT) Payment Rates and Instructions for Retrieving the January 2024 Home Infusion Therapy (HIT) Services Payment Rates Through the CMS Mainframe Telecommunications System.
12407	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12411	New Place of Service (POS) Code 27—"Outreach Site/Street".
12413	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12414	Ambulance Inflation Factor (AIF) for Calendar Year (CY) 2024 and Productivity Adjustment.
12415	New Waived Tests.
12416	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12418	Updates to Medicare Benefit Policy Manual and Medicare Claims Processing Manual for Opioid Treatment Programs (OTPs).
12419	January 2024 Integrated Outpatient Code Editor (I/OCE) Specifications Version 25.0.
12420	January 2024 Update of the Ambulatory Surgical Center (ASC) Payment System.
12421	January 2024 Update of the Hospital Outpatient Prospective Payment System (OPPS).
12422	April 2024 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing.
12423	Enforcing Billing Requirements for Intensive Outpatient Program (IOP) Services with New Condition Code 92.
12424	Implement Edits to Prevent Payment of Complexity Add-On Code G2211 When Associated Office/Outpatient Evaluation and Management Visit (Codes 99202–99205, 99211–99215) is Reported With Modifier 25.
12426	Calendar Year (CY) 2024 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment.
	Medicare Secondary Payer (CMS-Pub. 100–05)
12304	Changes to The Electronic Correspondence Referral System (ECRS) Web, Including Modified Medicare Secondary Payer (MSP) Health Insurance Master Record (HIMR) Screen and Remote Identity Process (RIDP). Attachment 1—ECRS Web User Guide, Software Version 7.4 2023/October 2. Attachment 2—ECRS Web Quick Reference Card Version 7.4 2023/October 2.
	Medicare Financial Management (CMS-Pub. 100–06)
12297	Notice of New Interest Rate for Medicare Overpayments and Underpayments—1st Qtr Notification for FY 2024.
12323	Revisions and Deletions to the Internet Only Manual (IOM), Publication 100–06, Chapter 4, Debt Collection Related to Extended Repayment Schedules (ERS) and Debt Management. Rates of Interest. Procedures for Applying Interest During Overpayment Recoupment. Recoupment by Withholding Payments. Establishing an Extended Repayment Schedule. Extended Repayment Schedule (ERS) Required Documentation—Physician is a Sole Proprietor. Extended Repayment Schedule (ERS) Required Documentation—Provider is an Entity Other Than a Sole Proprietor.

Transmittal No.	Manual/subject/publication No.
	Extended Repayment Schedule (ERS) Approval Process. Sending the Extended Repayment Schedule (ERS) Request to the Regional Office (RO). Monitoring an Approved Extended Repayment Schedule (ERS) and Reporting Requirement. Requests from Terminated Providers or Debts that are Pending Referral to Department of Treasury.
12329	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files to the Provider and Statistical Reimbursement (PS&R) System.
12346	Revisions and Deletions to the Internet Only Manual (IOM), Publication 100–06, Chapter 4, Debt Collection Related to Extended Repayment Schedules (ERS) and Debt Management. Rates of Interest. Procedures for Applying Interest During Overpayment Recoupment. Recoupment by Withholding Payments. Establishing an Extended Repayment Schedule (ERS). Extended Repayment Schedule (ERS) Required Documentation—Physician is a Sole Proprietor. Extended Repayment Schedule (ERS) Required Documentation—Provider is an Entity Other Than a Sole Proprietor. 4/50.3/Extended Repayment Schedule (ERS) Approval Process. 4/50.4/Sending the Extended Repayment Schedule (ERS) Request to the Regional Office (RO). Monitoring an Approved Extended Repayment Schedule (ERS) and Reporting Requirements. Requests from Terminated Providers or Debts that are Pending Referral to Department of Treasury.
Medicare State Operations Manual (CMS-Pub. 100–07)	
	None.
Medicare Program Integrity (CMS-Pub. 100–08)	
12279	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12280	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12281	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12295	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12296	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12300	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12302	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12333	Updates of Chapter 4 and Chapter 8 in Publication (Pub.) 100–08, Including Adding Guidance Regarding Handling of Freedom Information Act (FOIA) Requests. Requests for Information From Outside Organizations. Duration of the Payment Suspension. DME Payment Suspensions (MACs and UPICs). Non-DME National Payment Suspensions (MACs and UPICs).
12336	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12356	Incorporation of Recent Provider Enrollment Regulatory Changes into Chapter 10 of CMS Publication (Pub.) 100–08—Physician Fee Schedule (PFS) Final Rule. Additional Definitions. Marriage and Family Therapists (MFTs). Mental Health Counselors (MHCs). Medicare Diabetes Prevention Program (MDPP) Suppliers. Providers/Suppliers Not Eligible to Enroll. Denials—General Principles. Denial Reasons. Additional Denial Policies. Changes of Information. Revocation Effective Dates. Revocation Reasons. Reenrollment Bar. Additional Revocation Policies. Establishing Effective Dates. Opting-Out of Medicare. Appeals Process. Revalidation Notification Letters.
12358	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12393	Incorporation of Recent Provider Enrollment Regulatory Changes into Chapter 10 of CMS Publication (Pub.) 100–08—Home Health Prospective Payment System (HH PPS) Final Rule.
12394	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12395	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction.
12408	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100–09)	
	None.
Medicare Quality Improvement Organization (CMS-Pub. 100–10)	
	None.

Transmittal No.	Manual/subject/publication No.
	Medicare Program of All-Inclusive Care for the Elderly (CMS-Pub. 100–11)
12338	Update to the Internet Only Manual (IOM) Publication (Pub.) 100–11, IOM Chapter 4 Enrollment and Disenrollment.
	Medicare End Stage Renal Disease Network Organizations (CMS Pub 100–14)
	None.
	Medicaid Program Integrity Disease Network Organizations (CMS Pub 100–15)
	None.
	Medicare Managed Care (CMS-Pub. 100–16).
	None.
	Medicare Business Partners Systems Security (CMS-Pub. 100–17).
	None.
	Medicare Prescription Drug Benefit (CMS-Pub. 100–18)
	None.
	Demonstrations (CMS-Pub. 100–19).
12320	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction.
12348	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction.
12365	Guiding an Improved Dementia Experience (GUIDE) Model Implementation.
12366	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction.
12383	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction.
12390	Making Care Primary (MCP) Model Implementation.
12412	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction.
	One Time Notification (CMS-Pub. 100–20).
12286	Patient Driven Payment Model (PDPM) Corrections to Interrupted Stay Edits.
12292	Implementation to Expand Monetary Amount Fields Related to Billing and Payment to Accommodate 10-Digits in Length ($99,999,999.99)—Phase 2.
12303	Adjustment to Fraud Prevention System (FPS) and Unified Program Integrity Contractor (UPIC) Edits to Increase Billing Increments From 30 Days to 90 Days for Continuous Glucose Monitor (CGM) Supplies.
12308	User Enhancement Change Request (UECR): ViPS Medicare System (VMS)—Hold Data on the Program Integrity Management Reporting (PIMR) Audit Record History Screen (BUDS19).
12309	Fiscal Intermediary Shared System (FISS) User Enhancement Change Request (UECR)—Expiration of a Unique Tracking Number (UTN) on the Prior Authorization (PA) Tracking File.
12310	Fiscal Intermediary Shared System (FISS) User Enhancement Change Request (UECR)—New Reason Code to Prevent Adjustments and Cancels From Being Submitted for the Same Claim, on the Same Day.
12313	User Enhancement Change Request (UECR)—Update the Multi-Carrier System (MCS) to Add a Location Field to the Data Correction Window in the MCS Desktop Tool (MCSDT).
12314	User Enhancement Request (UECR)—Update the Multi-Carrier System (MCS) to Create a Summary Report for Healthcare Integrated General Ledger Accounting System (HIGLAS) Interface File Errors.
12317	User Enhancement Change Request (UECR): New Multi-Carrier System (MCS) Inquiry Search Screen Using a Procedure Code to Display an Associated Edit or Audit.
12318	International Classification of Diseases, 10th Revision (ICD–10) and Other Coding Revisions to National Coverage Determinations (NCDs)—April 2024 Update—CR 1 of 2.
12319	International Classification of Diseases, 10th Revision (ICD–10) and Other Coding Revisions to National Coverage Determinations (NCDs)—April 2024 Update—CR 2 of 2.
12324	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12327	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12328	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction.
12330	Implement Edits on Hospice Claims.
12331	Report of Hospice Election for Part D (Response File).
12334	Remittance Advice (RA) Changes due to Durable Medical Equipment Medicare Administrative Contractors (DME MACs) Transition to Healthcare Integrated General Ledger Accounting System (HIGLAS).
12335	Allowing Audiologists to Furnish Certain Diagnostic Tests Without a Physician Order.
12340	Implementation to Expand Monetary Amount Fields Related to Billing and Payment to Accommodate 10-Digits in Length ($99,999,999.99)—Phase 3.
12345	Implementation of a National Fee Schedule for Medicare Part B Vaccine Administration CMS.
12349	Pricing and Coding Services (PCS) Application Programming Interface (API) Report Dissemination Proof of Concept.
12350	International Classification of Diseases, 10th Revision (ICD–10) and Other Coding Revisions to National Coverage Determinations (NCDs)—April 2024 Update—CR 2 of 2.
12351	Requirements for a Provider Direct Mailing and Education & Outreach for Behavioral Health Initiatives.
12353	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.

Transmittal No.	Manual/subject/publication No.
12355	International Classification of Diseases, 10th Revision (ICD–10) and Other Coding Revisions to National Coverage Determinations (NCDs)—January 2024 Update.
12362	User Enhancement Change Request (UECR): ViPS Medicare System (VMS)—Fix Beneficiary Update and Display System (BUDS) Queries for Remark Code and Biller Number.
12363	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12367	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12368	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
12392	Enforcing Billing Requirements for Intensive Outpatient Program (IOP) Services with Revenue Code 0905 for Federally Qualified Health Centers (FQHC) and Rural Health Clinics (RHC).
12397	Payment of Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions.
12405	Direct Mailing Notification to Hospice Providers Regarding the Value-Based Insurance Design (VBID) Model, Hospice Benefit Component, Participating Medicare Advantage Organizations.
12410	Updating Calendar Year (CY) 2024 Medicare Diabetes Prevention Program (MDPP) Payment Rates.
12428	Provider Education for the Review Choice Demonstration (RCD) for Inpatient Rehabilitation Facility Services (IRFs).
Medicare Quality Reporting Incentive Programs (CMS-Pub. 100–22)	
12293	Payments to Home Health Agencies That Do Not Submit Required Quality Data This CR Rescinds and Fully Replaces CR 10874.
12294	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction.
State Payment of Medicare Premiums (CMS-Pub. 100–24).	
	None.
Information Security Acceptable Risk Safeguards (CMS-Pub. 100–25).	
	None.

For questions or additional information, contact Ismael Torres (410–786–1864).

Addendum II: Regulation Documents Published in the Federal Register (October Through December 2023)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register**, contact GPO at *www.gpo.gov/fdsys.* When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through *GPO Access.* The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at *http://www.gpoaccess.gov/fr/index.html.* The following website *http://www.archives.gov/federal-register/* provides information on how to access electronic editions, printed editions, and reference copies.

For questions or additional information, contact Terri Plumb (410–786–4481).

Addendum III: CMS Rulings (October Through December 2023)

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings.*

For questions or additional information, contact Tiffany Lafferty (410–786–7548).

Addendum IV: Medicare National Coverage Determinations (October Through December 2023)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. For the purposes of this quarterly notice, there were no specific updates to national coverage determinations (NCDs), or reconsiderations of completed NCDs published in the 3-month period. This information is available at: *www.cms.gov/medicare-coverage-database/.*

For questions or additional information, contact Wanda Belle, MPA (410–786–7491).

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (October Through December 2023)

(Inclusion of this addenda is under discussion internally.)

Addendum VI: Approval Numbers for Collections of Information (October Through December 2023)

All approval numbers are available to the public at *Reginfo.gov.* Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This

information is available at *www.reginfo.gov/public/do/PRAMain.*

For questions or additional information, contact William Parham (410–786–4669).

Addendum VII: Medicare-Approved Carotid Stent Facilities (October Through December 2023)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: *http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage.*

For questions or additional information, contact Sarah Fulton, MHS (410–786–2749).

Facility	Provider No.	Date approved	State
The following facilities are new listings for this quarter			
HCA Florida Englewood Hospital, 700 Medical Boulevard, Englewood, FL 34223	1639122864	09/09/2023	FL
Kaiser Permanente San Francisco, Medical Center, 2425 Geary Blvd Provider, San Francisco, CA 94115	050076	09/09/2023	CA
Sanford Bemidji Medical Center, 1300 Anne Street NW, Bemidji, MN 56601	240100	09/09/2023	MN
The following facilities have editorial changes (in bold)			
From: Galichia Heart Hospital, To: Wesley Woodlawn Hospital, 2610 N. Woodlawn Boulevard, Wichita, KS 67220–2729.	170123	05/16/2005	KS
From: Presence Resurrection Medical Center, To: Ascension Resurrection, 7435 West Talcott Avenue, Chicago, IL 60631.	140117	04/12/2005	IL
From: Fort Walton Beach Medical Center, To: HCA Fort Walton—Destin Hospital, 1000 Mar Walt Drive, Fort Walton Beach, FL 32547.	100223	04/14/2005	FL
From: Trumbull Memorial Hospital, To: Trumbull Regional Medical Center, 1350 E Market Street, Warren, OH 44483.	1053844671	03/14/2013	OH

Addendum VIII: American College of Cardiology's National Cardiovascular Data Registry Sites (October Through December 2023)

The initial data collection requirement through the American College of Cardiology's National Cardiovascular Data Registry (ACC–NCDR) has served to develop and improve the evidence base for the use of ICDs in certain Medicare beneficiaries. The data collection requirement ended with the posting of the final decision memo for Implantable Cardioverter Defibrillators on February 15, 2018.

For questions or additional information, contact Sarah Fulton, MHS (410–786–2749).

Addendum IX: Active CMS Coverage-Related Guidance Documents (October Through December 2023)

CMS issued a guidance document on November 20, 2014 titled ''Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document''. Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at *http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27.*

CMS published three proposed guidance documents on June 22, 2023 to provide a framework for more predictable and transparent evidence development and encourage innovation and accelerate beneficiary access to new items and services. The documents are available at:

https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=35&docTypeId=1&sortBy=title&bc=16.

https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=34&docTypeId=1&sortBy=title&bc=16.

https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=33&docTypeId=1&sortBy=title&bc=16.

For questions or additional information, contact Lori Ashby, MA (410 786 6322).

Addendum X: List of Special One-Time Notices Regarding National Coverage Provisions (October Through December 2023)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at *http://www.cms.gov.*

For questions or additional information, contact JoAnna Baldwin, MS (410–786 7205).

Addendum XI: National Oncologic PET Registry (NOPR)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on positron emission tomography (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at *http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage.*

For questions or additional information, contact David Dolan, MBA (410–786–3365).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (October Through December 2023)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at *http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage.*

For questions or additional information, contact David Dolan, MBA, (410–786–3365).

Facility	Provider No.	Date of initial certification	Date of re-certification	State
The following facility is a new listing.				
St. Bernard's Medical Center, 225 East Washington, Jonesboro, AR 72401 ..... *Other information: DNV–GL ID #:* C624530 *Previous Re-certification Dates:* n/a	040020	08/31/2023		AR
The following facilities have editorial changes (in bold).				
Sentara Norfolk General Hospital, 600 Gresham Drive, Norfolk, VA 23507 ..... *Other information: DNV–GL ID #:* C592382 *Previous Re-certification Dates:* 11/13/2008; 12/21/2010; 02/05/2013; 01/13/2015; 03/14/2017; 4/20/2019; 10/07/2021	49–0007	11/13/2008	09/05/2023	VA
Presbyterian Medical Center of the UPHS, 51 North 39th Street, Philadelphia, PA 19104. *Other information:* Joint Commission ID #6145 *Previous Re-certification Dates:* 10/05/2010; 11/07/2012; 12/09/2014; 03/21/2017; 4/17/2019; 07/29/2021	390223	10/05/2010	06/28/2023	PA
University of Alabama at Birmingham, 619 19th S. South, Birmingham, AL 35249–1900. *Other information:* Joint Commission ID # 2814 *Previous Re-certification Dates:* 12/09/2008; 04/22/2011; 04/09/2013; 04/07/2015; 05/16/2017; 7/3/2019; 08/21/2021	010033	10/29/2003	07/27/2023	AL
Virginia Commonwealth University Health System Authority, 1250 East Marshall Street, Richmond, VA 23298–051. *Other information:* Joint Commission ID # 6381 *Previous Re-certification Dates:* 11/04/2008; 12/14/2010; 12/21/2012;12/16/2014; 02/14/2017; 04/10/2019; 08/07/2021	490032	04/08/2004	07/19/2023	VA
Fresno Community Hospital and Medical Center, 2823 Fresno St., Fresno, CA 93721. *Other information:* Joint Commission ID # 9832 *Previous Re-certification Dates:* 1/04/2014; 12/13/2016; 2/13/2019; 08/11/2021	050060	01/04/2014	08/09/2023	CA
University Hospital (Stony Brook), Health Sciences Center Suny Stony Brook, Stony Brook, NY 11794–8503. *Other information:* Joint Commission ID # 5188 *Previous Re-certification Dates:* 01/30/2013; 01/15/2015; 03/14/2017; 05/08/2019; 09/17/2021	330393	03/02/2011	08/09/2023	NY
Maimonides Medical Center, 4802 Tenth Avenue, Brooklyn, NY 11219–2916 ..... *Other information:* Joint Commission ID #5734 *Previous Re-certification Dates:* 08/23/2012; 07/29/2014; 09/13/2016; 10/11/2018; 10/27/2021	330194	08/23/2012	10/18/2023	NY
The General Hospital Corporation, 55 Fruit Street, Boston, MA 02114 ..... *Other information:* Joint Commission ID# 5513 *Previous Re-certification Dates:* 12/08/2008; 01/19/2011; 02/13/2013; 01/06/2015; 02/28/2017; 05/22/2019; 10/14/2021	220071	12/15/2003	09/07/2023	MA
Montefiore Health System, 111 East 210th StreetM Bronx, NY 10467 ..... *Other information:* Joint Commission ID #2514 *Previous Re-certification Dates:* 09/23/2008; 10/08/2010; 10/23/2012; 09/23/2014; 10/08/2016; 11/07/2018; 10/29/2021	330059	11/14/2003	10/04/2023	NY
Bryan Medical Center, 1600 South 48th Street, Lincoln, NE 68506 ..... *Other information:* Joint Commission ID # 244330 *Previous Re-certification Dates:* 03/05/2013; 02/12/2015; 04/18/2017; 07/17/2019; 09/22/2021	280003	03/05/2013	08/23/2023	NE
Nebraska Medical Center, 987400 Nebraska Medical Center, Omaha, NE 68198–7400. *Other information:* Joint Commission ID # 186313	280013	02/02/2011	08/16/2023	NE

Facility	Provider No.	Date of initial certification	Date of re-certification	State
Previous Re-certification Dates: 01/20/2011; 01/29/2013; 02/24/2015; 02/14/2017; 04/17/2019; 09/09/2021				
Dignity Health, 350 West Thomas Road, Phoenix, AZ 85013	030024	05/08/2019	08/26/2023	AZ
Other information: Joint Commission ID # 9494				
Previous Re-certification Dates: 05/08/2019; 08/19/2021				
From: Norton Hospitals Inc.	180088	09/17/2020	10/13/2023	KY
To: Norton Audubon Hospital, 1 Audubon Plaza Drive, Louisville, KY 40217				
Other information: DNV ID #: C553570				
Previous Re-certification Dates: 09/17/2020				
From: University of Virginia Medical Center	490009	02/12/2010	09/15/2023	VA
To: Rector & Visitors of the University of Virginia, 1215 Lee Street, Charlottesville, VA 22903				
Other information: Joint Commission ID #: 6329				
Previous Re-certification Dates: 03/21/2012; 05/06/2014; 06/07/2016; 06/06/2018; 10/13/2021				
Temple University Hospital, Inc., 3401 North Broad Street, Philadelphia, PA 19140	390027	02/08/2012	09/13/2023	PA
Other information: Joint Commission ID #: 6152				
Previous Re-certification Dates: 02/08/2012; 02/11/2014; 04/07/2016; 04/04/2018; 10/13/2021				
Prisma Health Richland, 5 Richland Medical Park Drive, Columbia, SC 29203	420018	03/07/2013	09/13/2023	SC
Other information: Joint Commission ID #: 6588				
Previous Re-certification Dates: 03/06/2013; 04/21/2015; 06/06/2017; 6/28/2019; 10/08/2021				
Hillcrest Medical Center, 1120 S. Utica, Tulsa, OK 74104	370001	12/04/2017	11/17/2023	OK
Other information: DNV #: C584663				
Previous Re-certification Dates: 12/04/2017; 11/25/2020				
Beth Israel Deaconess Medical Center, 330 Brookline Avenue, Boston, MA 02215	220086	04/25/2017	09/29/2023	MA
Other information: Joint Commission ID #: 5501				
Previous Re-certification Dates: 4/25/2017; 05/22/2019; 11/04/2021				
Yale New Haven Hospital, 20 York Street, New Haven, CT 06510–3203	070022	01/25/2011	12/13/2023	CT
Other information: Joint Commission ID #: 5677				
Previous Re-certification Dates: 01/25/2011; 01/15/2013; 12/16/2014; 02/28/2017; 5/22/2019; 11/24/2021				
UMass Memorial Health Care, Inc, One Biotech Park 365 Plantation Street, Worcester, MA 01605.	220163	02/06/2019	10/27/2023	MA
Other information: Joint Commission ID #: 5640				
Previous Re-certification Dates: 02/06/2019; 11/06/2021				
North Carolina Baptist Hospital, dba Atrium Health Wake Forest Baptist, Medical Center Boulevard, Winston Salem, NC 27157.	340047	06/28/2011	10/25/2023	NC
Other information: Joint Commission ID #: 6571				
Previous Re-certification Dates: 06/28/2011; 08/13/2013; 08/04/2015; 08/18/2017; 10/9/2019; 10/16/2021				
Memorial Hermann—Texas Medical Center, 6411 Fannin Street, Houston, TX 77030–1501.	450068	03/19/2013	12/22/2023	TX
Other information: Joint Commission ID #: 9081				
Previous Re-certification Dates: 03/19/2013; 04/14/2015; 05/24/2017; 06/26/2019; 12/23/2021				
Cleveland Clinic Florida, 3100 Weston Road, Weston, FL 33331	100289	05/19/2015	11/02/2023	FL
Other information: Joint Commission ID #: 334451				
Previous Re-certification Dates: 05/19/2015; 06/20/2017; 7/24/2019; 11/04/2021				

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (October Through December 2023)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. For the purposes of this quarterly notice, there are no additions and deletions to a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. This information is available at *www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage.*

For questions or additional information, contact Sarah Fulton, MHS (410–786–2749).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (October Through December 2023)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery

procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at *www.cms.gov/MedicareApproved Facilitie/BSF/list.asp#TopOfPage.*

For questions or additional information, contact Sarah Fulton, MHS (410–786–2749).

Addendum XV: FDG–PET for Dementia and Neurodegenerative Diseases Clinical Trials (October Through December 2023)

There were no FDG–PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at *www.cms.gov/Medicare ApprovedFacilitie/PETDT/list.asp# TopOfPage.*

For questions or additional information, contact David Dolan, MBA (410–786–3365).

[FR Doc. 2024–01785 Filed 1–29–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4207–NC]

RIN 0938–ZB84

Medicare Program; Request for Information on Medicare Advantage Data

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: This request for information (RFI) seeks input from the public regarding various aspects of Medicare Advantage (MA) data. Responses to this RFI may be used to inform general efforts to strengthen Centers for Medicare & Medicaid Services' (CMS') MA data capabilities and guide policymaking.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by May 29, 2024.

ADDRESSES: In commenting, refer to file code CMS–4207–NC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this document to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4207–NC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4207–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Ilina Chaudhuri, (410) 786–8628.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

In a request for information that appeared in the **Federal Register** on August 1, 2022 (87 FR 46918) (hereinafter referred to as 2022 General MA RFI), CMS sought feedback on ways to strengthen Medicare Advantage (MA) to align with the Vision for Medicare (*https://www.cms.gov/blog/building-cms-strategic-vision-working-together-stronger-medicare*) and the CMS Strategic Pillars (*https://www.cms.gov/about-cms/what-we-do/cms-strategic-plan*). The 2022 General MA RFI set out to create more opportunities for stakeholders to engage with CMS, and in alignment with the agency's Strategic Pillars, prioritize increased engagement throughout the policy process with our partners and the communities we serve. As a result of this commitment, we received more than 4,000 responses from a wide variety of voices. One key theme that emerged was an interest in greater beneficiary protections, such as strengthened MA marketing regulations and prior authorization protections. Respondents also focused on issues related to payment, including accurate risk adjustment and value-based payment arrangements between providers and insurers, as well as competition in the market, such as topics related to insurer consolidation and vertical integration. Additionally, we received strong feedback from respondents who stated that CMS should have comprehensive high-quality MA programmatic data and promote more program transparency through increased public releases of MA data. Respondents underscored the urgency for more complete MA data and data transparency as enrollment in MA

has for the first time reached half of all people enrolled in Medicare.[1]

Recommendations regarding MA data included calls for CMS to collect and release more MA data on key areas of concern, such as supplemental benefit costs and utilization, value-based payment arrangements between providers and plans, utilization management and prior authorization including denials and appeals and access to inpatient services and post-acute care, network adequacy and provider directory accuracy, competitive forces in the market such as the effects of market shifts and vertical integration and consolidation on consumers, care outcomes, and Medicare Loss Ratios (MLRs). Commenters also raised data considerations on topics such as MA marketing activity, especially predatory behavior, care outcomes and data available in MA compared to Traditional Medicare (Medicare Parts A and B), and geographic impacts including on rural areas, among other important topic areas. Respondents emphasized that CMS should improve its data capabilities to measure impacts of MA on underserved communities. HHS' Office of Inspector General (OIG), the Government Accountability Office (GAO), and the Medicare Payment Advisory Commission (MedPAC) have pointed out program areas that would benefit from better or more MA data as well.[2]

During the Biden-Harris Administration, we have finalized policies for 2024 [3] and proposed policies [4] that will improve MA data capabilities, among other important MA policy changes. We have also issued requirements for collecting more data related to supplemental benefits in the updated Part C reporting requirements,[5] required MA organizations to improve prior authorization processes [6] and final interoperability requirements,[7] and begun collecting race and ethnicity data on a voluntary basis on MA and Part D enrollment forms.[8]

This RFI is an extension of our ongoing work on MA data as we solicit feedback from the public on how best to meet the shared goals of enhancing data capabilities to have better insight into our programs, consider areas to increase MA data transparency, and propose future rulemaking. Our eventual goal is to have, and make publicly available, MA data commensurate with data available for Traditional Medicare to advance transparency across the Medicare program, and to allow for analysis in the context of other health programs like accountable care organizations, the Marketplace, Medicaid managed care, integrated delivery systems, among others.

II. Solicitation of Public Comments

We encourage feedback from a wide array of interested parties, including beneficiaries and beneficiary advocates, plans, providers, community-based organizations, researchers, employers and unions, and all other interested parties, including the public at large. Our interest in this RFI is to solicit comments on all aspects of data related to the MA program. Intimate knowledge of CMS' current data availability or capability is not needed to provide input on the aspects of MA for which commenters think policymakers and the public should have more data.

In this RFI, CMS requests comments on all aspects of data related to the MA program—both data not currently collected as well as data currently collected. We are especially interested in: data-related recommendations related to beneficiary access to care including provider directories and networks; prior authorization and utilization management, including denials of care and beneficiary experience with appeals processes as well as use and reliance on algorithms; cost and utilization of different supplemental benefits; all aspects of MA marketing and consumer decision-making; care quality and outcomes, including value-based care arrangements and health equity; healthy competition in the market, including the impact of mergers and acquisitions, high levels of enrollment concentration, and the effects of vertical integration, data topics related to Medicare Advantage prescription drug plans (MAPDs); and special populations such as individuals dually eligible for Medicare and Medicaid, individuals with end stage renal disease (ESRD), and other enrollees with complex conditions. We ask that academic researchers and other data analysts provide precise detail and definitions on the data format, fields, and content that would facilitate comprehensive analyses of any publicly released MA data, including comparisons with existing data sets, for example, between Traditional Medicare and MA. Additionally, we seek detail regarding the rationale, goals, and questions that you could address with newly released data and suggestions for how such data could support new action or regulation by CMS. We are also interested to hear if you have insight in ways in which CMS could leverage existing private sector data.

It would also be helpful for plans, providers, data vendors, and other stakeholders with a deep understanding of MA data to provide recommendations related to operational considerations as part of this effort. Comments are welcome on ways that we could improve our current MA data collection and release methods, including recommendations on the preferred cadence of data releases. Finally, we seek detailed information from beneficiary advocates, health care providers, and other stakeholders on common challenges and experiences in

[1] From ''Medicare Advantage and Medicare Prescription Drug Programs to Remain Stable in 2024'', available at *https://www.cms.gov/newsroom/press-releases/medicare-advantage-and-medicare-prescription-drug-programs-remain-stable-2024.*

[2] Examples of such studies and reports include: ''Priority Open Recommendations: Department of Health and Human Services.'' May 2023. *https://www.gao.gov/assets/gao-23-106467.pdf;* ''The Inability To Identify Denied Claims in Medicare Advantage Hinders Fraud Oversight.'' OEI–03–21–00380. March 2023. *https://oig.hhs.gov/oei/reports/OEI-03-21-00380.asp;* ''Medicare Advantage: Plans Generally Offered Some Supplemental Benefits, but CMS Has Limited Data on Utilization.'' Jan 2023. *https://www.gao.gov/products/gao-23-105527;* ''OIG's Top Unimplemented Recommendations: Solutions to Reduce Fraud, Waste, and Abuse in HHS Programs.'' 2022. *https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2022.pdf;* ''CMS Generally Ensured That Medicare Part C and Part D Sponsors Did Not Pay Ineligible Providers for Services to Medicare Beneficiaries.'' A–02–20–01027. Oct 2022. *https://oig.hhs.gov/oas/reports/region2/22001027.pdf;* ''Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care.'' OEI–09–18–00260. Apr 2022. *https://oig.hhs.gov/oei/reports/oei-09-18-00260.asp;* ''Medicare Advantage Organizations Are Missing Opportunities To Use Ordering Provider Identifiers to Protect Integrity.'' OEI Report OEI–03–19–00432. Apr 2021. *https://oig.hhs.gov/oei/reports/OEI-03-19-00432.asp; https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch7_medpac_reportto congress_sec.pdf;* ''*The Inability To Identify Denied Claims in Medicare Advantage Hinders Fraud Oversight.*'' *(OEI–03–21–00380) March 2023. https://oig.hhs.gov/oei/reports/OEI-03-21-00380.asp.*

[3] *https://www.cms.gov/newsroom/fact-sheets/2024-medicare-advantage-and-part-d-final-rule-cms-4201-f.*

[4] *https://www.cms.gov/newsroom/fact-sheets/contract-year-2025-policy-and-technical-changes-medicare-advantage-plan-program-medicare; https://www.cms.gov/newsroom/fact-sheets/contract-year-2024-policy-and-technical-changes-medicare-advantage-and-medicare-prescription-drug.*

[5] *https://www.cms.gov/medicare/enrollment-renewal/health-plans/part-c.*

[6] *https://www.cms.gov/newsroom/fact-sheets/contract-year-2024-policy-and-technical-changes-medicare-advantage-and-medicare-prescription-drug; https://www.cms.gov/newsroom/fact-sheets/contract-year-2025-policy-and-technical-changes-medicare-advantage-plan-program-medicare.*

[7] *https://www.cms.gov/newsroom/fact-sheets/cms-interoperability-and-prior-authorization-final-rule-cms-0057-f.*

[8] *https://www.cms.gov/regulations-and-guidance legislationpaperworkreductionactof1995pra-listing/cms-10718.*

the MA program for which limited data are currently available.

III. Collection of Information Requirements

This is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. In addition, this RFI does not commit the Government to any policy decision and CMS will follow established methods for proposing future policy changes, including the MA Advance Notice and Rate Announcement process. We note that not responding to this RFI does not preclude participation in any future procurement or rulemaking, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this RFI.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on January 22, 2024.

Dated: January 25, 2024.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–01832 Filed 1–25–24; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Office of Human Services Emergency Preparedness and Response Disaster Human Services Case Management Intake Assessment, Resource Referral, and Case Management Plan

AGENCY: Office of Human Services Emergency Preparedness and Response, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Human Services Emergency Preparedness and Response (OHSEPR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting an extension for approval of the following information collection: OHSEPR Disaster Human Services Case Management Intake Assessment, Resource Referral, and Case Management Plan; OMB No.: 0970–0619. This information collection was originally approved for 6 months through an emergency approval.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* All emailed requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: OHSEPR is seeking to continue data collection with all forms approved under OMB No. 0970–0619, which OMB recently approved through an emergency approval for 6 months. OHSEPR's Disaster Human Services Intake Assessment, Resource Referral, and Case Management Plan collection is part of a system of tools that OHSEPR utilizes to support disaster survivors during response missions. OHSEPR's case managers would use this collection during an intake assessment to identify a disaster survivor's unmet needs and to work with the survivor to develop a case management plan based on the survivor's responses.

Respondents: Disaster survivors.

ANNUAL BURDEN ESTIMATES

Data collection	Annual number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Disaster Human Services Case Management Intake Assessment—Survivor	9,000	1	1.5	13,500
Case Management Plan—Case Manager	180	50	1	9,000
Resource Referral Form—Case Manager	180	50	1	9,000
Case Record Notes—Case Manager	180	50	1	9,000
Survivor Satisfaction Survey—Survivor	9,000	1	.25	2,250
Estimated Total Annual Burden Hours:	.....	.....	.....	42,750

Authority: The Disaster Human Services Case Management Program is authorized through appropriations language under the Children and Families Services account. It is operated by the ACF Office of Human Services

Emergency Preparedness and Response, which is the lead in HHS for human service preparation for, response to, and recovery from, natural disasters.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–01728 Filed 1–29–24; 8:45 am]

BILLING CODE 4184–PC–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0404]

Considerations for the Development of Chimeric Antigen Receptor T Cell Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products; Guidance for Industry.'' The guidance is intended to assist sponsors, including industry and academic sponsors, developing ex vivo-manufactured CAR T cell products. The guidance provides CAR T cell specific recommendations regarding chemistry, manufacturing, and control (CMC), pharmacology and toxicology, and design of clinical studies for oncology indications (including hematologic malignancies and solid tumors). The guidance announced in this notice finalizes the draft guidance of the same title dated March 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on January 30, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–0404 for ''Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products; Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products; Guidance for Industry.'' The guidance is intended to assist sponsors, including industry and academic sponsors, developing ex vivo-manufactured CAR T cell products. The guidance provides CAR T cell specific recommendations regarding CMC, pharmacology and toxicology, and design of clinical studies for oncology indications (including hematologic malignancies and solid tumors). Recommendations

specific to autologous or allogeneic CAR T cell products are noted in the guidance. The guidance also provides recommendations for analytical comparability studies for CAR T cell products. While the guidance specifically focuses on CAR T cell products, some of the information and recommendations provided may also be applicable to other genetically modified lymphocyte products, such as CAR Natural Killer cells or T cell receptor modified T cells.

In the **Federal Register** of March 16, 2022 (87 FR 14893), FDA announced the availability of the draft guidance of the same title dated March 2022. FDA received numerous comments on the draft guidance and those comments were considered as the guidance was finalized. Changes to the guidance include clarifying the scope, focusing on treatment for oncology indications, and the recommendations for CAR T cells manufactured using cellular starting material from patients who have received CAR T cells previously, potency for CAR T cells that express multiple transgene elements, stability studies, and clinical monitoring. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated March 2022.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of another human gene therapy final guidance entitled ''Human Gene Therapy Products Incorporating Human Genome Editing; Guidance for Industry.''

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 50 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 211 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR part 1271 have been approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Date: January 24, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01789 Filed 1–29–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–3561]

Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for Food and Drug Administration-Regulated Medical Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products.'' The purpose of this guidance is to provide FDA's expectations for, and recommendations on, use of a standardized approach for collecting and reporting race and ethnicity data in submissions including information collected and reported from clinical studies and clinical trials for FDA-regulated medical products. Using standard terminology for race and ethnicity helps ensure that data are collected and reported consistently in submissions to FDA. This draft guidance revises the final guidance for industry and FDA staff entitled ''Collection of Race and Ethnicity Data in Clinical Trials'' issued on October 26, 2016.

DATES: Submit either electronic or written comments on the draft guidance by April 29, 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–2016–D–3561 for ''Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993–0002, 301–796–2500; James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7256, Silver Spring, MD 20993, 240–402–7911; or Office of Minority Health and Health Equity, *healthequity@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products.'' FDA's recommended approach is based on the Office of Management and Budget (OMB) Statistical Policy Directive No. 15 (Policy Directive 15) and was developed in accordance with section 4302 of the Affordable Care Act (42 U.S.C. 300kk); the Health and Human Services Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status; and the Food and Drug Administration Safety and Innovation Act (FDASIA) Section 907 Action Plan.[1]

OMB standards for the classification of Federal data on race and ethnicity were developed to provide a common framework for uniformity and consistency in the collection and use of data on race and ethnicity by Federal agencies (Policy Directive 15). This guidance provides recommendations on:

1. Meeting the requirements set forth in the 1998 final rule (63 FR 6854, February 11, 1998) regarding presentation of demographic data in investigational new drug applications and new drug applications (known as the Demographic Rule);

2. Collection of race and ethnicity data in biologics license applications (BLAs) and medical device applications; and

3. Addressing the FDASIA Section 907 Action Plan to improve the completeness and quality of demographic data collection and reporting.

This guidance is also intended to help an applicant preparing a BLA or medical device application, which should be done in accordance with the OMB standards described in the guidance.

In the **Federal Register** of January 27, 2023 (88 FR 5375) OMB announced a formal review of OMB Policy Directive 15 and requested public comments on initial proposals to revise the directive to account for large societal, political, and economic demographic shifts in the United States over the 25 years since its publication. FDA intends to update this guidance as appropriate if OMB revises Policy Directive 15.

This guidance revises the final guidance for industry and FDA staff entitled ''Collection of Race and Ethnicity Data in Clinical Trials'' issued in October 2016. When finalized, this guidance will replace the October 2016 guidance. Changes from the 2016 version include broadening the draft guidance to include non-interventional (observational) clinical studies in addition to the interventional clinical trials discussed in the 2016 guidance. Other changes include a revised title and editorial changes for clarity, as well as updated references and contact information for FDA.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no new 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 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB Control Number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB Control Number 0910–0001; the collections of information in 21 CFR part 601 have been approved under OMB Control Number 0910–0338; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB Control Number 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB Control Number 0910–0078; the

[1] *https://www.fda.gov/media/89307/download.*

collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB Control Number 0910–0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB Control Number 0910–0332; the collections of information in 21 CFR part 860, subpart D, have been approved under OMB Control Number 0910–0844; and the collections of information in 42 CFR part 11 have been approved under OMB Control Number 0925–0586.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov.*

Dated: January 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01782 Filed 1–29–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0398]

Human Gene Therapy Products Incorporating Human Genome Editing; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Human Gene Therapy Products Incorporating Human Genome Editing; Guidance for Industry.'' The guidance document provides recommendations to sponsors developing human gene therapy products incorporating genome editing (GE) of human somatic cells. Specifically, the guidance provides recommendations regarding information that should be provided in an investigational new drug (IND) application to assess the safety and quality of the investigational GE product, including information on product design, product manufacturing and testing, nonclinical safety assessment, and clinical trial design. The guidance announced in this notice finalizes the draft guidance of the same title dated March 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on January 30, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–0398 for ''Human Gene Therapy Products Incorporating Human Genome Editing.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See

the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Human Gene Therapy Products Incorporating Human Genome Editing; Guidance for Industry.'' The guidance document provides recommendations to sponsors developing human gene therapy products incorporating GE of human somatic cells. Specifically, the guidance provides recommendations regarding information that should be provided in an IND application to assess the safety and quality of the investigational GE product, including information on product design, product manufacturing and testing, nonclinical safety assessment, and clinical trial design.

In the **Federal Register** of March 16, 2022 (87 FR 14897), FDA announced the availability of the draft guidance of the same title dated March 2022. FDA received numerous comments on the draft guidance and those comments were considered as the guidance was finalized. Changes to the guidance include clarifying the recommendations for GE components used only once (for example, in the manufacture of a master cell bank), expectations for potency assays, considerations for nonclinical studies with respect to potential for off-target toxicity, and applicability of accelerated approval to GE products. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated March 2022.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of another human gene therapy final guidance document entitled ''Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products; Guidance for Industry.''

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Human Gene Therapy Products Incorporating Human Genome Editing.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR parts 210 and 211 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 1271 have been approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: January 24, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01788 Filed 1–29–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0016]

Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Oncologic Drugs Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on March 14, 2024, from 9:30 a.m. to 3 p.m. eastern time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2024–N–0016. The docket will close on March 13, 2024. 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 March 13, 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.

Comments received on or before February 29, 2024, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–0016 for ''Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–2855, email: *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. The Committee will discuss new drug application (NDA) 217779 for imetelstat for injection, submitted by Geron Corporation. The proposed indication for this product is for the treatment of transfusion-dependent anemia in adult patients with low- to intermediate-1 risk myelodysplastic syndromes who have failed to respond or have lost response to or are ineligible for erythropoiesis-stimulating agents.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before February 29, 2024, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 1:15 p.m. and 2:15 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 21, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 22, 2024.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact LaToya Bonner (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers.

The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: January 25, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01797 Filed 1–29–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Interest Rate on Overdue Debts

Section 30.18 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest, which is determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that the Department of Health and Human Services becomes entitled to recovery. The rate cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the ''Schedule of Certified Interest Rates with Range of Maturities'' unless the Secretary waives interest in whole or part, or a different rate is prescribed by statute, contract, or repayment agreement. The Secretary of the Treasury may revise this rate quarterly. The Department of Health and Human Services publishes this rate in the **Federal Register**.

The current rate of 12 ⅜%, as fixed by the Secretary of the Treasury, is certified for the quarter ended December 31, 2023. This rate is based on the Interest Rates for Specific Legislation, ''National Health Services Corps Scholarship Program (42 U.S.C. 254o(b)(1)(A))'' and ''National Research Service Award Program (42 U.S.C. 288(c)(4)(B)).'' This interest rate will be applied to overdue debt until the Department of Health and Human Services publishes a revision.

David C. Horn,

Director, Office of Financial Policy and Reporting,

[FR Doc. 2024–01817 Filed 1–29–24; 8:45 am]

BILLING CODE 4150–048–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel; AD/ADRD Management Evolution.

Date: March 19, 2024.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Maurizio Grimaldi, M.D., Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Bldg., Suite 2C218, Bethesda, MD 20892, 301–496–9374, *grimaldim2@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 25, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–01816 Filed 1–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, PAR Panel Hypersensitivity, Allergies and Mucosal Immunology, February 08, 2024, 10:00 a.m. to February 08, 2024, 07:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, which was published in the **Federal Register** on January 19, 2024, 89 FR 3675, Doc 2024–00948.

This meeting is being amended to change the SRO Contact Person from Velasco Cimica, Ph.D., to Marcus Ferrone, Ph.D., Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, *Marcus.Ferrone@nih.gov,* 301–402–2371. This amendment supersedes the previous amendment because the name of the meeting was mistakenly omitted in the first amendment and to provide the new SRO's contact information. The meeting is closed to the public.

Dated: January 24, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–01778 Filed 1–29–24; 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; Cure Glomerulonephropathy (CureGN) Review.

Date: March 19, 2024.

Time: 1:00 p.m. to 4:00 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: Paul A. Rushing, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7345, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8895, *rushingp@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes,

Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 25, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–01815 Filed 1–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Board of Scientific Counselors, National Cancer Institute, March 04, 2024, 11:00 a.m. to March 05, 2024, 01:30 p.m., National Cancer Institute, 9609 Medical Center Drive, Rockville, MD, 20892 which was published in the **Federal Register** on October 30, 2023, FR Doc 2023–23881, 88 FR 74198.

This notice is being amended to change the meeting start and end times on March 4–5, 2024. On March 4, 2024, the open session will now be held from 10:00 a.m. to 10:45 a.m. and the closed session will now be held from 11:00 a.m. to 4:10 p.m. On March 5, 2024, the closed session will now be held from 10:00 a.m. to 12:30 p.m. The meeting will be held as a virtual meeting and is partially closed to the public.

Dated: January 24, 2024.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–01777 Filed 1–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 General Medical Sciences Special Emphasis Panel; Review of Support for Research Excellence—First Independent Research (SuRE-First) Award (R16).

Date: March 27, 2024.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of General Medical Sciences, Natcher Building, 45 Center Drive, Bethesda, Maryland 20892 (Virtual Meeting).

Contact Person: Jason M. Chan, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of General Medical Sciences, 45 Center Drive, MSC 6200, Bethesda, Maryland 20892, 301–594–3663, *jason.chan2@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: January 25, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–01819 Filed 1–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; Chemical Threat Agent-induced Pulmonary and Ocular Pathophysiological (CCRP)-Tissue Specific Mode of Action Meeting.

Date: February 21, 2024.

Time: 10:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences; Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P. O. Box 12233, MD EC–30/Room 3171, Research Triangle Park, NC 27709, 984–287–3340, *worth@niehs.nih.gov.*

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; Chemical Threat Agent Exposure Resource and Coordination Core (ExRC) Meeting.

Date: February 22, 2024.

Time: 10:30 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences; Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P. O. Box 12233, MD EC–30/Room 3171, Research Triangle Park, NC 27709, 984–287–3340, *worth@niehs.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: January 25, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–01811 Filed 1–29–24; 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; Acute Renal Injury Sequelae in NICU Graduates (ARISING).

Date: March 7, 2024.

Time: 1:00 p.m. to 2:30 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: Paul A. Rushing, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7345, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8895, *rushingp@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 25, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–01814 Filed 1–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; AMSC Member Conflict Review.

Date: February 20, 2024.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kan Ma, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, NIH, 6701 Democracy Boulevard, Suite 814, Bethesda, MD 20892, 301–451–4838, *mak2@mail.nih.gov.*

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; NIAMS AMS Member Conflict Review Meeting.

Date: March 12, 2024.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sushmita Purkayastha, Ph.D., Scientific Review Officer, Scientific Review Branch National Institute of Arthritis, Musculoskeletal and Skin Diseases, NIH, One Democracy Plaza, 6701 Democracy Boulevard, Room 814, Bethesda, MD 20892, *sushmita.purkayastha@nih.gov.*

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; P30 Core Centers for Clinical Research Meeting.

Date: March 14–15, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kan Ma, Ph.D., Scientific Review Officer Scientific Review Branch National Institute of Arthritis, Musculoskeletal and Skin Diseases, NIH, 6701 Democracy Boulevard, Suite 814, Bethesda, MD 20892, 301–451–4838, *mak2@mail.nih.gov.*

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; NIAMS Ancillary Studies Review Meeting.

Date: March 19, 2024.

Time: 10:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Archana Jha, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, NIH, 6701 Democracy Boulevard, Suite 800, Bethesda, MD 20892 301–480–2159 *archana.jha@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: January 25, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–01812 Filed 1–29–24; 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 Initial Review Group; Diabetes, Endocrinology and Metabolic Diseases B Study Section Diabetes, Endocrinology and Metabolic Diseases B Study Section (DDK–B).

Date: March 6–8, 2024.

Time: 10:00 a.m. to 3:30 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: Charlene J. Repique, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7347, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7791, *charlene.repique@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 25, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–01822 Filed 1–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Maximizing Investigators' Research Award A Study Section.

Date: February 20–21, 2024.

Time: 9:30 a.m. to 8:00 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: Mollie Kim Manier, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–0510, *mollie.manier@nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Human Complex Mental Function Study Section.

Date: February 20–21, 2024.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joanna Szczepanik, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1000D, Bethesda, MD 20892, (301) 827–2242, *szczepaj@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Pregnancy and Neonatology Study Section.

Date: February 20–21, 2024.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Andrew Maxwell Wolfe, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, Bethesda, MD 20892, (301) 402–3019, *andrew.wolfe@nih.gov.*

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Basic Mechanisms of Cancer Health Disparities Study Section.

Date: February 21–22, 2024.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Sulagna Banerjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Bethesda, MD 20892, (612) 309–2479 *sulagna.banerjee@nih.gov.*

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Pathobiology of Kidney Disease Study Section.

Date: February 21–22, 2024.

Time: 9:00 a.m. to 8:00 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: Atul Sahai, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2188, MSC 7818 Bethesda, MD 20892 301–435–1198 *sahaia@csr.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Neurological, Mental and Behavioral Health Study Section.

Date: February 21–22, 2024.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Allison Kurti, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1007J, Bethesda, MD 20892, (301) 594–1814, *kurtian@csr.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Science of Implementation in Health and Healthcare Study Section.

Date: February 21–22, 2024.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health; Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Hybrid Meeting).

Contact Person: Wenjuan Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3154, Bethesda, MD 20892, (301) 480–8667, *wangw22@mail.nih.gov.*

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Therapeutic Development and Preclinical Studies Study Section.

Date: February 21–22, 2024.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Richard D. Schneiderman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, Bethesda, MD 20817, 301–402–3995, *richard.schneiderman@nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Aging Systems and Geriatrics Study Section.

Date: February 21–22, 2024.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Roger Alan Bannister, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1010–D, Bethesda, MD 20892, (301) 435–1042, *bannisterra@csr.nih.gov.*

Name of Committee: Interdisciplinary Molecular Sciences and Training Integrated Review Group; Cellular and Molecular Technologies Study Section.

Date: February 21–22, 2024.

Time: 9:30 a.m. to 8:00 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: Tatiana V. Cohen, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Room 5213, Bethesda, MD 20892, 301–455–2364, *tatiana.cohen@nih.gov.*

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Integrative Myocardial Physiology/Pathophysiology B Study Section.

Date: February 21–22, 2024.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kirk E. Dineley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 806E, Bethesda, MD 20892, (301) 867–5309, *dineleyke@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 25, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–01821 Filed 1–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Literature Selection Technical Review Committee, February 22, 2024, 8 a.m. to 4 p.m. and February 23, 2024, 10 a.m. to 4 p.m., which was published in the **Federal Register** on December 21, 2023, 88 FR 244, Page 88404.

This meeting will be amended to change the meeting times to 10 a.m. to 4 p.m. for both days. The entire meeting will be closed to the public, other than an open session on February 22, 2024 from 1:30 p.m. to 1:50 p.m.

The open session of the meeting will be virtual. Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice no later than 7 days prior to the meeting. The statement should include the name, address, telephone number and, when applicable, the business or professional affiliation of the interested person. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Dianne Babski, Associate Director, Division of Library Operations, National Library of Medicine at *babskid@mail.nih.gov.* The open session will be videocast and can be accessed from the NIH Videocast website at *https://videocast.nih.gov/.*

Dated: January 25, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–01825 Filed 1–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel; Aging Hormone Study.

Date: March 19, 2024.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ramesh Vemuri, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Bldg., Suite 2C212, Bethesda, MD 20892, 301–402–7700, *rv23r@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 25, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–01820 Filed 1–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; NIEHS Support for Conferences and Scientific Meetings.

Date: February 28, 2024.

Time: 11:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

Contact Person: Alfonso R. Latoni, Ph.D., Senior Advisor to the Director and Scientific Review Officer, Office of the Division Director, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709, (984) 287–3279, *alfonso.latoni@nih.gov.*

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; External In Vivo & In Vitro Toxicological Evaluation within the Division of Translational Toxicology (DTT).

Date: February 29, 2024.

Time: 10:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate contract proposals,

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting),

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30/Room 3171, Research Triangle Park, NC 27709, 984–287–3340, *worth@niehs.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: January 25, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–01823 Filed 1–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS–NIH–CDC–SBIR PHS 2024–1 Phase I and Phase II: Adjuvant Discovery and Down-Selection for Vaccines against Infectious and Immune-Mediated Diseases (Topic 130).

Date: February 23, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31B, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: James T. Snyder, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31B, Rockville, MD 20892, (240) 669–5060, *james.snyder@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 24, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–01776 Filed 1–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Arthritis and Musculoskeletal and Skin Diseases Initial Review Group; Arthritis and Musculoskeletal and Skin Diseases Clinical Trials Study Section.

Date: February 22–23, 2024.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Sushmita Purkayastha, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis and Musculoskeletal and Skin Diseases, 6701 Democracy Boulevard, Room 814, Bethesda, MD 20817, *sushmita.purkayastha@nih.gov.*

Name of Committee: Arthritis and Musculoskeletal and Skin Diseases Initial Review Group; Arthritis and Musculoskeletal and Skin Diseases Special Grants Study Section.

Date: February 29–March 1, 2024.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Yasuko Furumoto, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis and Musculoskeletal and Skin Diseases, 6701 Democracy Boulevard, Room 820, Bethesda, MD 30892, 301–827–7835, *yasuko.furumoto@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: January 25, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–01813 Filed 1–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket Number DHS–2023–0017]

Agency Information Collection Activities: USSS Citizens Academy Application, Electronic Form

AGENCY: Department of Homeland Security (DHS).

ACTION: 30-Day notice and request for comments.

SUMMARY: The Department of Homeland Security will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. DHS Previously published this ICR in the **Federal Register** on Friday, November 17, 2023 for a 60-day public comment period. There was one comment received by DHS. The purpose of this notice is to allow additional 30-days for public comments

DATES: Comments are encouraged and will be accepted until February 29, 2024. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: You may submit comments, identified by docket number Docket #DHS–2023–0017, at:

○ *Federal eRulemaking Portal: https://www.regulations.gov.* Please follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number Docket #DHS–2023–0017. All comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.*

SUPPLEMENTARY INFORMATION: The Agency has initiated a Citizens Academy to inform the public about its mission, focused on participation from local community leaders. The academy will take place in local Agency field offices. Prior to participating, applicants will need to provide information as their community leadership role and provide PII so that a background investigation can be conducted to check for criminal history, open warrants, etc. The application allows for the Agency to gather the information necessary for each applicant to determine if they are eligible for participation. Authority to collect the information sought on this form is derived from Title 28 U.S.C. 599A, 28 CFR 0.130, and 18 U.S.C. 3056.

This will be a new collection of information. The Agency has initiated a Citizens Academy for local community members, who will need to fill out an application to express interest and to provide PII for the Agency to initiate a background investigation for the applicants prior to participating in the USSS Citizens Academy. The information will be gathered by electronic submission of the USSS Citizens Academy Application to local Agency Field Offices. Applicant information will also be used to contact any applicants placed on a wait list to join future USSS Citizens Academies.

All information collected will be via electronic submission. The applicant will receive a PDF form via email to complete and submit to the agency. All respondents are individuals, not small businesses/entities.

The collection will only occur one time per year upon initial application to the Agency requesting to participate in the USSS Citizens Academy. There would be no way to reduce the frequency or else community members

would not be able to apply for the USSS Citizens Academy. There is no change in the burden as this is a new collection.

While the Agency does not provide any assurance of confidentiality, information provided by the respondents will be protected from disclosure to the extent appropriate under the applicable provisions of the Freedom of Information Act and the Privacy Act of 1974. Personally identifying information will be collected and transmitted in accordance with the Privacy Act. However, to the extent that the information collected is Sensitive Security Information (SSI) as defined in 49 CFR part 1520, Protection of Sensitive Security Information, such information is protected from public disclosure.

The application provides a Privacy Act Statement and requests signed Consent to collect the information. Further, this collection is covered under DHS/ALL–023—Department of Homeland Security Personnel Security Management, which is the baseline system for personnel security activities to ensure that all DHS components follow the same privacy rules for collecting and handling personnel security management records (74 FR 3084, January 16, 2009).

The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Analysis

Agency: Department of Homeland Security (DHS).

Title: USSS Citizens Academy Application.

OMB Number: 1620–NEW.

Frequency: Annually.

Affected Public: Individuals.

Number of Respondents: 80.

Estimated Time per Respondent: 15 Minutes.

Total Burden Hours: 20 Hours.

Laura Chavez,

Deputy Division Chief, Enterprise Policy Division, Office of Strategic Planning and Policy.

[FR Doc. 2024–01780 Filed 1–29–24; 8:45 am]

BILLING CODE 9110–18–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7087–N–01]

60-Day Notice of Proposed Information Collection: Requirements for Notification, Evaluation and Reduction of Lead-Based Paint Hazards in Federally-Owned Residential Properties and Housing Receiving Federal Assistance; OMB Control No.: 2539–0009

AGENCY: Office of Lead Hazard Control and Healthy Homes, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for renewal of the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* April 1, 2024.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be submitted within 60 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting, ''Currently under 60-day Review—Open for Public Comments'' or by using the search function. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and can be sent to: Anna Guido, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000 or email at *PaperworkReductionActOffice@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Anna Guido, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email; *Anna.P.Guido@hud.gov;* telephone (202) 402–5535 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for renewal of the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Requirements for Notification, Evaluation and Reduction of Lead-Based Paint Hazards in Federally-Owned Residential Properties and Housing Receiving Federal Assistance.

OMB Approval Number: 2539–0009.

Type of Request: Revision of a currently approved collection with some changes due to program changes.

Form Number: Not applicable.

Description of the need for the information and proposed use: Provision of a pamphlet on lead poisoning prevention to tenants and purchasers; provision of a notice to occupants on the results of lead hazard evaluation or reduction activities; special reporting requirements for a child with an environmental intervention blood lead level; and recordkeeping and periodic summary reporting requirements. Required notifications under the Lead Safe Housing Rule, 24 CFR 35.

Respondents: Residential property owners; housing agencies; Federal grantees; and tribally designated housing entities and/or participating jurisdictions.

The revised hour burden estimates are presented in the table below. In the table, the 16.58 hourly cost per response reflects the weighted average of cases, first, in which the respondent is simply giving someone a pamphlet, putting something in a file, or retrieving something from a file, and sending summary information from it to the Department, valued at $11.26 per hour; and second, processing notices as above as well as providing information in cases of lead-poisoned children, valued at $18.00 per hour.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Total	63,000	As needed	Various	2.2	138,600	$16.58	$2,297,988

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comments in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Matthew Ammon,

Director, Office of Lead Hazard Control and Healthy Homes.

[FR Doc. 2024–01759 Filed 1–29–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7092–N–13]

Privacy Act of 1974; System of Records

AGENCY: Office of the Chief Financial Officer (OCFO), HUD.

ACTION: Notice of a modified system of records.

SUMMARY: Line of Credit Controls System (LOCCS), an Office of the Chief Financial Officer (OCFO) system, is a disbursement and cash management system that services the funding needs of HUD's grant, loan, and subsidy clients. Under the Privacy Act of 1974, the Department of Housing and Urban Development, the Office of the Chief Financial Officer proposes to update the system of records titled, Line of Credit Controls System. This system of records allows the Department of Housing and Urban Development OCFO's LOCCS to collect and maintain records on grantees. Because of a review of this system, information has been updated within the System Location section of the SORN and the authorities to collect information for LOCCS has been updated.

DATES: Comments will be accepted on or before February 29, 2024. The SORN becomes effective immediately, while the routine uses become effective after the comment period immediately upon publication except for the routine uses, which will become effective on the date following the end of the comment period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number by one of these methods:

Federal e-Rulemaking Portal: https://www.regulations.gov. Follow the instructions provided on that site to submit comments electronically.

Fax: 202–619–8365.

Email: www.privacy@hud.gov. Mail: Attention: Privacy Office; Ladonne L. White; The Executive Secretariat; 451 Seventh Street SW, Room 10139; Washington, DC 20410–1001.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *https://www.regulations.gov.* including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: LaDonne White; 451 Seventh Street SW, Room 10139; Washington, DC 20410; telephone number 202–708–3054 (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: The following are to be updated:

- The system location is being changed. LOCCS records are no longer in South Charleston, WV. It is at HUD Headquarters; Microsoft Azure Cloud US East Data Center. Microsoft is responsible for securing their data center per FedRAMP requirements.
- Routine uses previously included by reference are not explicitly listed in the SORN. This change adds no new routine uses, but merely reorganizes them. The routine uses included by reference to HUD's Appendix I are now explicitly listed.
- Remove instances of Program Accounting System (PAS) because it has been decommissioned. A new module has been added to LOCCS. LOCCS incorporated the entire Program Accounting System (PAS) functionality in this new Award Funding module. PAS users now access LOCCS to perform their daily tasks in the LOCCS Award Funding Module. However, no new Personally Identifiable Information (PII) is being collected, stored, maintained, or disclosed because of the PAS module being incorporated. Social Security Numbers have been removed from the system.
- Authority for Maintenance of the System: Replace ''Sec. 113 of the Budget and Accounting Act of 1951 (31 U.S.C.66a)'' with ''31 U.S.C. 3511''
- Updated Categories of Individuals Covered by System
- Updated Policies and Practices for Retention and Disposal of Records
- Slight changes to the Record Access Procedures, Contesting Records Procedures, and Notification Procedures sections have been made. Minor non-substantive changes have been made to these sections to more accurately describe HUD's practices for accessing, contesting, and notifying.

SYSTEM NAME AND NUMBER:

Line of Credit Control System (LOCCS, A67).

SECURITY CLASSIFICATION:

Sensitive but Unclassified.

SYSTEM LOCATION:

HUD Headquarters, 451 7th Street SW, Washington, DC 20410 and Microsoft Azure Cloud US East Data Center.

SYSTEM MANAGER(S):

Sairah Ijaz, Assistant Chief Financial Officer for Systems, Office of the Chief

Financial Officer, Department of Housing and Urban Development, 451 Seventh Street SW, Room 3100, Washington, DC 20410

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

- 31 U.S.C. 3511
- The Chief Financial Officers Act of 1990 (31 U.S.C. 901, *et seq.*)
- Executive Order 9397, as amended by Executive Order 13478
- Housing and Community Development Act of 1987, 42 U.S.C. 3543

PURPOSE(S) OF THE SYSTEM:

The system is to process and make grant, loan, and subsidy disbursements. LOCCS ensures that payments are made promptly thus achieving efficient cash management practices. It creates accounting transactions with the appropriate accounting classification elements to correctly record disbursements and collections to the grant/project level subsidiary.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Section 8 Contract Administrators (S8CA) and grant recipients (excludes Section 8 Voucher Program).

CATEGORIES OF RECORDS IN THE SYSTEM:

Vendor name, Vendor Number (*e.g.* EIN, SSN, or TIN), address, DUNS, Banking Account/Routing numbers, and financial data.

RECORD SOURCE CATEGORIES:

Section 8 Contract Administrators and grant recipients provide data to Ft. Worth Accounting Center to enter LOCCS.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES

(1) To the National Archives and Records Administration (NARA) and the General Services Administration (GSA) for records having sufficient historical or other value to warrant its continued preservation by the United States Government, or for inspection under authority of title 44, chapter 29, of the United States Code.

(2) To a congressional office from the record of an individual, in response to an inquiry from the congressional office made at the request of that individual.

(3) To appropriate Federal, State, and local governments, or persons, under showing compelling circumstances affecting the health or safety or vital interest of an individual or data subject, including assisting such agencies or organizations in preventing the exposure to or transmission of a communicable or quarantinable disease, or to combat other significant public health threats, if upon such disclosure appropriate notice was transmitted to the last known address of such individual to identify the health threat or risk.

(4) To Federal agencies, non-Federal entities, their employees, and agents (including contractors, their agents or employees; employees or contractors of the agents or designated agents); or contractors, their employees or agents with whom HUD has a contract, service agreement, grant, cooperative agreement, or computer matching agreement for: (1) detection, prevention, and recovery of improper payments; (2) detection and prevention of fraud, waste, and abuse in major Federal programs administered by a Federal agency or non-Federal entity; (3) detection of fraud, waste, and abuse by individuals in their operations and programs, but only if the information shared is necessary and relevant to verify pre-award and prepayment requirements before the release of Federal funds, prevent and recover improper payments for services rendered under programs of HUD or of those Federal agencies and non-Federal entities to which HUD provides information under this routine use.

(5) (a) To contractors, grantees, experts, consultants, Federal agencies, and non-Federal entities, including, but not limited to, State and local governments and other research institutions or their parties, and entities and their agents with whom HUD has a contract, service agreement, grant, or cooperative agreement, when necessary to accomplish an agency function, related to a system of records, for statistical analysis and research supporting program operations, management, performance monitoring, evaluation, risk management, and policy development, or to otherwise support the Department's mission. Records under this routine use may not be used in whole or in part to make decisions that affect the rights, benefits, or privileges of specific individuals. The results of the matched information may not be disclosed in identifiable form.

(b) To a recipient who has provided the agency with advance, adequate written assurance that the record provided from the system of records will be used solely for statistical research or reporting purposes. Records under this condition will be disclosed or transferred in a form that does not identify an individual.

(6) To contractors, grantees, experts, consultants and their agents, or others performing or working under a contract, service, grant, or cooperative agreement with HUD, when necessary to accomplish an agency function related to a system of records. Disclosure requirements are limited to only those data elements considered relevant to accomplishing an agency function. Individuals provided information under these routine use conditions are subject to Privacy Act requirements and disclosure limitations imposed on the Department.

(7) To contractors, experts and consultants with whom HUD has a contract, service agreement, or other assignment of the Department, when necessary to utilize data to test new technology and systems designed to enhance program operations and performance.

(8) (a) To appropriate agencies, entities, and persons when (1) HUD suspects or has confirmed there has breached the system of records; (2) HUD has determined that because of the suspected or confirmed breach there is a risk of harm to individuals, HUD, the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist with HUD's efforts to respond to the suspected or confirmed breach to prevent, minimize, or remedy such harm.

(9) To another Federal agency or Federal entity, when HUD 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) To appropriate Federal, State, local, tribal, or governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where HUD determines that the information would help to enforce civil or criminal laws when such records, either alone or in conjunction with other information, indicate a violation or potential violation of law.

(11) To a court, magistrate, administrative tribunal, or arbitrator while presenting evidence, including disclosures to opposing counsel or witnesses in civil discovery, litigation, mediation, or settlement negotiations; or in connection with criminal law proceedings; or in response to a

subpoena or to a prosecution request when such records to be released are specifically approved by a court provided order. Disclosures made pursuant to this routine use are limited to when HUD determines that use of such records is relevant and necessary to the litigation, provided, however, that in each case, HUD determines that the disclosure of the records is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

(12) To the Department of Justice (DOJ) when seeking legal advice for a HUD initiative or in response to DOJ's request for the information, after either HUD or DOJ determine that such information relates to DOJ's representatives of the United States or any other components in legal proceedings before a court or adjudicative body, provided that, in each case, the agency also determines before disclosure that disclosure of the records to DOJ is a use of the information in the records that is compatible with the purpose for which HUD collected the records. HUD on its own may disclose records in this system of records in legal proceedings before a court or administrative body after determining that disclosing the records to the court or administrative body is a use of the information in the records that is compatible with the purpose for which HUD collected the records.

(13) To the U.S. Treasury for transactions such as disbursements of funds and related adjustments;

(14) To the IRS for reporting payments for goods and services and for reporting of discharge indebtedness;

(15) Disclosures under 5 U.S.C. 552a(b)(12). Disclosures may be made from the system to consumer reporting agencies as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f) or the Federal Claims Collection Act of 1966, 31 U.S.C. 3701(a)(3)). The disclosure is limited to information to establish the identity of the individual, including name, social security number, and address; the amount, status, history of the claim, and the agency or program under which the claim arose solely to allow the consumer reporting agency to prepare a credit report.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Electronic files are stored on servers. Paper printouts or original input documents are stored in locked file cabinets at HUD or as imaged documents on magnetic media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by business partner name, tax ID number, schedule number, voucher number, and contract number.

POLICIES AND PRACTICIES FOR RENTENTION AND DISPOSAL OF RECORDS:

General Records Schedule 1:1; Financial Management and Reporting Records. This schedule covers records created by Federal agencies in carrying out the work of financial management. Temporary. Destroy 6 years after final payment or cancellation, but longer retention is authorized if required for business use.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

All HUD employees have undergone background investigations. HUD buildings are guarded and monitored by security personnel, cameras, ID checks, and other physical security measures. Access is restricted to authorized personnel or contractors whose responsibilities require access. System users must take the mandatory security awareness training annually as mandated by the Federal Information Security Modernization Act (FISMA) (44 U.S.C. 3541, *et seq.*). Users must also sign a Rules of Behavior form certifying that they agree to comply with the requirements before they are granted access to the system. LOCCS resides on the Microsoft Azure Cloud, a FedRAMP certified Infrastructure-as-a-Service (IaaS). The system is limited to those with a business need to know. LOCCS Authorizing Officials authorize LOCCS access for users, and OCFO ensures the user is eligible for access (*e.g.* suitability, System Security Administrator approval), which allow for segregation of duties. Also, system user recertifications is conducted semi-annually for external users and quarterly for internal users.

RECORD ACCESS PROCEDURES:

Individuals requesting records of themselves should address written inquiries to the Department of Housing Urban and Development 451 7th Street SW, Washington, DC 20410–0001. For verification, individuals should provide their full name, current address, and telephone number. In addition, the requester must provide either a notarized statement or an unsworn declaration made under 24 CFR 16.4.

CONTESTING RECORD PROCEDURES:

The HUD rule for accessing, contesting, and appealing agency determinations by the individual concerned are published in 24 CFR part 16 or may be obtained from the system manager.

NOTIFICATION PROCEDURES:

Individuals requesting notification of records of themselves should address written inquiries to the Department of Housing Urban Development, 451 7th street SW, Washington, DC 20410–0001. For verification purposes, individuals should provide their full name, office or organization where assigned, if applicable, and current address and telephone number. In addition, the requester must provide either a notarized statement or an unsworn declaration made under 24 CFR 16.4.

EXEMPTIONS PROMULGATED FOR THE SYSTEM: NONE.

HISTORY: 87 FR 50640.

LaDonne L. White,

Chief, Privacy Officer.

[FR Doc. 2024–01768 Filed 1–29–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7092–N–14]

Privacy Act of 1974; System of Records

AGENCY: Office of Housing, HUD.

ACTION: Notice of a rescindment of a system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, the Department of the Housing and Urban Development (HUD), the Office of Housing, the Office of Lender Activities and Program Compliance is issuing a public notice of its intent to rescind the Institution Master File (IMF) System, because the system was decommissioned effective June 1, 2017.

DATES: Comments will be accepted on or before February 29, 2024. This proposed action will be effective immediately upon publication.

ADDRESSES: You may submit comments, identified by one of the following methods:

Federal e-Rulemaking Portal: https://www.regulations.gov. Follow the instructions provided on that site to submit comments electronically.

Fax: 202–619–8365.

Email: www.privacy@hud.gov.

Mail: Attention: Privacy Office; LaDonne White, Chief Privacy Officer; The Executive Secretariat; 451 Seventh Street SW, Room 10139; Washington, DC 20410–0001.

Instructions: All submissions received must include the agency name and

docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov* including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: LaDonne White, Chief Privacy Officer; 451 Seventh Street SW, Room 10139; Washington, DC 20410–0001; telephone number (202) 708–3054 (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: The Institution Master File (IMF) System formerly maintained a file of institutions (Title I lenders and Title II mortgagees) which have been approved by HUD to participate in the Federal Housing Administration (FHA) Mortgage Insurance Programs. The principal objective of the IMF was to consolidate information on the approval status of mortgagees and lenders participating in FHA's insurance program. The Leader Electronic Assessment Portal (LEAP) has replaced IMF's role as the system of records and IMF no longer processes lender institution information. The active records for IMF were transferred to LEAP. Any records past its retention time were sent to the Records Warehouse.

SYSTEM NAME AND NUMBER:

Institution Master File (IMF).

HISTORY:

The previously published notice in the **Federal Register** [Docket Number FR–5291–N–05], on August 25, 2009, at 74 FR 42910.

Ladonne White,

Chief Privacy Officer, Office of Administration.

[FR Doc. 2024–01766 Filed 1–29–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7092–N–12]

Privacy Act of 1974; System of Records

AGENCY: Office of Chief Information Officer (OCIO) and Infrastructure and Operations (IOO), HUD.

ACTION: Notice of a new system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, the Department of the Housing and Urban Development (HUD), Office of Chief Information Officer (OCIO) and Infrastructure and Operations (IOO) is issuing a public notice of its intent to create a Privacy Act System of Records titled ''Active Directory (a component of the Local Area Network (LAN) File Server system—LFS)''. The purpose of the LFS is to provide the infrastructure needed to support internal HUD systems locally at all HUD locations. This technology includes Active Directory. Active Directory (AD) stores information about objects on the network and makes this information easy for administrators and users to find and use. Active Directory uses a structured data store as the basis for a logical, hierarchical organization of directory information. The information in Active Directory originates from the Digital Identity and Access Management System (DIAMS).

DATES: Comments will be accepted on or before February 29, 2024. This proposed action will be effective on the date following the end of the comment period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number or by one of the following methods:

Federal e-Rulemaking Portal: https://www.regulations.gov. Follow the instructions provided on that site to submit comments electronically.

Fax: 202–619–8365.

Email: www.privacy@hud.gov.

Mail: Attention: Privacy Office; LaDonne White, Chief Privacy Officer; Office of the Executive Secretariat; 451 Seventh Street SW, Room 10139; Washington, DC 20410–0001.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *https://www.regulations.gov.* including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: LaDonne White; 451 Seventh Street SW, Room 10139; Washington, DC 20410–0001; telephone number 202–708–3054 (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: HUD maintains the Active Directory (AD) system of records. Active Directory Domain Services (ADDS) are the foundation of every Windows domain network. It stores information about domain members, including devices and users, verifies their credentials, and defines their access rights. The server running this service is called a domain controller. A domain controller is contacted when a user logs into a device, accesses another device across the network, or runs a line-of-business Metro-style app sideloaded into a machine. Other Active Directory services and most Microsoft server technologies rely on or use Domain Services.

SYSTEM NAME AND NUMBER:

Active Directory (a component of P209 LAN File Server) HUD/CIO–03.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are maintained at the U.S Housing of Urban and Development 451 7th Street SW, Washington, DC 20410–1000. HUD Data Center locations include the Mid-Atlantic Data Center at 250 Burlington Drive, Clarksville Virginia, 23927 and and the Stennis Data Center at 9300 Building Complex, Stennis, Mississippi 35929.

SYSTEM MANAGER(S):

Jacquelyn Rosales, Network Services Branch Chief, Unified Communication Services Division, 451 7th Street SW, Washington DC, 20410–1000.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Information Technology Management Reform Act of 1996 (Pub. L. 104–106, 40 U.S.C. 11101 *et seq.*), E-Government Act (Pub. L. 107–347, sec. 203, 44 U.S.C. 3501 note), Federal Information Security Management Act, as amended (Pub. L. 107–347, 44 U.S.C. 3554), Paperwork Reduction Act of 1995

(Pub. L. 104–13, 44 U.S.C. 3501 *et seq.*), Government Paperwork Elimination Act (Pub. L. 105–277, Title XVII, 44 U.S.C. 3504), Homeland Security Presidential Directive 12 (HSPD–12), Policy for a Common Identification Standard for Federal Employees and Contractors, August 27, 2004, OMB Circular No. A–130, Managing Information as a Strategic Resource (7/28/2016) OMB Memo M–05–24, and Executive Order 13636—Improving Critical Infrastructure Cyber Security (February 12, 2013).

PURPOSE(S) OF THE SYSTEM:

The purpose of the LAN File Server (LFS) is to provide the infrastructure needed to support internal HUD systems locally at all HUD locations. This technology includes Active Directory. Active Directory stores information about objects on the network and makes this information easy for administrators and users to find and use. Active Directory uses a structured data store as the basis for a logical, hierarchical organization of directory information. This data store, also known as the directory, contains information about Active Directory objects. These objects typically include shared resources such as servers, volumes, printers, and the network user and computer accounts.

A. Supports the provision of user accounts and authenticates users to HUD enterprise Web applications for non-dual personal personnel with HUD's Personal Identity Verification (PIV)—Authentication (Auth) certificate.

B. Provides an Enterprise-wide hierarchical directory structure designed to employ greater centralization and standardization of network management for user data, security, and distributed resources and services across the HUD Enterprise; and

C. Synchronizes with HUD's Azure Active Directory instance for the purpose of Microsoft Azure Cloud Service collaboration, wherein HUD employees and contractors use cloud applications available in the Microsoft 365 application suite.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current HUD employees and contractors.

CATEGORIES OF RECORDS IN THE SYSTEM:

Full Name, Work Phone Number, Work Email Address, and Unique User ID (*e.g.,* H or C ID number), Device Identifier, and internet Protocol (IP)/Media Access Control (MAC) Address of assigned Device Identifier (if applicable).

RECORD SOURCE CATEGORIES:

The information originates from the Digital Identity and Access Management System (DIAMS) managed by HUD.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

1. To contractors, grantees, experts, consultants and their agents, or others performing or working under a contract, service, grant, cooperative agreement, or other agreement with HUD, when necessary to accomplish an agency function related to this system of record. Disclosure requirements are limited to only those data elements considered relevant to accomplishing an agency function.

2. To contractors, experts and consultants with whom HUD has a contract, service agreement, assignment, or other agreement of the Department, when necessary to utilize relevant data for the purpose of testing new technology and systems designed to enhance program operations and performance.

3. To appropriate agencies, entities, and persons when: (1) HUD suspects or has confirmed that there has been a breach of the system of records; (2) HUD has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, HUD (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 HUD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

4. To another Federal agency or Federal entity, when HUD determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to 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.

5. To appropriate Federal, State, local, tribal, or other governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where HUD determines that the information would assist in the enforcement of civil or criminal laws and when such records, either alone or in conjunction with other information, indicate a violation or potential violation of law.

6. To a court, magistrate, administrative tribunal, or arbitrator in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, mediation, or settlement negotiations, or in connection with criminal law proceedings; when HUD determines that use of such records is relevant and necessary to the litigation and when any of the following is a party to the litigation or have an interest in such litigation: (1) HUD, or any component thereof; or (2) any HUD employee in his or her official capacity; or (3) any HUD employee in his or her individual capacity where HUD has agreed to represent the employee; or (4) the United States, or any agency thereof, where HUD determines that litigation is likely to affect HUD or any of its components.

7. To the National Archives and Records Administration, Office of Government Information Services (OGIS), to the extent necessary to fulfill its responsibilities in 5 U.S.C. 552(h), to review administrative agency policies, procedures, and compliance with the Freedom of Information Act (FOIA), and to facilitate OGIS' offering of mediation services to resolve disputes between persons making FOIA requests and administrative agencies.

8. To a congressional office from the record of an individual, in response to an inquiry from the congressional office made at the request of that individual.8. To any component of the Department of Justice or other Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when HUD determines that the use of such records is relevant and necessary to the litigation and when any of the following is a party to the litigation or have an interest in such litigation: (1) HUD, or any component thereof; or (2) any HUD employee in his or her official capacity; or (3) any HUD employee in his or her individual capacity where the Department of Justice or agency conducting the litigation has agreed to represent the employee; or (4) the United States, or any agency thereof, where HUD determines that litigation is likely to affect HUD or any of its components.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Electronic Records.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Full Name and HUD Network ID (H or C ID).

POLICIES AND PRACTICIES FOR RETENTION AND DISPOSAL OF RECORDS:

Under General Records Schedule 3.2, System Access Records, items 030 and 031. Item 030 applies to systems not requiring special accountability for access. Item 030 records can be destroyed when the business use cases. Item 031 applies to systems requiring special accountability for access. Item 031 requires records to be destroyed/deleted 6 years after the user account is terminated or password is altered, or when no longer required for business us, whichever is later. Backup and Recovery digital media will be destroyed or otherwise rendered irrecoverable per NIST SP 800–88, Rev. 1 ''Guidelines for Media Sanitization'' (December 2014).

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

PII is secured in cipher locks, combination locks, key cards, security guards, closed circuit TV and safes. Identification badges are required to ensure the records are not accessed and strict access controls are governed for electronic records using a user ID and password that require authentication before access is granted to Active Directory.

RECORD ACCESS PROCEDURES:

Individuals requesting records of themselves should address written inquiries to the Department of Housing Urban and Development 451 7th Street SW, Washington, DC 20410–0001. For verification, individuals should provide their full name, current address, and telephone number. In addition, the requester must provide either a notarized statement or an unsworn declaration made under 24 CFR 16.4.

CONTESTING RECORD PROCEDURES:

The HUD rule for contesting the content of any record pertaining to the individual by the individual concerned is published in 24 CFR 16.8 or may be obtained from the system manager.

NOTIFICATION PROCEDURES:

Individuals requesting notification of records of themselves should address written inquiries to the Department of Housing Urban Development, 451 7th street SW, Washington, DC 20410–0001. For verification purposes, individuals should provide their full name, office or organization where assigned, if applicable, and current address and telephone number. In addition, the requester must provide either a notarized statement or an unsworn declaration made under 24 CFR 16.4.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

N/A

HISTORY:

N/A.

LaDonne White,

Chief Privacy Officer, Office of Administration.

[FR Doc. 2024–01765 Filed 1–29–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7092–N–15]

Privacy Act of 1974; System of Records

AGENCY: Office of Single Family Asset Management, HUD.

ACTION: Notice of a rescindment of a system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, the Department of the Housing and Urban Development (HUD), the Office of Single-Family Asset Management is issuing a public notice of its intent to rescind the Single-Family Default Monitoring System (SFDMS) because it is consolidated into the Federal Housing Administration (FHA) Catalyst as of March 1, 2022.

DATES: Comments will be accepted on or before February 29, 2024. This proposed action will be effective immediately upon publication.

ADDRESSES: You may submit comments, identified by one of the following methods:

Federal e-Rulemaking Portal: http://www.regulations.gov. Follow the instructions provided on that site to submit comments electronically.

Fax: 202–619–8365.

Email: privacy@hud.gov.

Mail: Attention: Privacy Office; LaDonne White, Chief Privacy Officer; The Executive Secretariat; 451 Seventh Street SW, Room 10139; Washington, DC 20410–0001.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov* including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: LaDonne White, Chief Privacy Officer, 451 Seventh Street SW, Room 10139; Washington, DC 20410; telephone number (202) 708–3054 (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: The Single-Family Default Monitoring System (SFDMS) is used to report mortgages 30 days or more delinquent. The Mortgagee or Servicer must submit a monthly status and/or is terminated or deleted. Under Mortgagee Letter 2021–31, published on December 30, 2021, update to FHA Catalyst Transition for Single-Family Default Monitoring System (SFDMS) Reporting Module, FHA announced that the mortgagee default reporting functionality would be transitioned to the FHA Catalyst: SFDMS Reporting Module and that February 7, 2022. Beginning March 1, 2022, Mortgagees began reporting directly through FHA Catalyst SFDMS module. The method used for retrieving records was assessed, and it was found that the system's records are retrieved using the FHA Case Number (also known as case file number) assigned to the loan. While the system can search using the default borrowers Social Security Numbers, Property Addresses, these fields were never the primary methods of retrieval. The SFDMS system of records is being rescinded since it does not meet the legal definition. All data were handled under HUD's Media Protection Procedures and NIST SP 800–88, Guidelines for Media Sanitization.

SYSTEM NAME AND NUMBER:

Single Family Default Monitoring System (SFDMS), F42D.

HISTORY:

72 FR 65350 (November 20/2007), Agency Docket No. FR–5130–N–16.

Ladonne White,

Chief Privacy Officer, Office of Administration.

[FR Doc. 2024–01767 Filed 1–29–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7087–N–02]

60-Day Notice of Proposed Information Collection: Application for Healthy Homes and Lead Hazard Control Grant Programs and Quality Assurance Plans; OMB Control No.: 2539–0015

AGENCY: Office of Lead Hazard Control and Healthy Homes, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* April 1, 2024.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be submitted within 60 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting, ''Currently under 60-day Review—Open for Public Comments'' or by using the search function. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and can be sent to: Anna Guido, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000 or email at *PaperworkReductionActOffice@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Anna Guido, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email; *Anna.P.Guido@hud.gov;* telephone (202) 402–5535 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Application for Healthy Homes and Lead Hazard Control Grant Programs and Quality Assurance Plans.

OMB Approval Number: 2539–0015.

Type of Request: Renewal with some changes due to program changes.

Form Numbers: SF 424, SF 424, HUD–424CBW, HUD–27061, HUD–2880, HUD–2991, HUD–96008, HUD–96011, SF–LLL, HUD–96012, HUD–96013, HUD–96014, HUD–96015.

Description of the need for the information and proposed use: Applications for Lead-Based Paint Hazard Reduction, Healthy Homes Technical Studies, Lead Technical Studies, Older Adult Home Modification Program, Healthy Homes and Weatherization Cooperation Demonstration grants, Radon Mitigation grants and quality assurance plans for the technical studies grants.

Respondents: Cities, States, counties, municipalities, Public Housing Authorities, universities, non-governmental organizations and private companies.

Estimated Number of Respondents: 450.

Estimated Number of Responses: 1035.

Frequency of Response: Annual.

Average Hours per Response: 60.

Total Estimated Burdens: 62,100 hours; $1,117,800.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comments in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Matthew Ammon,

Director, Office of Lead Hazard Control and Healthy Homes.

[FR Doc. 2024–01760 Filed 1–29–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7080–N–06]

30-Day Notice of Proposed Information Collection: Electronic Closing and Continued First Lien Priority Certificates for FHA-Insured Commercial Mortgage Transactions; OMB Control No.: 2502–0618

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* February 29, 2024.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. 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. Interested persons are also invited to submit comments regarding this proposal and comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Clearance Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000; email *PaperworkReductionActOffice@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, REE, Department of Housing

and Urban Development, 451 7th Street SW, Washington, DC 20410; email *Colette.Pollard@hud.gov;* telephone 202–402–3400. 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 and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on December 11, 2023 at 88 FR 85904.

A. Overview of Information Collection

Title of Information Collection: Electronic Closing and Continued First Lien Priority Certificates for FHA-Insured Commercial Mortgage Transactions.

OMB Approval Number: 2502–0618.

OMB Expiration Date: 03/31/2024.

Type of Request: Revision of currently approved collection.

Form Numbers: HUD–5985L, HUD–5985B, and HUD–5985IRR.

Description of the need for the information and proposed use: HUD is adding to the collection two (2) documents (HUD–5985L and HUD–5985B) that will be used to facilitate uniform electronic closings of FHA-insured commercial mortgage closings, allow for the use of digital signatures and digital records where they are consistent with program obligations, and determine the parties' compliance with applicable legal requirements and therefore ensure protection of the FHA insurance fund; and one (1) document (HUD–5985IRR) that will be used by the FHA Lender to certify to HUD certain conditions required as part of a request to reduce the interest rate of an existing FHA-insured commercial mortgage (often due to market fluctuations that lower the interest rate and save the project money by making this reduction). In addition, the name of this collection is being changed from COVID19 HUD Contingency Plan for HUD Multifamily Rental Project Closing Documents to Electronic Closing and Continued First Lien Priority Certificates for FHA-Insured Commercial Mortgage Transactions.

Respondents: Business or other for-profit, Not-for-profit institutions, State, Local or Tribal Government.

Estimated Number of Respondents: 3,094.

Estimated Number of Responses: 3,217.

Frequency of Response: 1.033 per annum.

Average Hours per Response: 0.833 hour.

Total Estimated Burden: 2,900.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected;

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(5) Ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Colette Pollard,

Department Reports Management Officer, Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2024–01761 Filed 1–29–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037316; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Department of the Interior, Bureau of Land Management, Anchorage, AK

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the U.S. Department of the Interior, Bureau of Land Management (BLM Alaska) has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice. The human remains and associated funerary objects were removed from near Point Hope in the North Slope Borough, AK.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after February 29, 2024.

ADDRESSES: Miriam (Nicole) Hayes, 222 W. 7th Avenue, #13, Anchorage, AK 99513, telephone (907)–271–4354, email *mnhayes@blm.gov.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of BLM Alaska. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by BLM, Alaska State Office.

Description

During 1939–1941, human remains representing, at minimum, 706 individuals were removed from numerous burial locations including at Tigara, Ipiutak, and Jabbertown, all within two miles of Point Hope, AK. These include ones from within what is presently referred to as the Ipiutak early village site that is now within a National Historic Landmark in the southern shore of Ipiutak Lagoon as well as a few from an early 20th century cemetery. The human remains, which are estimated to range in age from around 100 years old up to 2,500 years old, were removed under federal permit in 1939–1941 by archeologists Froelich Rainey and Helge Larsen and others associated with the University of Alaska (UAF) Museum in Fairbanks, AK (now the University of Alaska Museum of the North (UAMN)) and the American Museum of Natural History (AMNH). The human remains were all initially brought back to the AMNH where 701 are presently located with the other five in the UAMN. There are 2,174 associated funerary objects, with 1,462 in the AMNH and 712 in the UAMN.

In 1960, human remains representing, at minimum, three individuals were removed by Fredrick H. West, an archeologist associated with the UAF, from an archeological site near Cape Thompson, AK, about 26 miles southeast of Point Hope, AK. No associated funerary objects are present. These human remains are currently in the UAMN.

In 1961, human remains representing, at minimum, two individuals were removed by W. O. Pruit, an archeologist associated with the UAF, from an archeological site near Cape Thompson, AK, about 26 miles southeast of Point Hope, AK. No associated funerary objects are present. These human remains are currently in the UAMN.

In 1961, human remains representing, at minimum, 46 individuals were removed by Otto W. Geist, an archeologist associated with the UAF, from an archeological site during construction of an airfield near Point Hope, AK. No associated funerary objects are present. These human remains are currently in the UAMN.

In 1975, human remains representing, at minimum, one individual were removed by Anne Shinkwin, an archeologist associated with the UAF, as a surface collection from an archeological site within Point Hope, AK. No associated funerary objects are present. These human remains are currently in the UAMN.

Cultural Affiliation

The human remains and associated funerary objects in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: archeological information and oral tradition.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, BLM Alaska has determined that:

- The human remains described in this notice represent the physical remains of 758 individuals of Native American ancestry.
- The 2,174 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and the Native Village of Point Hope, Point Hope, AK.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after February 29, 2024. If competing requests for repatriation are received, BLM Alaska must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. BLM Alaska is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

This notice was submitted before the effective date of the revised regulations (88 FR 86452, December 13, 2023, effective January 12, 2024). As the notice conforms to the mandatory format of the **Federal Register** and includes the required information, the National Park Service is publishing this notice as submitted.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: January 24, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–01803 Filed 1–29–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037318; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Department of the Interior, National Park Service, Fort Vancouver National Historic Site, Vancouver, WA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the U.S. Department of the Interior, National Park Service, Fort Vancouver National Historic Site (FOVA) has completed an inventory of human remains and an associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice. The human remains and associated funerary objects were removed from Clatsop County, OR.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after February 29, 2024.

ADDRESSES: Tracy Fortmann, Superintendent, Fort Vancouver National Historic Site, 800 Hathaway Road, Building 722, Vancouver, WA 98661, telephone (360) 816–6205, email *Tracy Fortmann@nps.gov.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Superintendent, FOVA. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by FOVA.

Description

Human remains representing, at minimum, one individual were removed from Clatsop County, OR, in 1925 by a private individual. They were donated to the National Park Service at Fort Clatsop National Memorial in 1962 (redesignated Lewis and Clark National Historical Park in 2004). In 1987, the human remains and associated funerary objects were transferred to Fort Vancouver National Historic Site. The seven associated funerary objects are one bag of dentalium shells, one copper kettle, one bag of glass and shell beads, one ceramic plate, and three brass bracelets.

Cultural Affiliation

The human remains and associated funerary objects in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: anthropological information, geographical information, and historical information.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, FOVA has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- The seven objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a relationship of shared group identity that can be reasonably traced between the human remains and associated funerary objects described in this notice and the Confederated Tribes of Siletz Indians of Oregon and the Confederated Tribes of the Grand Ronde Community of Oregon.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes identified in this notice and, if joined to a request from one or more of the Indian Tribes, the Chinook Indian Nation, and the Clatsop-Nehalem Confederated Tribe.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after February 29, 2024. If competing requests for repatriation are received, FOVA must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. FOVA is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

This notice was submitted before the effective date of the revised regulations (88 FR 86452, December 13, 2023, effective January 12, 2024). As the notice conforms to the mandatory format of the **Federal Register** and includes the required information, the National Park Service is publishing this notice as submitted.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: January 24, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–01804 Filed 1–29–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0037315; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Department of the Interior, Fish and Wildlife Service, Stillwater National Wildlife Refuge, Fallon, NV

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the U.S. Department of the Interior, Fish and Wildlife Service, Stillwater National Wildlife Refuge has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice. The human remains and associated funerary objects were removed from Churchill County, NV.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after February 29, 2024.

ADDRESSES: Patrick W. Rennaker, Archaeologist, U.S. Fish and Wildlife Service, Cultural Resources Team, Columbia Pacific Northwest and Pacific Islands (R1), and Pacific Southwest (R8), 20555 Gerda Lane, Sherwood, OR 97140, telephone (503) 294–7490, email *665atrick_rennaker@fws.gov.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Stillwater National Wildlife Refuge. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the Stillwater National Wildlife Refuge.

Description

Human remains representing, at minimum, one individual was removed from Churchill County, NV. In 1969, modern human activity exposed skeletal material in a sand dune near the shore of a small lake located on Stillwater Wildlife Management Area. The site was brought to the attention of the Nevada Archaeological Survey at the Desert Research Institute, Nevada. Dr. Hardesty a professor of anthropology and archaeology at the University of Nevada, Reno inspected the site and determined the likelihood of further damage was high and the best possible recourse at the time was to recover as much of the disturbed material as possible. He recovered all human bone, a mano fragment, and a freshwater shell. Also noted in the vicinity was scattered shell and charcoal to a depth of 15 cm below the surface, but the origin of this material could not be determined. Site dating was not possible as a result. The two associated funerary objects are one stone mano fragment and one shell.

Cultural Affiliation

The human remains and associated funerary objects in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: based on lifeway, oral tradition, folklore, geography, anthropology, ethnography, archeology, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate

Indian Tribes and Native Hawaiian organizations, the Stillwater National Wildlife Refuge has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- The two objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a relationship of shared group identity that can be reasonably traced between the human remains and associated funerary objects described in this notice and the Paiute-Shoshone Tribe of the Fallon Reservation and Colony, Nevada.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after February 29, 2024. If competing requests for repatriation are received, the Stillwater National Wildlife Refuge must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The Stillwater National Wildlife Refuge is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

This notice was submitted before the effective date of the revised regulations (88 FR 86452, December 13, 2023, effective January 12, 2024). As the notice conforms to the mandatory format of the **Federal Register** and includes the required information, the National Park Service is publishing this notice as submitted.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: January 24, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–01802 Filed 1–29–24; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1350]

Certain Integrated Circuits, Components Thereof, and Products Containing the Same; Notice of Request for Submissions on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that on January 19, 2024, the presiding administrative law judge (''ALJ'') issued an Initial Determination on Violation of Section 337. The ALJ also issued a Recommended Determination on remedy and bonding should a violation be found in the above-captioned investigation. The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation. This notice is soliciting comments from the public and interested government agencies only.

FOR FURTHER INFORMATION CONTACT: Lynde Herzbach, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3228. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: Section 337 of the Tariff Act of 1930 provides that, if the Commission finds a violation, it shall exclude the articles concerned from the United States unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry. (19 U.S.C. 1337(d)(1)). A similar provision applies to cease and desist orders. (19 U.S.C. 1337(f)(1)).

The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation, specifically: a limited exclusion order directed to certain integrated circuits, components thereof, and products containing the same imported, sold for importation, and/or sold after importation by respondent Advanced Micro Devices, Inc. of Santa Clara, CA (''AMD''); and cease and desist orders directed to AMD. Parties are to file public interest submissions pursuant to 19 CFR 210.50(a)(4).

The Commission is interested in further development of the record on the public interest in this investigation. Accordingly, members of the public and interested government agencies are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the ALJ's Recommended Determination on Remedy and Bonding issued in this investigation on January 19, 2024. Comments should address whether issuance of the recommended remedial orders in this investigation, should the Commission find a violation, would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the recommended remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third-party suppliers have the capacity to replace the volume of articles potentially subject to the recommended orders within a commercially reasonable time; and

(v) explain how the recommended orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on February 23, 2024.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (Mar. 19, 2020). Submissions should refer to the investigation number (''Inv. No. 337–TA–1350'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing and must be served in accordance with Commission Rule 210.4(f)(7)(ii)(A) (19 CFR 210.4(f)(7)(ii)(A)). All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: January 24, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–01744 Filed 1–29–24; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1318]

Certain Graphics Systems, Components Thereof, and Digital Televisions Containing the Same; Notice of Final Determination Finding a Violation of Section 337; Issuance of a Limited Exclusion Order and Cease and Desist Orders; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined that respondents TCL Industries Holdings Co., Ltd. of Guangdong, China; TCL Industries Holdings (H.K.) Co. Limited of Hong Kong, China; TCL Electronics Holdings Ltd. f/k/a TCL Multimedia Technology Holdings, Ltd. of Hong Kong, China; TCL Technology Group Corporation of Guangdong, China; TTE Corporation of Hong Kong, China; TCL Holdings (BVI) Ltd. of Hong Kong, China; TCL King Electrical Appliances (Huizhou) Co. Ltd. of Guangdong, China; Shenzhen TCL New Technology Co., Ltd. of Guangdong, China; TCL MOKA International Ltd. of Hong Kong, China; TCL Smart Device (Vietnam) Co., Ltd. of Binh Duong Province, Vietnam; Manufacturas Avanzadas SA de CV of Chihuahua, Mexico; TCL Electronics Mexico, S de RL de CV of Benito Juarez, Mexico; TCL Overseas Marketing Ltd. of Hong Kong, China; TTE Technology, Inc. (''TTE Technology'') of Corona, California; and Realtek Semiconductor Corporation (''Realtek'') of Hsinchu, Taiwan (collectively, ''Respondents'') have violated section 337 of the Tariff Act of 1930, as amended, by importing, selling for importation, or selling within the United States after importation certain graphics systems, components thereof, and digital televisions containing the same that infringe claims 19 and 20 of U.S. Patent No. 8,854,381 (''the '381 patent''). The Commission has determined that the appropriate remedies are a limited exclusion order (''LEO'') against the Respondents' infringing products and cease and desist orders (''CDOs'') against each of Respondents except for Realtek. The Commission has also determined to set no (0 percent) bond for importations of the excluded articles imported during the period of Presidential review. This investigation is hereby terminated.

FOR FURTHER INFORMATION CONTACT: Richard P. Hadorn, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3179. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on June 7, 2022, based on a complaint filed by Advanced Micro Devices, Inc. of Santa Clara, California and ATI Technologies ULC of Ontario, Canada (together, ''AMD''). 87 FR 34718–19 (June 7, 2022). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), based on certain graphics systems, components thereof, and digital televisions containing the same by reason of infringement of certain claims of U.S. Patent Nos. 7,742,053 (''the '053 patent''); 8,760,454 (''the '454 patent''); 11,184,628 (''the '628 patent''); 8,468,547 (''the '547 patent''); and the '381 patent. *Id.* at 34718. The complaint further alleges that a domestic industry (''DI'') exists. *Id.* The notice of investigation (''NOI'') named 14 of the respondents listed above (with the exception of TTE Technology). *Id.* at 34719, as amended, 87 FR 62452–53 (Oct. 14, 2022). The Office of Unfair Import Investigations is not named as a party to this investigation. 87 FR at 34719.

On August 4, 2022, the Commission terminated the investigation as to the '454 patent. *See* Order No. 10 (July 14, 2022), *unreviewed by* Comm'n Notice (Aug. 4, 2022).

On September 26, 2022, the Commission allowed TTE Technology to intervene in this investigation as an

additional respondent. *See* Order No. 17 (Aug. 30, 2022), *unreviewed by* Comm'n Notice (Sept. 26, 2022).

On October 7, 2022, the Commission terminated the investigation as to claims 17–21 of the '547 patent and amended the complaint and NOI to correct the names of two respondents by changing ''TCL Industries Holdings (H.K.) Limited'' to ''TCL Industries Holdings (H.K.) Co. Limited,'' and ''Shenzhen TCL New Technologies Co., Ltd.'' to ''Shenzhen TCL New Technology Co., Ltd.'' *See* Order Nos. 23 (Sept. 20, 2022) and 24 (Sept. 20, 2022), *unreviewed by* 87 FR 62452–53 (Oct. 14, 2022). The corrected names of these respondents are included in the list of infringing respondents listed above.

On February 22, 2023, the Commission terminated the investigation as to the '547 patent. *See* Order No. 56 (Jan. 24, 2023), *unreviewed by* Comm'n Notice (Feb. 22, 2023). On March 7, 2023, the Commission terminated the investigation as to claims 1–4 and 7 of the '053 patent and claims 8, 11, and 12 of the '628 patent. *See* Order No. 64 (Feb. 7, 2023), *unreviewed by* Comm'n Notice (Mar. 7, 2023).

On March 15, 2023, the Commission granted summary determination that the economic prong of the DI requirement has been satisfied in this investigation as to the remaining asserted patents—*i.e.,* the '053, '628, and '381 patents. *See* Order No. 62 (Feb. 6, 2023), *aff'd by* Comm'n Notice (Mar. 15, 2023).

On March 30, 2023, the Commission terminated the investigation as to claim 8 of the '053 patent and claim 18 of the '381 patent. *See* Order No. 70 (Mar. 14, 2023), *unreviewed by* Comm'n Notice (Mar. 30, 2023). On April 19, 2023, the Commission terminated the investigation as to the '628 patent. *See* Order No. 72 (Apr. 3, 2023), *unreviewed by* Comm'n Notice (Apr. 19, 2023).

On July 7, 2023, the administrative law judge issued a final initial determination (''ID'') on violation, which included a recommended determination (''RD'') on remedy and bonding. The ID finds no violation of section 337 as to the '053 patent, but does find a violation as to claims 19 and 20 of the '381 patent. The RD recommends that, should the Commission determine that a violation of section 337 has occurred, the Commission should: (i) issue an LEO against the Respondents' infringing products; (ii) issue a CDO against each of Respondents except for Realtek and TTE Technology; and (iii) issue no (0 percent) bond for importations of infringing products during the period of Presidential review.

On October 16, 2023, the Commission determined to review the final ID in part. 88 FR 72537–39 (Oct. 20, 2023). Specifically, the Commission determined to review the ID's infringement finding regarding claim 19 of the '381 patent. *Id.* at 72538. The Commission also determined to review and, on review, take no position on the ID's findings regarding the ALJ's construction of limitation 5[c] (''a plurality of command processing engines, coupled to the arbiter, each operable to receive and process the command thread'') of claim 5 of the '053 patent, as well as infringement and satisfaction of the technical prong of the DI requirement with respect to limitation 5[c]. *Id.* The Commission further determined not to review the remaining findings in the ID. *Id.* The Commission's notice requested written submissions on the issue under review, as well as on remedy, the public interest, and bonding. *Id.*

The Commission did not receive submissions on the public interest from the parties pursuant to Commission Rule 210.50(a)(4), 19 CFR 210.50(a)(4). The Commission also did not receive any submissions on the public interest from members of the public in response to the Commission's **Federal Register** notice. *See* 88 FR 48262–63 (July 26, 2023).

On October 30, 2023, AMD and Respondents each filed initial briefs with written submissions on the issue under review as well as on remedy, the public interest, and bonding. On November 6, 2023, AMD and Respondents each filed reply briefs.

The Commission, having reviewed the record in this investigation, including the final ID, the parties' petitions and responses thereto, and the parties' briefs on remedy, the public interest, and bonding, has determined that Respondents have violated section 337 by importing, selling for importation, or selling within the United States after importation certain graphics systems, components thereof, and digital televisions containing the same that infringe claims 19 and 20 of the '381 patent. Specifically, the Commission affirms with modification the ID's finding that AMD has proven that the Accused Products practice claim 19 of the '381 patent to include supplemental findings and evidence.

The Commission has determined that the appropriate remedy is: (i) an LEO prohibiting the importation of certain graphics systems, components thereof, and digital televisions containing the same that infringe one or more of claims 19 and 20 of the '381 patent; and (ii) CDOs against each of the Respondents except for Realtek. The Commission has also determined that the public interest factors do not preclude issuance of the remedial orders. The Commission has further determined to set no (0 percent) bond for importations of the excluded articles imported during the period of Presidential review (19 U.S.C. 1337(j)).

The Commission issues its opinion herewith setting forth its determinations on certain issues. This investigation is hereby terminated.

The Commission's orders and opinion were delivered to the President and United States Trade Representative on the day of their issuance.

The Commission vote for this determination took place on January 24, 2024.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: January 24, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–01753 Filed 1–29–24; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Disaster Unemployment Assistance Activities Report

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employment and Training Administration (ETA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before February 29, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Michael Howell by telephone at 202–693–6782, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: Unemployment compensation claims, financial management and data on disaster unemployment assistance (DUA) activity are needed for timely program monitoring necessary for competent administration of Sections 410 and 423 of the Stafford Disaster Relief and Emergency Act through ETA–902. Workload items are also used with fiscal reports to estimate the cost of administering the Act. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on June 7, 2023 (88 FR 37279).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–ETA.

Title of Collection: Disaster Unemployment Assistance Activities Report.

OMB Control Number: 1205–0051.

Affected Public: State, Local and Tribal Governments.

Total Estimated Number of Respondents: 30.

Total Estimated Number of Responses: 210.

Total Estimated Annual Time Burden: 210 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Michael Howell,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2024–01800 Filed 1–29–24; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Certification and Qualification To Examine, Test, Operate Hoists and Perform Other Duties

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Mine Safety and Health Administration (MSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before February 29, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Michael Howell by telephone at 202–693–6782, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: Pertains to certification of certain persons to perform specific exams and tests. Also contains procedures under which coal mine operators are required to maintain a list of certified and qualified persons, and to develop an approved training plan for hosting engineers or host men. 30 CFR 75.159 and 77.106 require coal mine operators to maintain a list of persons who are certified and those who are qualified to perform duties under parts 75 and 77, such as conduct examinations for hazardous conditions, conduct tests for methane and oxygen deficiency, conduct tests of air flow, perform electrical work, repair energized surface high-voltage lines, and perform duties of hoisting engineer. The information collection is necessary to ensure that only persons who are properly trained and sufficiently experienced are permitted to perform these duties. Although MSHA does not specify a format for the recordkeeping, it normally consists of the names of the certified and qualified persons listed in two columns on a sheet of paper. One column is for certified persons and the other is for qualified persons. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on August 16, 2023 (88 FR 55728).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–MSHA.

Title of Collection: Certification and Qualification to Examine, Test, Operate Hoists and Perform Other Duties.

OMB Control Number: 1219–0127.

Affected Public: Businesses or other for-profits.

Total Estimated Number of Respondents: 990.

Total Estimated Number of Responses: 3,980.

Total Estimated Annual Time Burden: 334 hours.

Total Estimated Annual Other Costs Burden: $3.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Michael Howell,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2024–01773 Filed 1–29–24; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2021–0005]

Labtest Certification Inc.: Grant of Expansion of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces the final decision to expand the scope of recognition for Labtest Certification Inc., as a Nationally Recognized Testing Laboratory (NRTL).

DATES: The expansion of scope of recognition becomes effective on January 30, 2024.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, phone: (202) 693–1999 or email: *meilinger.francis2@dol.gov.*

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, phone: (202) 693–1911 or email: *robinson.kevin@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. Notice of Final Decision

OSHA hereby gives notice of the expansion of the scope of recognition for Labtest Certification Inc. (LCI). LCI's expansion covers the addition of nine test standards to the NRTL scope of recognition.

OSHA recognition of a NRTL signifies that the organization meets the requirements specified in 29 CFR 1910.7. Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within the scope of recognition. Each NRTL's scope of recognition includes: (1) the type of products the NRTL may test, with each type specified by the applicable test standard; and (2) the recognized site(s) that has/have the technical capability to perform the product-testing and product-certification activities for test standards within the NRTL's scope. Recognition is not a delegation or grant of government authority; however, recognition enables employers to use products approved by the NRTL to meet OSHA standards that require product testing and certification.

The agency processes applications by a NRTL for initial recognition and for an expansion or renewal of this recognition, following requirements in appendix A to 29 CFR 1910.7. This appendix requires that the agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides a preliminary finding. In the second notice, the agency provides a final decision on the application. These notices set forth the NRTL's scope of recognition or modifications of that scope. OSHA maintains an informational web page for each NRTL, including LCI, which details the NRTL's scope of recognition. These pages are available from the OSHA website at: https://www.osha.gov/nationally-recognized-testing-laboratory-program.

LCI submitted an application dated March 8, 2022 (OSHA–2021–0005–0005), requesting the addition of ten test standards to the NRTL scope of recognition. That application was updated on June 26, 2023 (OSHA–2021–0005–0006), to remove one standard from the original submission. This expansion will cover the remaining nine standards. OSHA staff performed a detailed analysis of the application packet and reviewed other pertinent information. OSHA did not perform any on-site reviews in relation to this application.

OSHA published the preliminary notice announcing LCI's expansion application in the **Federal Register** on December 1, 2023 (88 FR 83972). The agency requested comments by December 18, 2023, but it received no comments in response to this notice. OSHA is now proceeding with this final notice to grant expansion of LCI's NRTL scope of recognition.

To review copies of all public documents pertaining to LCI's application, go to *http://www.regulations.gov* or contact the Docket Office, Occupational Safety and Health Administration, U.S. Department of Labor at (202) 693–2350. Docket No. OSHA–2021–0005 contains all materials in the record concerning LCI's recognition. All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350 for assistance in locating docket submissions.

II. Final Decision and Order

OSHA staff examined LCI's expansion application, its capability to meet the requirements of the test standards, and other pertinent information. Based on its review of this evidence, OSHA finds that LCI meets the requirements of 29 CFR 1910.7 for expansion of its recognition, subject to the limitations and conditions. OSHA, therefore, is proceeding with this final notice to grant LCI's expanded scope of recognition. OSHA limits the expansion of LCI's recognition to include the testing and certification of products for demonstration of conformance to the test standards shown below in Table 1.

TABLE 1—LIST OF APPROPRIATE TEST STANDARDS FOR INCLUSION IN LCI'S NRTL SCOPE OF RECOGNITION

Test standard	Test standard title
UL 48	Electric Signs.
UL 508	Electric Industrial Control Equipment.
UL 508A	Industrial Control Panels.
UL 61010–1	Electrical Equipment for Measurement, Control and Laboratory Use; Part 1: General Requirements.
UL 62368–1	Audio/Video, Information and Communication Technology Equipment—Part 1: Safety Requirements.
UL 8750	Standard for Light Emitting Diode (LED) Equipment for Use in Lighting Products.
NFPA 496	Purged and Pressurized Enclosures for Electrical Equipment.
UL 1203	Explosion-Proof and Dust-Ignition-Proof Electrical Equipment for Use in Hazardous (Classified) Locations.
UL 121201	Nonincendive Electrical Equipment for Use in Class I and II, Division 2 and Class III, Divisions 1 and 2 Hazardous (Classified) Locations.

OSHA's recognition of any NRTL for a particular test standard is limited to equipment or materials for which OSHA standards require third-party testing and certification before using them in the workplace. Consequently, if a test standard also covers any products for which OSHA does not require such

testing and certification, a NRTL's scope of recognition does not include these products.

A. Conditions

Recognition is contingent on continued compliance with 29 CFR 1910.7, including but not limited to, abiding by the following conditions of recognition:

1. LCI must inform OSHA as soon as possible, in writing, of any change of ownership, facilities, or key personnel, and of any major change in its operations as a NRTL, and provide details of the change(s);

2. LCI must meet all the terms of its recognition and comply with all OSHA policies pertaining to this recognition; and

3. LCI must continue to meet the requirements for recognition, including all previously published conditions on LCI's scope of recognition, in all areas for which it has recognition.

Pursuant to the authority in 29 CFR 1910.7, OSHA hereby expands the scope of recognition of LCI as a NRTL, subject to the limitations and conditions specified above.

III. Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 8–2020 (85 FR 58393; Sept. 18, 2020), and 29 CFR 1910.7.

Signed at Washington, DC, on January 24, 2024.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2024–01795 Filed 1–29–24; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2007–0039]

Intertek Testing Services NA, Inc.: Grant of Expansion of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces the final decision to expand the scope of recognition for Intertek Testing Services NA, Inc., as a Nationally Recognized Testing Laboratory (NRTL).

DATES: The expansion of the scope of recognition becomes effective on January 30, 2024.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, phone: (202) 693–1999 or email: *meilinger.francis2@dol.gov.*

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, phone: (202) 693–1911 or email: *robinson.kevin@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. Notice of Final Decision

OSHA hereby gives notice of the expansion of the scope of recognition of Intertek Testing Services NA, Inc. (ITSNA) as a NRTL. ITSNA's expansion covers the addition of one test standard to the NRTL scope of recognition.

OSHA recognition of a NRTL signifies that the organization meets the requirements specified in 29 CFR 1910.7. Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within the scope of recognition. Each NRTL's scope of recognition includes (1) the type of products the NRTL may test, with each type specified by the applicable test standard; and (2) the recognized site(s) that has/have the technical capability to perform the product-testing and product-certification activities for test standards within the NRTL's scope. Recognition is not a delegation or grant of government authority; however, recognition enables employers to use products approved by the NRTL to meet OSHA standards that require product testing and certification.

The agency processes an application by a NRTL for initial recognition and for an expansion or renewal of this recognition, following requirements in Appendix A, 29 CFR 1910.7. This appendix requires that the agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides the preliminary finding. In the second notice, the agency provides the final decision on the application. These notices set forth the NRTL's scope of recognition or modifications of that scope. OSHA maintains an informational web page for each NRTL, including ITSNA, which details the NRTL's scope of recognition. These pages are available from the OSHA website at *http://www.osha.gov/dts/otpca/nrtl/index.html.*

ITSNA submitted an application dated April 5, 2023 (OSHA–2007–0039–0051), requesting the addition of one test standard to the NRTL scope of recognition. OSHA staff performed a detailed analysis of the application packet and reviewed other pertinent information. OSHA did not perform any on-site reviews in relation to this application.

OSHA published the preliminary notice announcing ITSNA's expansion application in the **Federal Register** on December 18, 2023 (88 FR 87460). The agency requested comments by January 2, 2024, but it received no comments in response to this notice. OSHA is now proceeding with this final grant of expansion of ITSNA's NRTL recognition.

To obtain or review copies of all public documents pertaining to the ITSNA applications, go to *https://www.regulations.gov* or contact the Docket Office, Occupational Safety and Health Administration, U.S. Department of Labor. Docket No. OSHA–2007–0039 contains all materials in the record concerning ITSNA's recognition. All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350 for assistance in locating docket submissions.

II. Final Decision and Order

OSHA staff examined ITSNA's expansion application, its capability to meet the requirements of the test standard, and other pertinent information. Based on its review of this evidence, OSHA finds that ITSNA meets the requirements of 29 CFR 1910.7 for expansion of its recognition, subject to the limitations and conditions listed in this notice. OSHA, therefore, is proceeding with this final notice to grant ITSNA's expanded scope of recognition. OSHA limits the expansion of ITSNA's recognition to testing and certification of products for demonstration of conformance to the test standard listed below in table 1.

TABLE 1—APPROPRIATE TEST STANDARD FOR INCLUSION IN ITSNA'S NRTL SCOPE OF RECOGNITION

Test standard	Test standard title
UL 2225	Cables and Cable-Fittings for Use in Hazardous (Classified) Locations.

OSHA's recognition of any NRTL for a particular test standard is limited to equipment or materials for which OSHA standards require third-party testing and certification before using them in the workplace. Consequently, if a test standard also covers any products for which OSHA does not require such testing and certification, a NRTL's scope of recognition does not include these products.

The American National Standards Institute (ANSI) may approve the test standards listed above as American National Standards. However, for convenience, we may use the designation of the standards-developing organization for the standard as opposed to the ANSI designation. Under the NRTL Program's policy (see OSHA Instruction CPL 01–00–004, chapter 2, section VIII), any NRTL recognized for a particular test standard may use either the proprietary version of the test standard or the ANSI version of that standard. Contact ANSI to determine whether a test standard is currently ANSI-approved.

A. Conditions

Recognition is contingent on continued compliance with 29 CFR 1910.7, including, but not limited to, abiding by the following conditions of the recognition:

1. ITSNA must inform OSHA as soon as possible, in writing, of any change of ownership, facilities, or key personnel, and of any major change in its operations as a NRTL, and provide details of the change(s);

2. ITSNA must meet all the terms of its recognition and comply with all OSHA policies pertaining to this recognition; and

3. ITSNA must continue to meet the requirements for recognition, including all previously published conditions on ITSNA's scope of recognition, in all areas for which it has recognition.

Pursuant to the authority in 29 CFR 1910.7, OSHA hereby expands the scope of recognition of ITSNA as a NRTL, subject to the limitations and conditions specified above.

III. Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 8–2020 (85 FR 58393, Sept. 18, 2020), and 29 CFR 1910.7.

Signed at Washington, DC, on January 24, 2024.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2024–01774 Filed 1–29–24; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Office of the Workers' Compensation Programs

Agency Information Collection Activities; Comment Request; Agreement and Undertaking (OMB Control No. 1240–0039)

AGENCY: Division of Coal Mine Workers' Compensation, (OWCP/DCMWC), Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor (DOL) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Agreement and Undertaking.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by April 1, 2024.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free by contacting Anjanette Suggs by telephone at 202–354–9660 or by email at *suggs.anjanette@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Office of Workers' Compensation Programs, Room S3323, 200 Constitution Avenue NW, Washington, DC 20210; by email: *suggs.anjanette@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Anjanette Suggs by telephone at 202–354–9660 or by email at *suggs.anjanette@dol.gov.*

SUPPLEMENTARY INFORMATION: The DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the OMB for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

The Black Lung Benefits Act (30 U.S.C. 901 *et seq.*) and its implementing regulations necessitate this information collection. The OWCP–1 form is executed by the self-insurer who agrees to abide by the Department's rules and authorizes the Secretary, in the event of default, to file suit to secure payment from a bond underwriter or, in the case of a Federal Reserve account, to sell the securities for the same purpose. This information collection is currently approved for use through April 30, 2021. 30 U.S.C. 933 and 20 CFR 726.110 authorize this information collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB under the PRA approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Written comments will receive consideration, and summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention 1240–0039.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. The DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

The DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including

whether the information will have practical utility.

• 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

• 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.

Agency: DOL—Office of Workers' Compensation Programs.

Type of Review: Extension.

Title of Collection: Agreement and Undertaking.

Form: Agreement and Undertaking, OWCP–1.

OMB Control Number: 1240–0039.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 20.

Frequency: As requested.

Total Estimated Annual Responses: 20.

Estimated Average Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 5 hours.

Total Estimated Annual Other Cost Burden: $120.74.

Authority: 44 U.S.C. 3506(c)(2)(A).

Dated: January 24, 2024.

Anjanette Suggs,

Agency Clearance Officer.

[FR Doc. 2024–01757 Filed 1–29–24; 8:45 am]

BILLING CODE 4510–CK–P

LIBRARY OF CONGRESS

Copyright Office

[Docket No. 2024–1]

Periodic Review of the Designations of the Mechanical Licensing Collective and Digital Licensee Coordinator

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Notification of inquiry.

SUMMARY: The U.S. Copyright Office is issuing a notification of inquiry, as required by the Music Modernization Act, regarding whether the existing designations of the mechanical licensing collective and digital licensee coordinator should be continued.

DATES: Initial submissions by the currently designated mechanical licensing collective and digital licensee coordinator must be received no later than 11:59 p.m. Eastern Time on April 1, 2024. Written initial public comments must be received no later than 11:59 p.m. Eastern Time on May 29, 2024. Written reply public comments must be received no later than 11:59 p.m. Eastern Time on June 28, 2024. Reply submissions of the currently designated mechanical licensing collective and digital licensee coordinator must be received no later than 11:59 p.m. Eastern Time on July 29, 2024.

ADDRESSES: For reasons of government efficiency, the Copyright Office is using the *regulations.gov* system for the submission and posting of public comments in this proceeding. All public comments in response to this notice are therefore to be submitted electronically through *regulations.gov.* Specific instructions for submitting comments are available on the Copyright Office's website at *https://www.copyright.gov/rulemaking/mma-designations/2024.* If electronic submission of comments is not feasible due to lack of access to a computer or the internet, please contact the Office using the contact information below for special instructions. Initial and reply submissions by the currently designated mechanical licensing collective and digital licensee coordinator should be made by email to the Copyright Office's Assistant to the General Counsel.

FOR FURTHER INFORMATION CONTACT: Rhea Efthimiadis, Assistant to the General Counsel, by email at *meft@copyright.gov* or telephone at (202) 707–8350.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

The Orrin G. Hatch–Bob Goodlatte Music Modernization Act (''MMA'') [1] created a statutory blanket mechanical license for the reproduction and distribution of nondramatic musical works by digital music providers (''DMPs'') in the form of digital phonorecord deliveries, including permanent downloads, limited downloads, and interactive streams (the ''blanket license''), and eliminated the song-by-song ''notice of intention'' process for such uses.

The MMA directed the Copyright Office (''Office'') to designate a mechanical licensing collective (''MLC'') to administer the blanket license [2] and a digital licensee coordinator (''DLC'') to represent DMPs in matters related to the administration of the blanket license. However, if the Office is unable to identify an entity that meets the statutory qualifications to serve as the DLC, it may decline to designate one.[3] As discussed further below, the Office made its initial MLC and DLC designations in July 2019.[4] At that time, it designated the entity ''Digital Licensee Coordinator, Inc.'' as the DLC and the entity ''Mechanical Licensing Collective'' as the MLC.[5] The Office is required to review these designations every five years, with the first review to begin in January 2024.[6] This notice initiates the review process.

A. The MLC's Designation Criteria

The MMA provides that an entity wishing to be designated as the MLC must: (1) be a single nonprofit entity, not owned by any other entity, created by copyright owners to carry out its statutory responsibilities; [7] (2) be ''endorsed by, and enjoy[] substantial support from, musical work copyright owners that together represent the greatest percentage of the licensor market for uses of such works in covered activities, as measured over the preceding 3 full calendar years''; [8] and (3) possess the administrative and technological capabilities necessary to carry out a wide array of responsibilities associated with administering the blanket license.[9] If no entity meets these statutory criteria, the Office must designate an entity as the MLC that most nearly fits them.[10]

While the first criterion regarding nonprofit status is straightforward, the second and third criteria require more explanation. As part of the initial MLC designation proceeding, the Office had to address the correct construction and

[1] Public Law 115–264, 132 Stat. 3676 (2018).

[2] 17 U.S.C. 115(d)(3)(B); *see also id.* at 115(e)(15).

[3] *Id.* at 115(d)(3)(D)(i)(IV), (d)(5).

[4] 37 CFR 210.23; 84 FR 32274, 32296 (July 8, 2019).

[5] 37 CFR 210.23; 84 FR at 32292, 32296. In this notice, the currently designated digital licensing coordinator will be designated as the ''Digital Licensing Coordinator'' and the statutory digital licensing coordinator will be designated in lowercase or by using the abbreviated term, ''the DLC.'' Similarly, the currently designated mechanical licensing collective will be designated via capitalization (the ''Mechanical Licensing Collective'') and the statutory mechanical licensing collective will be designated in lowercase or by using the abbreviated term, ''the MLC.''

[6] 17 U.S.C. 115(d)(3)(B)(ii) (noting that the review occurs ''every 5 years, beginning with the fifth full calendar year to commence after the initial designation''); *id.* at 115(d)(5)(B)(ii) (same).

[7] *Id.* at 115(d)(3)(A)(i).

[8] *Id.* at 115(d)(3)(A)(ii).

[9] *Id.* at 115(d)(3)(A)(iii); *see also id.* at 115(d)(3)(C)(i)–(iii) (enumerating thirteen functions, in addition to the ability to administer voluntary licenses).

[10] *Id.* at 115(d)(3)(B)(iii).

application of the statute's endorsement criterion. The Office sought public input on this issue.[11] After considering the relevant comments and evaluating the statute, it concluded that the statute's endorsement criterion ''mandates that the entity designated as the MLC be endorsed and supported by musical work copyright owners that together earned the largest aggregate percentage (among MLC candidates) of total royalties from the use of their musical works in covered activities in the U.S. during the statutory three-year period.'' [12] It further concluded that ''the endorsement criterion is a plurality requirement based on market share, measured by applicable licensing revenue.'' [13]

The third MLC designation criterion addresses the administrative and technological capabilities associated with carrying out its statutory responsibilities. Those responsibilities are executed by the MLC's board of directors and task-specific committees. The MMA provides that the MLC's board will consist of 14 voting members and 3 nonvoting members.[14] It also requires the MLC's board to establish three committees: an operations advisory committee; an unclaimed royalties oversight committee; and a dispute resolution committee.[15]

The MLC's responsibilities under the MMA include the following tasks:

- Offering and administering blanket licenses;
- Collecting and distributing royalties from DMPs for covered activities;
- Identifying musical works embodied in sound recordings and identifying and locating copyright owners of such musical works; [16]
- Establishing and maintaining a musical works database relevant to licensing activities under the MMA;
- Administering a process by which copyright owners can claim ownership of musical works;
- Investing in relevant resources, and arranging for services of outside vendors and others to support the MLC's activities; and
- Maintaining records of its activities and engaging in and responding to audits.[17]

B. The DLC's Designation Criteria, Authorities, and Functions

Similar to the MLC, the DLC must be a single nonprofit entity that is endorsed by and enjoys substantial support from DMPs, and must possess the administrative and technological capabilities necessary to carry out its responsibilities.[18] Unlike the MLC, in the event the Office is unable to identify an entity that fulfills the criteria for the DLC, it may decline to designate one.[19]

The statute authorizes the DLC to perform the following functions: (1) establishing a governance structure, criteria for membership, and any dues to be paid by its members; (2) engaging in activities related to the administrative assessment, including participating in administrative assessment proceedings before the Copyright Royalty Judges and engaging in efforts to enforce DMPs' notice and payment obligations related to the assessment; (3) gathering and providing documentation for use in proceedings before the Copyright Royalty Judges to set the statutory mechanical license's rates and terms; (4) initiating and participating in proceedings before the Copyright Office with respect to the blanket license; (5) maintaining records of its activities; and (6) assisting in publicizing the MLC's existence and functions to copyright owners.[20]

Further, under the MMA, the DLC is required to ''make reasonable, good-faith efforts'' to assist the MLC in its efforts to locate and identify copyright owners of unmatched musical works by encouraging DMPs to publicize the MLC's existence and the ability of copyright owners to claim unclaimed accrued royalties, including by posting contact information for the collective at reasonably prominent locations on DMP websites and applications and conducting in-person outreach activities with songwriters.[21]

The DLC also appoints a representative to act as a nonvoting member of the MLC's board and DMP representatives to the MLC's operations advisory committee.[22]

II. Regulatory Background

A. Initial Designation

For the initial MLC and DLC designations, the Office published a notice in the **Federal Register** soliciting proposals from parties who wished to be designated as those entities, and requested information from those parties regarding governance, administrative and technological capabilities to perform the MMA's required functions, and indicia of endorsement and support.[23] The Office also requested public comments on the parties' proposals.[24]

The Office received one proposal for designation as the DLC and two proposals for designation as the MLC. It received over 600 public comments responding to the proposals and held several *ex parte* meetings addressing them.[25] After considering these comments and the statutory designation criteria, the Office concluded that the entity ''Digital Licensee Coordinator, Inc.,'' incorporated in Delaware on March 20, 2019, ''me[t] each of the statutory criteria required of the digital licensee coordinator,'' and would be designated as the DLC.[26] With respect to the MLC, the Office concluded that, while both candidates to become the MLC ''[met] the statutory criteria to be a nonprofit created to carry out its statutory responsibilities,'' the Mechanical Licensing Collective ''made a better showing as to its prospective administrative and technological capabilities'' and was the only candidate that met the statute's ''endorsement'' criteria.[27] Therefore, it designated the entity ''Mechanical Licensing Collective,'' incorporated in Delaware on March 5, 2019, as the MLC.[28]

B. The Periodic Designation Review Process

The MMA requires the Office to periodically evaluate whether the existing MLC and DLC designations

[11] 83 FR 65747, 65753 (Dec. 21, 2018).

[12] 84 FR at 32282.

[13] *Id.* For a full discussion of the Office's conclusions regarding how the endorsement criterion is applied, interested parties should review that portion of the initial designation determination. *Id.* at 32280–86.

[14] For the statutory requirements regarding the board described in this paragraph, *see* 17 U.S.C. 115(d)(3)(D)(i).

[15] *Id.* at 115(d)(3)(D)(iv). Further discussion of the MLC's board and committees can be found in the Office's initial designation notice. 83 FR at 65748–50.

[16] The statute also mentions ''and shares of such works'' when referring to musical works. *See, e.g.,* 17 U.S.C. 115(d)(3)(C)(i)(III). For brevity's sake, this notice will omit references to such shares.

[17] *Id.* at 115(d)(3)(C)(i)(I)–(V), (VII), (XII); *see also id.* at 115(d)(3)(C)(i), (iii) (identifying the MLC's additional statutory authorities and functions).

[18] *Id.* at 115(d)(3)(C)(i)–(iii) (enumerating thirteen functions, in addition to the ability to administer voluntary licenses); *see also id.* at 115(d)(3)(B)(iii).

[19] *Id.* at 115(d)(5)(B)(iii).

[20] *Id.* at 115(d)(5)(C)(i). The ''administrative assessment'' is the fee paid by digital music providers for the MLC's costs in establishing, maintaining, and operating the MLC to fulfill its statutory functions, excluding any added costs related to providing services under voluntary licenses. *Id.* at 115(d)(7)(D), (e)(3), (e)(6).

[21] *Id.* at 115(d)(5)(C)(i)(VII), (d)(5)(C)(iii).

[22] *Id.* at 115(d)(3)(D)(iv)(II), (i)(IV).

[23] 83 FR 65747.

[24] *Id.*

[25] U.S. Copyright Office, *Ex Parte Communications, https://www.copyright.gov/rulemaking/mma-designations/ex-parte-communications.html* (last visited Jan. 24, 2024) (hosting *ex parte* meeting summary letters related to the Office's initial designations).

[26] 37 CFR 210.23; 84 FR at 32292, 32296.

[27] 84 FR at 32276, 32296.

[28] 37 CFR 210.23; 84 FR at 32296.

should be continued or, if either designation is not continued, whether a different entity should be designated instead.[29] The Office commences this process by publication of a notice in the **Federal Register** by the end of January in the relevant year.

For the instant review of the MLC and DLC designations, the Office is first soliciting information from the currently designated entities regarding their past performance and capabilities, as well as future plans. The responses from the Mechanical Licensing Collective and the Digital Licensing Coordinator will be available for public review. The Office encourages public comments concerning whether the existing MLC and DLC designations should be continued, or different entities should be designated. Once the public has submitted comments, the currently designated entities will be given an opportunity to respond. After the time for submissions from the Mechanical Licensing Collective, Digital Licensee Coordinator, and the public have expired, the Office may also utilize informal meetings to address discrete issues prior to issuing a determination. Any such meetings will occur after written comments have been submitted and will follow the Office's *ex parte* meeting guidelines.[30]

After evaluating the record in this proceeding, the Office will determine whether the current MLC and DLC designations should be continued. If it concludes that a designation should be continued, it will publish its determination in the **Federal Register**, ending this proceeding.[31] If the Office decides that either designation should not be continued, it will solicit proposals for designation in the **Federal Register**. If the Office ultimately designates a new MLC or DLC, it will provide the reasons for such a designation and the designation's effective date.[32] Further, if it designates a new MLC, it will ''adopt regulations to govern the transfer of licenses, funds, records, data, and administrative responsibilities from the existing mechanical licensing collective to the new entity.'' [33]

III. Request for Information From the Current Designees

The Copyright Office seeks information to assist its review of the existing MLC and DLC designations and whether they should be continued. The questions in this notification of inquiry are intended to focus the current designees' submissions on the statutory designation criteria and certain areas of interest to the Office. The parties also may provide additional information they wish the Office to consider in deciding whether to continue the current designations.

A. Mechanical Licensing Collective-Directed Inquiries

The Office requests the following information from the Mechanical Licensing Collective, organized by the criteria categories below.

1. Nonprofit Status

The MLC must be a nonprofit entity, not owned by any other entity, that is created by copyright owners to carry out its statutory responsibilities. The Office requests proof that the Mechanical Licensing Collective continues to meet this criterion.

2. Indicia of Endorsement and Support

The MLC must be ''endorsed by, and enjoy[] substantial support from, musical work copyright owners that together represent the greatest percentage of the licensor market for uses of such works in covered activities, as measured over the preceding 3 full calendar years.'' [34] The Office requests information from the Mechanical Licensing Collective regarding whether it continues to satisfy the endorsement criterion.

3. Administrative and Technological Capabilities

The MLC must have the administrative and technological capabilities to perform its statutorily required functions.[35] The Office requests a detailed description explaining how the Mechanical Licensing Collective has the administrative and technological capabilities to perform its required functions. It asks that the response address the following subjects:

i. Progress Implementing the Recommendations in the Office's ''Unclaimed Royalties'' Report

The Office requests an update on the Mechanical Licensing Collective's efforts to implement recommendations contained in the Office's report ''Unclaimed Royalties: Best Practice Recommendations for the Mechanical Licensing Collective,'' [36] including what recommendations have been implemented to date, what efforts are in progress, its plans to implement recommendations in the future, and a discussion of any recommendations it is not planning to implement, including the reasons for such decision(s).

ii. Ownership Identification, Matching, and Claiming Process and Maintenance of Musical Works Database

The Office requests information about the Mechanical Licensing Collective's ability to identify musical works embodied in particular sound recordings, and to identify and locate the copyright owners of such musical works, including the following:

(a) Please describe how the Mechanical Licensing Collective has worked to improve automated and manual matching since the blanket license became available and plans to further enhance such matching over the next 5 years, including with respect to the matching of reported sound recordings to musical works as well as the matching of those musical works to identified and located copyright owners;

(b) Please identify the Mechanical Licensing Collective's target goals or estimates, including any relevant industry benchmarks, for matching reported sound recordings to musical works and identifying and locating copyright owners over the next five years, as expressed in terms of (1) a match rate (*i.e.,* the total amount of royalties matched to musical works registered in the Mechanical Licensing Collective's database, compared to the total royalties reported by DMPs); and (2) a distribution rate (*i.e.,* the total amount of royalties matched and paid to the Mechanical Licensing Collective's members, compared to the total royalties reported by DMPs);

(c) Please explain how the Mechanical Licensing Collective: (1) is using quantifiable measurements to monitor its match rate confidence; and (2) tunes confidence levels without using numerical metrics; [37]

[29] 17 U.S.C. 115(d)(3)(B)(ii); *id.* at 115(d)(5)(B)(ii).

[30] 37 CFR 205.24. Instructions on how to request an *ex parte* meeting are available on the Office's website at *https://www.copyright.gov/ex-parte-meetings/.*

[31] 17 U.S.C. 115(d)(3)(B)(ii)(I); *see also id.* at 115(d)(5)(B)(ii).

[32] *Id.* at 115(d)(3)(B)(ii)(I); *see also id.* at 115(d)(5)(B)(ii).

[33] *Id.* at 115(d)(3)(B)(ii)(II).

[34] *Id.* at 115(d)(3)(A)(ii).

[35] *Id.* at 115(d)(3)(A)(iii).

[36] U.S. Copyright Office, *Unclaimed Royalties: Best Practice Recommendations for the Mechanical Licensing Collective* (2021) (''Unclaimed Royalties Report''), *https://www.copyright.gov/policy/unclaimed-royalties/unclaimed-royalties-final-report.pdf.*

[37] *See* The Mechanical Licensing Collective, *2022 Annual Report* 9 (2022), *https://www.themlc.com/hubfs/The%20MLC%202022%20Annual%20Report.pdf* (stating that the Mechanical Licensing Collective ''does not use numerical metrics to monitor match rate confidence''); Designation Proposal of Mechanical Licensing Collective at 40,

(d) Please address whether the Mechanical Licensing Collective has identified any notable trends or patterns in reported usage that it has been unable to match through its efforts to date. If it has identified such trends or patterns, please describe what targeted efforts have been undertaken to date, and are planned to take place over the next 5 years, to attempt to address these trends or patterns;

(e) Please describe any efforts the Mechanical Licensing Collective has undertaken to enhance database and claiming portal functionality, including with respect to searching the database, sorting and filtering queries, and sharing and exporting results, as well as specific plans to develop additional functionality over the next five years;

(f) Please describe any plans the Mechanical Licensing Collective's has to address disputes and overclaims (or overlapping claims) via a module within its portal;

(g) Please describe the Mechanical Licensing Collective's efforts to develop portal access (or a unique portal), or equivalent database functionalities, for songwriters who are not self-administered (*e.g.,* those represented by a publisher, administrator, or collective management organization) to permit them to access, provide, or correct information about themselves and their works maintained by the MLC, including the ability for such songwriters to flag data issues with their publisher or other representative, to provide data directly to the MLC, and to have permissions-based access to view information such as stream counts and revenue associated with their musical works; [38]

(h) Please describe how the Mechanical Licensing Collective is ''maintain[ing] at regular intervals historical records of the information contained in the public musical works database, including a record of changes to such database information and changes to the source of information in database fields, in order to allow tracking of changes to the ownership of musical works in the database over time,'' the length of such ''regular intervals,'' and how it has determined ''the most appropriate method for archiving and maintaining such historical data to track ownership and other information changes in the database''; [39]

(i) The Mechanical Licensing Collective stated that it would employ application program interfaces (''APIs'') ''to allow for bulk submission and updating of rights data'' and to otherwise support data exchange.[40] Please describe how the Mechanical Licensing Collective has employed systems with APIs to support data exchange to date [41] and its plans to implement any additional such systems over the next five years.

iii. Collection and Distribution of Royalties, Including Unclaimed Accrued Royalties

The Office requests information about the Mechanical Licensing Collective's royalty distributions, including the following topics:

(a) In its initial designation proposal, the Mechanical Licensing Collective stated that it ''does not intend to ever distribute the entirety of unclaimed royalties simultaneously [and] intends to implement policies allowing use of that discretion to retain unclaimed accrued royalties and continue matching efforts in situations where there is reasonable evidence that this will result in material increases in matching success.'' [42] Please address whether the Mechanical Licensing Collective continues to hold these views;

(b) Please provide information regarding: (1) any steps that the Mechanical Licensing Collective is taking to protect against the incidence of fraudulent ownership claims and frivolous ownership disputes; and (2) whether these steps have been successful; and

(c) Please provide information addressing whether and to what extent the Mechanical Licensing Collective is working with DMPs, distributors, aggregators, or others to protect against streaming fraud and the status of such efforts, including their success or failure.

iv. Investment in Resources and Vendor Engagement

The Office understands that the Mechanical Licensing Collective is relying on third-party vendors, including The Harry Fox Agency and ConsenSys, to support its operations and fulfill its statutory obligations.[43] It is also aware that the Mechanical Licensing Collective has recently announced a ''Supplemental Matching Network,'' consisting of Blòkur, Jaxsta, Pex, Salt and SX Works, to improve its matching efforts.[44] Please provide additional information about these relationships, including the specific functions that they perform, or have been asked to perform, the vendors' relevant experience with clients and projects involving similar scale and type, or their industry-specific knowledge. Please provide the same information with respect to any other vendors that the Mechanical Licensing Collective uses, or has plans to use, in performing its duties.

v. Funding

Docket No. 2018–11 (Mar. 21, 2019) (''Mechanical Licensing Collective Initial Designation Proposal''), *https://www.gov/comment/COLC-2018-0011-0012* (''Tuning the confidence levels of a matching system is critical to proper functioning.'').

[38] *See* Unclaimed Royalties Report at 49–51; The Mechanical Licensing Collective, *Welcome to The MLC's Public Work Search, https://portal.themlc.com/search#work* (last visited Jan. 24, 2024) (''Songwriters, Composers & Lyricists: . . . The MLC is working on additional ways to help you flag and report data errors to your publisher or administrator. We hope to launch those later this year.'').

[39] 37 CFR 210.31(f).

[40] Mechanical Licensing Collective Initial Designation Proposal at 37, 47.

[41] *See* The Mechanical Licensing Collective, *Data Programs, https://www.themlc.com/dataprograms#public-search-api* (last visited Jan. 24, 2024) (referencing the beta launch of Mechanical Licensing Collective's Public Search API).

[42] Mechanical Licensing Collective Initial Designation Proposal at 52–53.

[43] The Mechanical Licensing Collective, *2022 Annual Report* 36, 41 (2022), *https://www.themlc.com/hubfs/The%20MLC%202022%20Annual%20Report.pdf.*

[44] *See* Kristin Robinson, *The MLC Partners With 5 Data Matching Companies to Increase Royalties Match Rate,* Billboard (Dec. 7, 2023), *https://www.billboard.com/business/publishing/the-mlc-improve-royalties-match-rate-new-data-network-1235545949/.*

The statute directs the MLC to establish procedures to guard against ''abuse, waste, and the unreasonable use of funds.'' [45] Review of the MMA's legislative history instructs the Office to consider the Mechanical Licensing Collective's efficiency or, conversely, any ''evidence of fraud, waste, or abuse, including the failure to follow the relevant regulations adopted by the Copyright Office'' in evaluating whether the current MLC designation should be continued.[46] Accordingly the Office requests information about the Mechanical Licensing Collective's procedures to safeguard its use of the assessment funds against abuse, waste, and other unreasonable expenditures.[47] The Mechanical Licensing Collective should also provide information regarding whether it has become more efficient over time. It should address with specificity any expenditure categories (*e.g.,* personnel costs, information technology, professional fees, outreach, education, communication & events, insurance, rent, computer equipment & office expenses) that have significantly increased since January 2021, and a detailed explanation for the increase.

vi. Governance

The Office seeks information related to the Mechanical Licensing Collective's governance, including:

(a) A copy of the Mechanical Licensing Collective's current bylaws, including a summary of changes made, if any, from its initial bylaws;

(b) A list of all the committees the Mechanical Licensing Collective has created that are not required by statute, the membership of those committees, and how it determined the membership of those committees;

(c) Copies of all the Mechanical Licensing Collective's policies addressing its statutory duties, procedures, practices, and guidelines (*e.g.,* those governing the collection, processing, holding, and distribution of royalties, guidelines for adjustments, member registration, ownership disputes, automated and manual matching, data quality and verification, investments, conflicts of interest), but excluding policies unrelated to the MLC's statutory duties (*e.g.,* website terms of use, human resources), the location of these policies, procedures, and practices on its website if they are currently available to the public, and a summary of changes made, if any, from earlier versions of these policies, procedures, practices, and guidelines; [48]

(d) The status of any policies or procedures related to the distribution of unclaimed accrued royalties and accrued interest;

(e) An explanation of how the Mechanical Licensing Collective is ensuring that: (1) its policies, procedures, and practices are transparent and accountable; [49] and (2) that all board and committee members have equal access to information in the Mechanical Licensing Collective's possession;

(f) The results of the Mechanical Licensing Collective's ''Board Diversity Report'' for 2021 and 2023; [50] and

(g) How the Mechanical Licensing Collective approaches the resolution of disputes with other interested parties (*e.g.,* DMPs, songwriters, publishers, or record labels) regarding interpretation of the MMA or the Office's regulations.[51]

vii. Education and Outreach

The Office requests information regarding the Mechanical Licensing Collective's education and outreach efforts, including how it reaches diverse audiences to ''engage in diligent, good-faith efforts to publicize the collective and ability to claim unclaimed accrued royalties for unmatched musical works (and shares of such works).'' [52] The Office is also interested in how the Mechanical Licensing Collective ''tailor[s] its education and outreach activities in recognition of the industry's broad and diverse spectrum of songwriters and copyright owners, including by stakeholders' varying levels of sophistication, geographic location, age, and music genre,'' including how it ''employ[s] dedicated, persistent outreach to historically underserved groups.'' [53] The Office is further interested in how the Mechanical Licensing Collective is using data in decision-making and performance measurement, with respect to its education and outreach efforts, for example, how it is using data to evaluate its education and outreach efforts (*e.g.,* in-person outreach at events, webinars, advertising, interviews for articles and podcasts, partnerships) when considering whether to participate in an event or activity. Finally, the Office is interested in how the Mechanical Licensing Collective is using ''member demographic statistics and DMP usage analytics . . . to better target its education and outreach efforts towards under-participating groups.'' [54]

The Mechanical Licensing Collective is encouraged to provide any other information that it believes is relevant to demonstrate it continues to meet the statutory designation criteria.

B. Digital Licensee Coordinator-Directed Inquiries

The Office requests the following information from the Digital Licensee Coordinator relevant to determining whether its existing designation should be continued:

1. Nonprofit Status

The Office requests proof that Digital Licensee Coordinator is a nonprofit entity, not owned by any other entity,

[45] 17 U.S.C. 115(d)(3)(D)(ix)(II)(bb)(BB). As noted above, the DMPs fund the MLC's operations through an administrative assessment that is established by the Copyright Royalty Judges.

[46] H.R. Rep. No. 115–651, at 6 (2018).

[47] Note that the MMA requires the MLC to retain a qualified auditor to examine its books, records, and operations and prepare a report on these topics for the MLC's board. 17 U.S.C. 115(d)(3)(D)(ix)(II). The auditor's letter to the MLC's board can be found on the Mechanical Licensing Collective's website. Letter from WithumSmith+Brown, P.C. to the Board of Directors of the Mechanical Licensing Collective (Dec. 22, 2023), *https://www.themlc.com/hubfs/Auditor%20Letter%20to%20Board%20re%20MMA%20Audit%20Provision%20(115(d)(3)(D)(ix)(II)).pdf.*

[48] To the extent that any of these materials contain privileged or confidential commercial or financial information or trade secrets, it should provide two versions of such documents to the Office: one redacted copy appropriate for public viewing and an unredacted copy for the Office. *See, e.g., Five Years Later—The Music Modernization Act: Hearing Before the Subcomm. on Courts, Intell. Prop. and the Internet of the H. Comm. on the Judiciary,* 117th Cong. 6 (2023) (responses to questions for the record of Kris Ahrend, CEO, the Mechanical Licensing Collective) (''Our financial advisors have advised that we not make public any details about specific investment solutions [of the Mechanical Licensing Collective's investment policy]. Their reasons include security concerns and concerns that such information could be used alongside our public royalty distribution timelines to engage in market timing to the detriment of [the Mechanical Licensing Collective].''); *see also* 5 U.S.C. 552(b)(4) (exempting agencies from requiring disclosures if they involve ''trade secrets and commercial or financial information obtained from a person and privileged or confidential'').

[49] *See* 17 U.S.C. 115(d)(3)(D)(ix)(I)(aa).

[50] The Mechanical Licensing Collective's bylaws require a biennial ''Board Diversity Report,'' that ''address[es] the extent to which the Board fully and fairly represents the whole music publishing and songwriting communities, and should specifically note any actual or potential concerns or shortcomings.'' It also ''address[es] diversity in such areas as gender/race/ethnicity, income, musical genre, geography and expertise/experience.'' The Mechanical Licensing Collective, *Bylaws of the Mechanical Licensing Collective* sec. 4.8, *https://f.hubspotuserconte.net/hubfs/8718396/files/2020-05/Bylaws%20of%20The%20MLC.pdf* (last visited Jan. 24, 2024).

[51] The Office notes that certain stakeholders would welcome referring such questions or disputes to the Office. *See, e.g., Five Years Later—The Music Modernization Act: Hearing Before the Subcomm. on Courts, Intell. Prop. and the Internet of the H. Comm. on the Judiciary,* 117th Cong. 37, 57–58 (2023) (statements of Garrett Levin, President and CEO, Digital Media Association and Abby North, President, North Music Group).

[52] S. Rep. No. 115–339, at 14 (2018).

[53] Unclaimed Royalties Report at 29.

[54] *Id.* at 38.

that is created to carry out its statutory responsibilities.[55]

2. Indicia of Endorsement and Support

The Office requests information from the Digital Licensee Coordinator regarding whether it continues to be ''endorsed by and enjoy[] substantial support from digital music providers and significant nonblanket licensees that together represent the greatest percentage of the licensee market for uses of musical works in covered activities, as measured over the preceding 3 calendar years.'' [56]

3. Administrative Capabilities and Governance

The DLC must have the administrative capabilities to perform its statutory functions.[57] The Office requests a detailed description of the Digital Licensee Coordinator's administrative capabilities and its performance of the following functions:

i. Governance

The Office requests a copy of the Digital Licensee Coordinator's current bylaws, including a summary of changes made, if any, from its initial bylaws. To the extent not addressed by its bylaws, the Office also requests a summary of its governance structure, criteria for membership, and dues paid by its members. Lastly, the Office requests a list of the Digital Licensee Coordinator's current members, and a description of its efforts to grow its membership to other DMPs, and any challenges related to such efforts.

ii. Notice and Payment Obligations

The Office requests information addressing the Digital Licensee Coordinator's efforts to enforce notice and payment obligations with respect to the administrative assessment, including: (1) how it is coordinating such efforts with the Mechanical Licensing Collective; and (2) the extent to which it is disclosing information to, and receiving information from, the Mechanical Licensing Collective on this topic.

iii. Participation in Proceedings Before the Copyright Office and Copyright Royalty Judges

The Office requests a summary of the Digital Licensee Coordinator's participation in Office or Copyright Royalty Judge proceedings, including: (1) participating in proceedings before the Copyright Royalty Judges to establish the administrative assessment; (2) gathering and providing documentation for use in proceedings before the Copyright Royalty Judges to set rates and terms under the mechanical license; and (3) participating in proceedings before the Office with respect to activities regarding the blanket license.[58]

iv. Maintaining Records of the Digital Licensee Coordinator's Activities

The Office requests a description of how the Digital Licensee Coordinator is maintaining records of its activities, including efforts to ensure that confidential, private, proprietary, or privileged information contained in its records is not improperly disclosed or used.[59]

v. Assistance With Publicity for Unclaimed Royalties

The MMA directs the DLC to ''make reasonable, good-faith efforts to assist the mechanical licensing collective . . . by encouraging digital music providers to publicize the existence of the collective and the ability of copyright owners to claim unclaimed accrued royalties.'' [60] The Office requests a detailed description of the steps that the Digital Licensee Coordinator has taken to fulfill this requirement, including whether all its members have posted the MLC's contact information in a prominent location on their websites and applications.[61] The Office also requests a summary of the Digital Licensee Coordinator's in-person outreach activities with songwriters.[62]

The Digital Licensee Coordinator is encouraged to provide any other information that it believes is relevant to demonstrate it continues to meet the statutory designation criteria.

IV. Public Participation

Interested members of the public are encouraged to comment on the topics addressed in the designees' submissions or raised by the Office in this notification of inquiry.[63] Commenters may also address any topics relevant to this periodic review of the MLC and DLC designations. Without prejudice to its review of the current designations, the Office hopes that this proceeding will serve as an opportunity for any songwriter, publisher, or DMP who wishes to express concerns, satisfaction, or priorities with respect to the administration of the MMA's blanket licensing regime to do so, and that any designated MLC or DLC will use that feedback to continually improve its services.

Dated: January 25, 2024.

Suzanne V. Wilson,

General Counsel and Associate Register of Copyrights.

[FR Doc. 2024–01781 Filed 1–29–24; 8:45 am]

BILLING CODE 1410–30–P

[55] 17 U.S.C. 115(d)(5)(A)(i).

[56] *Id.* at 115(d)(5)(A)(ii).

[57] *Id.* at 115(d)(5)(A)(iii).

[58] *Id.* at 115(d)(5)(C)(i)(III)–(V).

[59] *Id.* at 115(d)(5)(C)(i)(VI), (d)(12)(C).

[60] *See id.* at 115(d)(5)(C)(iii).

[61] *Id.* at 115(d)(5)(C)(iii)(I).

[62] *Id.* at 115(d)(5)(C)(iii)(II).

[63] Submissions by the Mechanical Licensing Collective and Digital Licensee Coordinator will be found on the Office's website at *https://www.copyright.gov/rulemaking/mma-designations/2024* approximately sixty days after the publication of this Notification of Inquiry.

OFFICE OF MANAGEMENT AND BUDGET

Request for Information: Privacy Impact Assessments

AGENCY: Office of Management and Budget.

ACTION: Request for information.

SUMMARY: Pursuant to the Executive order on *Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence,* the Office of Management and Budget (OMB) is requesting public input on how privacy impact assessments (PIAs) may be more effective at mitigating privacy risks, including those that are further exacerbated by artificial intelligence (AI) and other advances in technology and data capabilities.

DATES: Consideration will be given to written comments received by April 1, 2024.

ADDRESSES: Please submit comments via *https://www.regulations.gov/* and follow the instructions for submitting comments. Public comments are valuable, and they will inform any potential updates to relevant OMB guidance; however, OMB will not respond to individual submissions.

Privacy Act Statement: OMB is issuing this request for information (RFI) pursuant to Executive Order 14110 on *Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence.*[1] Submission of comments in response to this RFI is voluntary. Comments may be used to inform sound decision making on topics related to this RFI, including potential updates to guidance. Please note that submissions received in response to this notice may be posted on *https://www.regulations.gov/* or otherwise released in their entirety, including any personal information, business confidential information, or other

[1] E.O. No. 14110, 88 FR 75191 (Nov. 1, 2023).

sensitive information provided by the commenter. Do not include in your submissions any copyrighted material; information of a confidential nature, such as personal or proprietary information; or any information you would not like to be made publicly available. Comments are maintained under the OMB Public Input System of Records, OMB/INPUT/01; the system of records notice accessible at 88 FR 20913 (*https://www.federalregister.gov/documents/2023/04/07/2023-07452/privacy-act-of-1974-system-of-records*) includes a list of routine uses associated with the collection of this information.

FOR FURTHER INFORMATION CONTACT: Alex Goodenough, Office of Management and Budget, via email at *MBX.OMB.PIA_RFI_FY24@omb.eop.gov* or via phone at 202–395–3039.

SUPPLEMENTARY INFORMATION: Privacy safeguards are foundational to the Executive Branch's ability to maintain the public's trust, and analysis of privacy risks associated with the various activities of Executive Branch departments and agencies (''agencies'') is key to establishment of those safeguards. PIAs are a tool that agencies use to conduct that analysis. Indeed, as described in OMB's Circular No. A–130, *Managing Information as a Strategic Resource,* ''[a] PIA is one of the most valuable tools Federal agencies use to ensure compliance with applicable privacy requirements and manage privacy risks.'' [2] In addition to being a key analytical tool, PIAs also make available to the public agencies' analysis of privacy risks and safeguards put in place to mitigate those risks.

Requirements exist in statute and in OMB guidance for how agencies conduct and publish PIAs. Section 208 of the E-Government Act establishes minimum requirements for PIAs, and it requires the OMB Director to issue guidance on the required contents of PIAs.[3] OMB M–03–22, *OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002,* requires agencies to ''conduct privacy impact assessments for electronic information systems and collections and, in general, make them publicly available.'' [4] Additionally, it includes requirements related to certain agency contractors. OMB reinforced and built on the requirements in OMB M–03–22 through additional guidance on PIAs in OMB M–10–23, *Guidance for Agency Use of Third-Party websites and Applications,*[5] and in OMB Circular No. A–130.

As agency programs and services increasingly rely on rapidly advancing technology and data capabilities (*e.g.,* artificial intelligence), the privacy risk landscape also is evolving. Existing privacy risks are escalating, and new privacy risks are emerging. It is important to hear from the public as OMB considers what updates to PIA guidance may be necessary to ensure that PIAs continue to facilitate robust analysis and transparency about how agencies address these evolving privacy risks.

Seeking Input on Improving the Use of PIAs To Mitigate Privacy Risks

OMB developed this RFI in consultation with the Department of Justice, National Economic Council, and Office of Science and Technology Policy, in accordance with Executive Order 14110. OMB seeks responses to the following questions:

Role of PIAs in Addressing and Mitigating Privacy Risks

1. A wide range of privacy risks are associated with the creation, collection, use, processing, storage, maintenance, dissemination, disclosure, and disposal of personally identifiable information (PII). What improvements to OMB guidance on PIAs as analytical tools and notices to the public would assist agencies in identifying, addressing, and mitigating these risks, including when an agency:

a. Develops, procures, or uses information technology to handle PII;

b. Initiates, consistent with the Paperwork Reduction Act, a new electronic collection of information that contains PII;

c. Uses a third-party website or application that makes PII available to the agency; or

d. Engages in a relevant cross-agency initiative that involves PII?

2. What other models or best practices for conducting and documenting PIAs or similar analyses could improve agencies' PIAs?

a. Are there approaches to analyzing and documenting how an entity addresses and mitigates privacy risks used by non-federal government entities, specific sectors or industries, academia, or civil society that OMB should consider?

b. Are there similar approaches to analyzing and documenting how an entity addresses and mitigates other risks in information governance (*e.g.,* security risks) that OMB should consider from other federal guidance or frameworks?

3. What guidance should OMB consider providing to agencies to help reduce any duplication that may arise in preparing PIAs along with other assessments focused on managing risks (*e.g.,* security authorization packages or the AI impact assessments proposed in OMB's *Draft Memorandum on Advancing Governance, Innovation, and Risk Management for Agency Use of Artificial Intelligence* [6]) and to support these assessments' different functions?

Role of PIAs in Facilitating Transparency

4. What role do PIAs play in your search for information about how agencies handle PII and address privacy risks? For what purpose(s) do you read agencies' PIAs?

5. What improvements to PIAs would help you better understand agencies' assessment of privacy impacts and risk mitigation strategies?

a. What improvement(s) would you recommend to make it easier to find and access agencies' PIAs?

b. What improvement(s) would you recommend to make it easier to read and understand agencies' PIAs?

6. How can agencies increase awareness of PIAs among stakeholders?

Privacy Risks Associated With Advances in Technology and Data Capabilities, Including AI

7. AI and AI-enabled systems used by agencies can rely on data that include PII, and agencies may develop those systems or procure them from the private sector.

a. What privacy risks specific to the training, evaluation, or use of AI and AI-enabled systems (*e.g.,* related to AI system inputs and outputs, including

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[2] Off. of Mgmt. & Budget, Exec. Off. of the President, Circular No. A–130, *Managing Information as a Strategic Resource* app. II, section 5(e) (July 28, 2016), *available at https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A130/a130revised.pdf.*

[3] E-Government Act of 2002, Public Law 107–347, section 208(b)(2), (3), 116 Stat. 2899, 2921 (codified as amended at 44 U.S.C. 3501 note).

[4] Off. of Mgmt. & Budget, Exec. Off. of the President, OMB M–03–22, *OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002,* attach. A, section I.A.a (Sept. 30, 2003), *available at https://www.whitehouse.gov/wp-content/uploads/2017/11/203-M-03-22-OMB-Guidance-for-Implementing-the-Privacy-Provisions-of-the-E-Government-Act-of-2002-1.pdf.*

[5] Off. of Mgmt. & Budget, Exec. Off. of the President, OMB M–10–23, *Guidance for Agency Use of Third-Party websites and Applications* (June 25, 2010), *available at https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/2010/m10-23.pdf.*

[6] OMB released for public comment a draft memorandum on agency use of AI. *See* Off. of Mgmt. & Budget, Exec. Off. of the President, *Draft Memorandum on Advancing Governance, Innovation, and Risk Management for Agency Use of Artificial Intelligence* (Nov. 2023), *available at https://ai.gov/wp-content/uploads/2023/11/AI-in-Government-Memo-Public-Comment.pdf.*

inferences and assumptions; obtaining consent to use the data involved in these activities; or AI-facilitated reidentification) should agencies consider when conducting PIAs?

b. What guidance updates should OMB consider to improve how agencies address and mitigate the privacy risks that may be associated with their use of AI?

8. What role should PIAs play in how agencies identify and report on their use of commercially available information (CAI) [7] that contains PII?

a. What privacy risks specific to CAI should agencies consider when conducting PIAs?

b. OMB M–03–22 requires PIAs ''when agencies systematically incorporate into existing information systems databases of information in identifiable form purchased or obtained from commercial or public sources,'' while noting that ''[m]erely querying such a source on an ad hoc basis using existing technology does not trigger the PIA requirement.'' [8] What guidance updates should OMB consider to improve how agencies address and mitigate the privacy risks that may be associated with their use of CAI that contains PII?

9. What guidance updates should OMB consider to improve how agencies address and mitigate the privacy risks that may be associated with their use of other emerging technology and data capabilities?

Other Considerations

10. What else could help promote greater effectiveness and consistency across agencies in how they approach PIAs?

11. What else should OMB consider when evaluating potential updates to its guidance on PIAs?

Richard L. Revesz,

Administrator, Office of Information and Regulatory Affairs.

[FR Doc. 2024–01756 Filed 1–26–24; 8:45 am]

BILLING CODE 3110–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: The meeting was noticed on January 25, 2024, at 89 FR 4998.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Monday, January 26, 2024, from 3:00–5:00 p.m. Eastern.

CHANGE IN THE MEETING: The correct date for the meeting is Monday, January 29, 2024. The time remains the same.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Chris Blair, *cblair@nsf.gov,* 703/292–7000.

Christopher Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2024–01851 Filed 1–26–24; 11:15 am]

BILLING CODE 7555–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: 3206–0201, Federal Employees Health Benefits (FEHB) Open Season Express Interactive Voice Response (IVR) System and Open Season Website

AGENCY: Office of Personnel Management.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Office of Personnel Management (OPM), Retirement Services, offers the general public and other Federal agencies the opportunity to comment on an expiring information collection request (ICR), with change: 3206–0201, Federal Employees Health Benefits (FEHB) Open Season Express Interactive Voice Response (IVR) System and the Open Season website, Open Season Online.

DATES: Comments are encouraged and will be accepted until February 29, 2024.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent via electronic mail to *RSPublicationsTeam@opm.gov* or faxed to (202) 606–0910 or via telephone at (202) 936–0403.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35), as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection. This information collection (OMB No. 3206–0201) was previously published in the **Federal Register** on November 14, 2023, at 88 FR 78069, allowing for a 60-day public comment period. No comments were received for this collection. The purpose of this notice is to allow an additional 30 days for public comments. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Federal Employees Health Benefits (FEHB) Open Season Express Interactive Voice Response (IVR) System, and the Open Season website, Open Season Online, are used by retirees and survivors. They collect information for changing FEHB enrollments, collecting dependent and other insurance information for self and family enrollments, requesting plan brochures, requesting a change of address, requesting cancellation or suspension of FEHB benefits, asking to make payment to the Office of Personnel Management when the FEHB payment is greater than the monthly annuity amount, or for requesting FEHB plan accreditation and Customer Satisfaction Survey information.

The revisions are as follows: The Open Season enrollment dates have been updated to reflect the upcoming benefits year of 2024 and enrollment period of November 13, 2023 through December 11, 2023. The Public Burden

[7] Section 3(f) of Executive Order 14110 defines ''commercially available information'' as ''any information or data about an individual or group of individuals, including an individual's or group of individuals' device or location, that is made available or obtainable and sold, leased, or licensed to the general public or to governmental or non-governmental entities.'' 88 FR 75194.

[8] OMB M–03–22, attach. A, section II.B.b.6.

Statement has been updated due to a systematic review.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Federal Employees Health Benefits (FEHB) Open Season Express Interactive Voice Response (IVR) System and Open Season Online.

OMB Number: 3206–0201.

Frequency: On occasion.

Affected Public: Individual or Households.

Number of Respondents: 350,100.

Estimated Time per Respondent: 10 minutes.

Total Burden Hours: 58,350 hours.

Office of Personnel Management.

Kayyonne Marston,

Federal Register Liaison.

[FR Doc. 2024–01742 Filed 1–29–24; 8:45 am]

BILLING CODE 6325–38–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99425; File No. SR–PEARL–2024–04]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change by MIAX PEARL, LLC To Amend Exchange Rule 2613, Usage of Data Feeds

January 24, 2024.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 22, 2024, MIAX PEARL, LLC (''MIAX Pearl'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Exchange Rule 2613(a), Usage of Data Feeds, to disclose that the Exchange will utilize direct data feeds from the Investors Exchange LLC (''IEX'') when performing order handling, order execution, routing, and related compliance processes for equity securities.

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-equities/pearl-equities/rule-filings,* at MIAX Pearl's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Exchange Rule 2613 identifies the data feeds that the Exchange utilizes for the handling, execution, and routing of orders in equity securities on the Exchange's equity trading platform (''MIAX Pearl Equities''), as well as for surveillance necessary to monitor compliance with applicable securities laws and Exchange Rules. The Exchange currently utilizes IEX market data from the Consolidated Quotation System (''CQS'')/UTP Quotation Data Feed (''UQDF'') for these purposes on MIAX Pearl Equities. The Exchange intends to begin to utilize IEX's direct feeds in place of market data from the CQS/UQDF. Therefore, the Exchange proposes to amend Exchange Rule 2613(a) to reflect that the Exchange will utilize IEX's direct feeds in place of market data from the CQS/UQDF when performing order handling, order execution, routing, and related compliance processes for equity securities on MIAX Pearl Equities. The Exchange does not currently utilize a secondary source for data from IEX. Once it begins to utilize direct feeds for data from IEX, the Exchange will also begin to utilize CQS/UQDF as a secondary source of data from IEX on MIAX Pearl Equities.

Implementation

Due to the technological changes associated with this proposed change, the Exchange will issue a trading alert publicly announcing the implementation date of this proposed rule change. The Exchange anticipates that the implementation date will be in either the second or third quarter of 2024.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[3] in general, and furthers the objectives of Section 6(b)(5),[4] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The proposal to update Exchange Rule 2613(a) to reflect that the Exchange will utilize IEX's direct feeds in place of market data from the CQS/UQDF on MIAX Pearl Equities will continue to provide market participants with insight and transparency into which data feeds the Exchange utilizes when performing order handling, order execution, routing, and related compliance processes for equity securities. The Exchange's proposal to utilize IEX's direct feeds promotes just and equitable principles of trade because it will allow the Exchange to receive market data directly from IEX, thereby potentially enhancing the performance of its order handling, order execution, routing, and related compliance processes for equity securities. The proposed rule changes also remove impediments to and perfects the mechanism of a free and open market and protects investors and the public interest because it will continue to ensure that Exchange Rule 2613(a) accurately reflects the Exchange's sources of market data it utilizes for each other equities exchange and the Financial Industry Regulatory Authority, Inc.'s Alternative Display Facility.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes the proposal would enhance competition by

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78f(b).

[4] 15 U.S.C. 78f(b)(5).

enhancing transparency and enabling market participants to better assess the quality of MIAX Pearl Equities' execution and routing services by continuing to provide market participants with insight and transparency into which data feeds the Exchange utilizes when performing order handling, order execution, routing, and related compliance processes for equity securities. The Exchange also believes the proposal would enhance competition because it will potentially enhance the performance of its order handling and execution of orders in equity securities by receiving market data directly from IEX. Lastly, the proposed rule change will not impact competition between market participants because it will affect all market participants equally.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act[5] and Rule 19b–4(f)(6)[6] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–PEARL–2024–04 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–PEARL–2024–04. 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–PEARL–2024–04 and should be submitted on or before February 20, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–01747 Filed 1–29–24; 8:45 am]

BILLING CODE 8011–01–P

[5] 15 U.S.C. 78s(b)(3)(A).

[6] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: Publishing in the FR of 1/29/24

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Wednesday, January 31, 2024, at 9:00 a.m.

CHANGES IN THE MEETING: The Open Meeting scheduled for Wednesday, January 31, 2024, at 9:00 a.m., has been changed to Wednesday, January 31, 2024, at 9:30 a.m.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Authority: 5 U.S.C. 552b.

Dated: January 26, 2024.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–01948 Filed 1–26–24; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99423; File No. SR–LCH SA–2023–008]

Self-Regulatory Organizations; LCH SA; Order Approving Proposed Rule Change, as Modified by Partial Amendment No. 1, Relating to Recovery and Resolution

January 24, 2024.

I. Introduction

On November 24, 2023, Banque Centrale de Compensation, which conducts business under the name LCH SA (''LCH SA''), filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend its CDS Clearing Rule Book (''Rule Book'') to make amendments relating to recovery and resolution. On December 5, 2023, LCH SA filed Partial Amendment No. 1 to the proposed rule change to make certain changes to the Exhibit 5 to File No. LCH SA–2023–008.[3] The proposed rule change, as

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Partial Amendment No. 1 updates the pagination throughout Exhibit 5 to File No. LCH SA–2023–008 and the Table of Contents in Exhibit 5 to File No. LCH SA–2023–008 to reflect the revised pagination. Partial Amendment No. 1 would also remove two references to field codes in Chapter 1 of Exhibit 5 to File No. LCH SA–2023–008.

modified by Partial Amendment No. 1 (hereinafter, the ''Proposed Rule Change'') was published for comment in the **Federal Register** on December 13, 2023.[4] The Commission has not received any comments on the Proposed Rule Change. For the reasons discussed below, the Commission is approving the Proposed Rule Change.

II. Description of the Proposed Rule Change

LCH SA is a clearing agency that offers clearing of, among other things, credit-default swaps (''CDS'').[5] LCH SA is registered with the Commission for clearing CDS that are security-based swaps (''SBS'') and with the Commodity Futures Trading Commission (''CFTC'') for clearing CDS that are swaps. In addition to being registered with the Commission and CFTC, LCH SA is authorized to offer clearing services in the European Union pursuant to rules established under European Markets Infrastructure Regulation (''EMIR'') for Central Counter Parties (''CCP''). LCH SA is required to amend its rules to remain in compliance with the CCP Recovery and Resolution Regulation under EMIR.[6] The goal of the CCP Recovery and Resolution Regulation is to ensure that both CCPs and national authorities in the European Union have the means to act decisively in a crisis scenario. LCH SA is proposing to amend its Rule Book to comply with Article 9(6) and Article 9(14) of the CCP Recovery and Resolution Regulation.[7] The Proposed Rule Change would amend Title I, Title II, Title IV, and Appendix 1 of the Rule Book.

Article 9(14) of the CCP Recovery and Resolution Regulation requires that, following a default event in respect of a clearing member, each CCP shall use an additional amount of its pre-funded, dedicated own resources (the ''second skin-in-the-game'') prior to the requirement of non-defaulting clearing members to make a contribution in cash to the CCP amounting to at least each clearing member's contribution to the default fund. This second skin-in-the-game is required in addition to the prefunded resources required in accordance with EMIR (the ''first skin-in-the-game''),[8] which will be used by the CCP before the use of each non-defaulting clearing member's initial contribution to the default fund.[9] On November 25, 2022, the European Commission adopted a delegated act specifying the methodology for calculation and maintenance of the second skin-in-the-game to be used in accordance with Article 9(14) of the CCP Recovery and Resolution Regulation (the ''Commission-Delegated Regulation'').[10] Separately, Article 9(6) of the CCP Recovery and Resolution Regulation requires that CCPs provide in their rules that they may deviate from their recovery plan measures and, in such circumstances, they shall notify their competent authority designated in accordance with EMIR.[11]

A. Defined Terms

Title I of LCH SA's Rule Book addresses general provisions and legal framework, including a set of defined terms in Chapter 1. LCH SA proposes to add two new defined terms to Chapter 1. First, LCH SA would add the term ''CCP Recovery and Resolution Regulation,'' which would be defined as Regulation (EU) 2021/23 of the European Parliament and of the Council of 16 December 2020 on a framework for the recovery and resolution of central counterparties. Second, LCH SA would add the term ''ACPR,'' which would be defined as the Autorité de Contrôle Prudentiel et de Résolution and any successor organization. The ACPR is one of LCH SA's national competent authorities.[12] LCH SA also proposes to replace each reference to Autorité de Contrôle Prudentiel et de Résolution in the Rule Book with the new defined term ACPR.

B. Recovery Plan

Title I of LCH SA's Rule Book includes provisions related to membership in LCH SA, including terms related to the suspension and termination of membership in Chapter 4 of Title II. LCH SA proposes to add a new section 2.4.4 to Chapter 4 that pertains specifically to recovery. LCH SA maintains a recovery plan. The recovery plan includes certain quantitative and qualitative indicators to identify the circumstances under which LCH SA may take specific measures, which are also specified in the recovery plan, in the case of a default or non-default event. The goal of such measures is the restoration of LCH SA's financial resources so it can continue providing critical functions in all relevant scenarios. As required by Article 9(6), proposed Article 2.4.4 would provide for an additional scenario in which LCH SA either takes measures provided for in its recovery plan despite the fact that the relevant indicators have not been met, or refrains from taking measures provided for in the recovery plan despite the fact that the relevant indicators have been met. In either event, the proposed rule change would require any such proposal to be submitted to the LCH SA board of directors for approval, and LCH to submit to the ACPR without delay any subsequent decision taken by the board of directors.

C. Default Waterfall

Title IV of LCH SA's Rule Book includes provisions related to risk management, including terms related to events of default in Chapter 3 of Title IV. LCH SA proposes to amend the default waterfall provisions in Article 4.3.3.1 of Chapter 3. Article 4.3.3.1 defines the waterfall of resources that LCH SA would apply to cover losses arising out of a member default. LCH SA proposes to add LCH SA's second skin-in-the-game as a new loss mitigation resource to its default waterfall.[13] The second skin-in-the-game would be applied immediately before the collateral deposited by the non-defaulting clearing members. The proposed amendment to the waterfall provisions will also provide that, in accordance with Article 9(14) of the CCP Recovery and Resolution

[4] Securities Exchange Act Release No. 99109 (Dec. 7, 2023), 88 FR 86389 (Dec. 13, 2023) (File No. SR–LCH–2023–008).

[5] Capitalized terms used but not defined herein have the meanings specified in the LCH CDS Rule Book as applicable.

[6] Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade reporting, Title III, Chapter 1, Section 1, Article 9.

[7] *Id.*

[8] Article 9(14) of Regulation (EU) 2021/23 of the European Parliament and of the Council of 16 December 2020 on a framework for the recovery and resolution of central counterparties. *http://data.europa.eu/eli/reg/2021/23/oj.*

[9] Regulation (EU) 2021/23 of the European Parliament and of the Council of 16 December 2020 on a framework for the recovery and resolution of central counterparties, *Article 9(14). http://data.europa.eu/eli/reg/2021/23/oj.*

[10] Commission Delegated Regulation (EU) 2023/840 of 25 November 2022 supplementing Regulation (EU) 2021/23 of the European Parliament and of the Council with regard to regulatory technical standards specifying the methodology for calculation and maintenance of the additional amount of pre-funded dedicated own resources to be used in accordance with Article 9(14) of that Regulation. *http://data.europa.eu/eli/reg_del/2023/840/oj.*

[11] Regulation (EU) 2021/23 of the European Parliament and of the Council of 16 December 2020 on a framework for the recovery and resolution of central counterparties, Article 9(6). *http://data.europa.eu/eli/reg/2021/23/oj.*

[12] EMIR requires that each EU member state designate the competent authority responsible for, *inter alia,* supervision of CCPs established in its territory. *See* Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories, Title III, Chapter 2, Section 1, Article 22 (Competent Authority).

[13] The new resource would be added as the sixth resource on the list, requiring LCH SA to renumber items (vi) and (vii) of the current list.

Regulation and Article 1 of the Commission-Delegated Regulation, the LCH SA additional dedicated own resources, as determined from time to time, will be (a) up to the amount of such dedicated own resources allocated to the CDS Default Fund in proportion to the size of the CDS Default Fund; and (b) in the case of an Event of Default occurring after a previous Event of Default, but before LCH SA has reinstated such dedicated own resources in accordance with Article 3(2) of the Commission Delegated Regulation, up to the residual amount of such dedicated own resources in the CDS Default Fund.

In the penultimate paragraph of Article 4.3.3.1, LCH SA proposes to clarify that the LCH SA second skin-in-the-game could be up to the amount of LCH SA's own resources allocated to the CDS Default Fund.[14]

III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act requires the Commission to approve a proposed rule change of a self-regulatory organization if it finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the organization.[15] For the reasons given below, the Proposed Rule Change is consistent with Section 17A(b)(3)(F) of the Act[16] and Rule 17Ad–22(e)(2)[17] thereunder.

A. Consistency With Section 17A(b)(3)(F) of the Act

Section 17A(b)(3)(F) of the Act requires, among other things, that the rules of LCH SA be designed to assure the safeguarding of securities and funds which are in the custody or control of LCH SA or for which it is responsible.[18] As discussed in more detail below, the Proposed Rule Change is consistent with Section 17A(b)(3)(F) of the Act.[19]

The Commission continues to regard skin-in-the-game as a potential tool to align the various incentives of a covered clearing agency's stakeholders, including management and clearing members.[20] LCH SA proposes to add a second skin-in-the-game as a resource to be used to cover the losses resulting from the implementation of the CDS Default Management Process before the collateral deposited by the non-defaulting clearing members as an additional contribution to the CDS Default Fund. Adding a second skin-in-the-game resource would create additional incentive for LCH SA to maintain the appropriate amount of resources to manage clearing member default because failure to do so would result in a direct cost to LCH SA. Creating additional incentive for LCH SA to maintain an appropriate amount of resources, in turn, could reduce the potential losses charged to the CDS Default Fund contributions of non-defaulting clearing members in the event of a clearing member default, which in turn would help assure the safeguarding of the CDS Default Fund contributions of non-defaulting clearing members.

As discussed above, LCH SA proposes to change its Rule Book so that it can either take measures provided for in its recovery plan even if relevant indicators have not been met, or refrain from taking measures provided for in the recovery plan even though the relevant indicators have been met, provided it obtains board approval and promptly notifies the ACPR of the board's decision. This too would provide LCH SA with additional flexibility to take actions to safeguard funds for which it is responsible.

Based on the foregoing, the Commission finds that the Proposed Rule Change is consistent with the requirements of Section 17A(b)(3)(F) of the Act.[21]

B. Consistency With Rule 17Ad–22(e)(2) Under the Act

Rule 17Ad–22(e)(2) under the Act requires that a covered clearing agency establish, implement, maintain, and enforce written policies and procedures reasonably designed to provide for governance arrangements that, among other things, support the public interest requirements of the Act.[22] In adopting Rule 17Ad–22(e)(2), the Commission stated that ''the proper alignment of incentives is an important element of a covered clearing agency's risk management practices,'' and noted that skin-in-the-game ''may play a role in those risk management practices in many instances.''[23] And, as noted above, the Commission continues to regard skin-in-the-game as a potential tool to align the various incentives of a covered clearing agency's stakeholders, including management and clearing members.[24]

As described above, LCH SA proposes to amend its Rule Book so that the second skin-in-the-game will be used to cover the losses resulting from the implementation of the CDS Default Management Process immediately before the collateral deposited by the non-defaulting clearing members. This would mean that, following a default event in respect of a clearing member, LCH SA would apply its own resources to mitigate losses before applying resources provided by non-defaulting clearing members. As discussed above, adding a second skin-in-the-game resource would help to create incentive for LCH SA to mitigate, manage, and maintain the appropriate amount of resources to manage clearing member default because failure to do so would result in a direct cost to LCH SA. Such mitigation of risk in the clearance and settlement of securities would be consistent with supporting the public interest because it helps reduce market disruptions. Accordingly, the Commission finds that that the Proposed Rule Change is consistent with Rule 17Ad–22(e)(2) under the Act.[25]

IV. Conclusion

On the basis of the foregoing, the Proposed Rule Change is consistent with the requirements of the Act, and in particular, Section 17A(b)(3)(F) of the Act[26] and Rule 17Ad–22(e)(2)[27] thereunder.

It is therefore ordered pursuant to Section 19(b)(2) of the Act that the proposed rule change (SR–LCH SA–2023–008), as modified by Partial Amendment No. 1, be, and hereby is, approved.[28]

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[29]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–01752 Filed 1–29–24; 8:45 am]

BILLING CODE 8011–01–P

[14] LCH SA also proposes conforming edits in Section 7 of Appendix 1 to the Rule Book, which deals with loss distributions in the context of the CDS default management process. Specifically, LCH SA proposes to add a reference in Section 7 of the appendix to section 4.3.3.1 as well as language consistent with the amended language of 4.3.3.1.

[15] 15 U.S.C. 78s(b)(2)(C).

[16] 15 U.S.C. 78q–1(b)(3)(F).

[17] 17 CFR 240.17Ad–22(e)(2).

[18] 15 U.S.C. 78q–1(b)(3)(F).

[19] 15 U.S.C. 78q–1(b)(3)(F).

[20] Securities Exchange Act Release No. 78961 (Sep. 28, 2016), 81 FR 70786, 70806 (Oct. 13, 2016) (S7–03–14) (''Covered Clearing Agency Standards'').

[21] 15 U.S.C. 78q–1(b)(3)(F).

[22] 17 CFR 240.17Ad–22(e)(2)(iii).

[23] Covered Clearing Agency Standards, 81 FR at 70806.

[24] Securities Exchange Act Release No. 78961 (Sep. 28, 2016), 81 FR 70786, 70806 (Oct. 13, 2016) (S7–03–14) (''Covered Clearing Agency Standards'').

[25] 17 CFR 240.17Ad–22(e)(2).

[26] 15 U.S.C. 78q–1(b)(3)(F).

[27] 17 CFR 240.17Ad–22(e)(2).

[28] In approving the Proposed Rule Change, the Commission considered the proposal's impacts on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[29] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 35114; File No. 812–15431]

Golub Capital BDC Inc., et al.

January 25, 2024.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of application for an order under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act.

Summary of Application: Applicants request an order to permit certain business development companies (''BDCs'') and closed-end management investment companies to co-invest in portfolio companies with each other and with certain affiliated investment entities.

Applicants: Golub Capital BDC Inc., Golub Capital BDC 3, Inc., Golub Capital Direct Lending Corp., Golub Capital BDC 4, Inc., Golub Capital Direct Lending Unlevered Corp., Golub Capital Private Credit Fund, GC Advisors, LLC, Golub Capital LLC, GC Investment Management LLC, GC OPAL Advisors LLC, OPAL BSL LLC (Management Series), Golub Capital Partners 9, L.P., Golub Capital Partners 10, L.P., Golub Capital Partners 12 Feeder Fund, L.P., Golub Capital Partners 12, L.P., Golub Capital Partners 14, L.P., Golub Capital Partners International 9, L.P., Golub Capital Partners International 10, L.P., Golub Capital Partners International 12, L.P., Golub Capital Partners International 14, L.P., Golub Capital Partners International Rollover Fund 2, L.P., Golub Capital Partners Private Credit Trust, Golub Capital Partners Rollover Fund 2, L.P., Golub Capital Partners TALF 2020–1, L.P., GPCT Holdings 1, L.P., Golub Capital Pearls Direct Lending Program, L.P., OPAL BSL LLC (EU Origination Series), OPAL BSL LLC (Retention Series), Golub Capital International Ltd., GEMS Fund, L.P., GEMS Fund 4, L.P., GEMS Fund 5 International, L.P., GEMS Fund 5, L.P., Golub Capital Partners ABS Funding 2019–1, L.P., Golub Capital Partners ABS Funding 2020–1, L.P., Golub Capital Partners ABS Funding 2021–1, L.P., Golub Capital Partners ABS Funding 2021–2, Golub Capital Partners ABS Funding 2022–1, Golub Capital Partners CLO 16(M)-R2, L.P., Golub Capital Partners CLO 17(M)-R, Ltd., Golub Capital Partners CLO 18(M)-R2, Golub Capital Partners CLO 19(B)-R2, Ltd., PEARLS IX, L.P., PEARLS X, L.P., Golub Capital Partners CLO 21(M)-R, Ltd., Golub Capital Partners CLO 22(B)-R, Ltd., Golub Capital Partners CLO 23(B)-R, Ltd., Golub Capital Partners CLO 24(M)-R, Ltd., Golub Capital Partners CLO 25(M)-R, Ltd., Golub Capital Partners CLO 26(B)-R, Ltd., Golub Capital Partners CLO 28(M)-R, L.P., Golub Capital Partners CLO 30(M)-R, Golub Capital Partners CLO 31(M)-R, Ltd., Golub Capital Partners CLO 33(M)-R2, L.P., GCP Finance 2 L.P., GCPF 7 Loan Funding A L.P., Golub Capital Partners CLO 34(M)-R, Ltd., GC International Ladder Ltd., Golub Capital Partners CLO 35(B), Ltd., Golub Capital Partners CLO 36(M), Ltd., Golub Capital Partners CLO 37(B), Ltd., Golub Capital Partners CLO 38(M), Ltd., GCP International Tranches Ltd., GCP Master Holdings, LP, GDLC Feeder Fund, L.P., GCP Finance 5 L.P., GCP Finance 6 L.P., GCP Finance 7 L.P., GCP Finance 8 L.P., GCP Finance 9 L.P., GCP Finance L.P., Golub Capital Partners 11, L.P., Golub Capital Partners International 11, L.P., Golub Capital Partners 11 Rollover Fund, L.P., GC Finance Operations Multicurrency Trust, Golub Capital Partners CLO 62(B), Ltd., Golub Capital Partners CLO 64(B), Ltd., Golub Capital Finance Funding III Trust, Golub Capital Finance Funding IV Trust, Golub Capital Finance Funding Trust, Golub Capital Partners CLO 39(B), Ltd., Golub Capital Partners CLO 40(B), Ltd., Golub Capital Partners CLO 41(B)-R, Ltd., Golub Capital Partners CLO 42(M), Ltd., Golub Capital Partners CLO 43(B), Ltd., Golub Capital Partners CLO 44(M), Ltd., Golub Capital Partners CLO 45(M), Ltd., Golub Capital Partners CLO 46(M), L.P., Golub Capital Partners CLO 47(M), L.P., Golub Capital Partners CLO 48(B), Ltd., Golub Capital Partners CLO 49(M)-R, Golub Capital Partners CLO 50(B)-R, Ltd., Golub Capital Partners CLO 51(M), L.P., Golub Capital Partners CLO 52(B), Ltd., Golub Capital Partners CLO 53(B), Ltd., Golub Capital Partners CLO 54(M), L.P., Golub Capital Partners CLO 55(B), Ltd., Golub Capital Partners CLO 56(M), Golub Capital Partners CLO 57(M), Golub Capital Partners CLO 58(B), Ltd., Golub Capital Partners CLO 59(M), Golub Capital Partners CLO 61(M), GBDC 3 Funding II LLC, GBDC 3 Funding LLC, GBDC 3 Holdings Coinvest, Inc., GBDC 3 Holdings ED Coinvest, Inc., GBDC Holdings Coinvest, Inc., GBDC Holdings ED Coinvest, Inc., GBDC Quick Quack Coinvest LLC, GBDC3 Quick Quack Coinvest LLC, GBDC3F Loan Subsidiary A LLC, GCBH 3 North Haven Stack Buyer Coinvest, Inc., GCIC CLO II Depositor LLC, GCIC CLO II LLC, GCIC Funding LLC, GCIC Holdings LLC, GCIC North Haven Stack Buyer Coinvest Inc., GCIC Quick Quack Coinvest LLC, GDLC Funding LLC, GDLC Holdings LLC, GDLC Holdings Coinvest Inc., Golub Capital 3 Holdings LLC, Golub Capital BDC 3 ABS 2022–1 Depositor LLC, Golub Capital BDC 3 ABS 2022–1 LLC, Golub Capital BDC 3 CLO 1 Depositor LLC, Golub Capital BDC 3 CLO 2 Depositor LLC, Golub Capital BDC 3 CLO 2 LLC, Golub Capital BDC 3 CLO 1 LLC, Golub Capital BDC CLO 2014 LLC, Golub Capital BDC CLO III Depositor LLC, Golub Capital BDC CLO III LLC, Golub Capital BDC Holdings LLC, Golub Capital 4 Holdings LLC, Golub Capital BDC 4 Funding LLC, Golub Capital 4 Holdings Coinvest, Inc., Golub Capital Direct Lending Unlevered Holdings LLC, Golub Capital Direct Lending Unlevered Holdings Coinvest, Inc., GCRED Holdings, LLC, GCP HS Fund, GCPF 1 Loan Funding F, L.P., Golub Capital Partners CLO 60(B), Ltd., Golub Capital Strategic Partners Fund 1, L.P., Golub Capital Strategic Partners Fund 2, L.P., Golub Capital Partners Short Duration 2022–1, Golub Emerald Fund, L.P., Golub Sapphire Fund, L.P., GEMS Fund 6, L.P., GEMS Fund 6 International, L.P., GCP Finance 11 L.P., GCP SG Warehouse 2022–1, Golub Capital Partners CLO 66(B), LLC, Golub Capital Partners 15, L.P., Golub Capital Partners International 15, L.P., GEMS Fund 6 International Feeder, L.P., Golub Capital Finance Funding Repo NW, Golub Capital Finance Funding CLO NW, Golub Capital Finance Funding V Trust, GCP CLO Warehouse BARC 2023–2, Ltd., Golub Capital Coinvestment LP, Golub Capital Partners CLO 66(B), Ltd., Golub Capital Partners CLO 67(M), Golub Capital Partners CLO 68(B) Ltd., Golub Capital Partners ABS-Funding 2023–1.

Filing Dates: The application was filed on January 30, 2023, and amended on July 26, 2023.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. Hearing requests should be received by the Commission by 5:30 p.m. on February 20, 2024 and should be accompanied by proof of service on the Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–

5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: David B. Golub, *legal@golubcapital.com,* and Steven B. Boehm, *stevenboehm@eversheds-sutherland.com.*

FOR FURTHER INFORMATION CONTACT: Shayna Gilmore, Senior Counsel, or Kyle R. Ahlgren, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' amended and restated application, dated July 26, 2023, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at, *https://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–01818 Filed 1–29–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99427; File No. SR–OCC–2023–801]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of Amendment No. 2 to Advance Notice Relating to The Options Clearing Corporation's Concerning Modifications to the Amended and Restated Stock Options and Futures Settlement Agreement Between The Options Clearing Corporation and the National Securities Clearing Corporation

January 24, 2024.

Pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, entitled Payment, Clearing and Settlement Supervision Act of 2010 (''Clearing Supervision Act'') [1] and Rule 19b–4(n)(1)(i) [2] of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act''),[3] notice is hereby given that on January 23, 2024, the Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') this amendment (''Amendment No. 2'') to an advance notice as described in Items I, II and III below, which Items have been prepared primarily by OCC. The Commission is publishing this notice to solicit comments on the advance notice from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Advance Notice

This Amendment No. 2 to the advance notice SR–OCC–2023–801 is submitted by OCC to: (1) modify the Amended and Restated Stock Options and Futures Settlement Agreement dated August 5, 2017 between OCC and National Securities Clearing Corporation (''NSCC,'' and together with OCC, the ''Clearing Agencies'') (''Existing Accord'') [4] to permit OCC to elect to make a cash payment to NSCC following the default of a common clearing participant that would cause NSCC's central counterparty trade guaranty to attach to certain obligations of that participant and to make certain related revisions to OCC By-Laws, OCC Rules,[5] OCC's Comprehensive Stress Testing & Clearing Fund Methodology, and Liquidity Risk Management Description and OCC's Liquidity Risk Management Framework (''Phase 1'') and (2) to improve information sharing between the Clearing Agencies to facilitate the upcoming transition to a T+1 standard securities settlement cycle and allow OCC, after the compliance date under amended Exchange Act Rule 15c6–1(a), to provide certain assurances to NSCC prior to the default of a common clearing participant that would enable NSCC to begin processing E&A/Delivery Transactions (defined below) before the central counterparty trade guaranty attaches to certain obligations of that participant (''Phase 2'').[6] This Amendment No. 2 would amend and replace the Initial Filing and Amendment No. 1 in their entirety.

The proposed changes are included in Exhibits 5A and 5B and confidential Exhibits 5C, 5D, and 5E of Amendment No. 2 to File No. SR–OCC–2023–801. Material proposed to be added is underlined and material proposed to be deleted is marked in strikethrough text.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Advance Notice

In its filing with the Commission, OCC included statements concerning the purpose of and basis for the advance notice and discussed any comments it received on the advance notice. The text of these statements may be examined at the places specified in Item IV below. OCC has prepared summaries, set forth in sections (A) and (B) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement on Comments on the Advance Notice Received From Members, Participants or Others

Written comments were not and are not intended to be solicited with respect to the proposed changes, and none have been received.

(B) Advance Notice Filed Pursuant to Section 806(e) of the Payment, Clearing, and Settlement Supervision Act

Description of Proposed Change

Background

OCC is filing this advance notice to (1) modify the Existing Accord between OCC and NSCC to permit OCC to elect to make a cash payment to NSCC following the default of a common clearing participant that would cause NSCC's central counterparty trade guaranty to attach to certain obligations of that participant and to make certain related revisions to OCC By-Laws, OCC Rules, OCC's Comprehensive Stress

[1] 12 U.S.C. 5465(e)(1).

[2] 17 CFR 240.19b–4(n)(1)(i).

[3] 15 U.S.C. 78a *et seq.*

[4] The Existing Accord was previously approved by the Commission. *See* Securities Exchange Act Release Nos. 81266, 81260 (July 31, 2017) (File Nos. SR–NSCC–2017–007; SR–OCC–2017–013), 82 FR 36484 (Aug. 4, 2017).

[5] OCC By-Laws are *available at https://www.theocc.com/getmedia/3309eceb-56cf-48fc-b3b3-498669a24572/occ_bylaws.pdf* and OCC Rules are *available at https://www.theocc.com/getmedia/9d3854cd-b782-450f-bcf7-33169b0576ce/occ_rules.pdf.*

[6] OCC initially filed an advance notice concerning the proposed Phase 1 changes on August 10, 2023. *See* Securities Exchange Act Release No. 98214 (Aug. 24, 2023), 88 FR 59988 (Aug. 30, 2023) (File No. SR–OCC–2023–801) (''Initial Filing''). OCC subsequently submitted a partial amendment (''Amendment No. 1'') to clarify the proposed implementation plan for the Initial Filing *available at https://www.theocc.com/getmedia/fb30a875-2438-4b2d-bb79-3ff364b6796b/SR-OCC-2023-801-Partial-Amendment-No-1.pdf.* NSCC also has filed a proposed rule change with the Commission in connection with this proposal. *See* Securities Exchange Act Release No. 98213 (Aug. 24, 2023), 88 FR 59968 (Aug. 30, 2023) (File No. SR–NSCC–2023–007); Securities Exchange Act Release No. 98930 (Nov. 14, 2023), 88 FR 80790 (Nov. 20, 2023) (Partial Amendment No. 1 to File No. SR–NSCC–2023–007).

Testing & Clearing Fund Methodology, and Liquidity Risk Management Description and OCC's Liquidity Risk Management Framework for Phase 1 and (2) improve information sharing between the Clearing Agencies to facilitate the upcoming transition to a T+1 standard securities settlement cycle and allow OCC, after the compliance date under amended Exchange Act Rule 15c6–1(a), to provide certain assurances to NSCC prior to the default of a common clearing participant that would enable NSCC to begin processing E&A/Delivery Transactions before the central counterparty trade guaranty attaches to certain obligations of that participant for Phase 2.

i. Executive Summary

NSCC is a clearing agency that provides clearing, settlement, risk management, and central counterparty services for trades involving equity securities. OCC is the sole clearing agency for standardized equity options listed on national securities exchanges registered with the Commission, including options that contemplate the physical delivery of equities cleared by NSCC in exchange for cash (''physically settled'' options).[7] OCC also clears certain futures contracts that, at maturity, require the delivery of equity securities cleared by NSCC in exchange for cash. As a result, the exercise/assignment of certain options or maturation of certain futures cleared by OCC effectively results in stock settlement obligations. NSCC and OCC maintain a legal agreement, generally referred to by the parties as the ''Accord'' agreement, that governs the processing of such physically settled options and futures cleared by OCC that result in settlement obligations in underlying equity securities to be cleared by NSCC (*i.e.,* the Existing Accord). The Existing Accord establishes terms under which NSCC accepts for clearing certain securities transactions that result from the exercise and assignment of relevant options contracts and the maturity of futures contracts that are cleared and settled by OCC.[8] It also establishes the time when OCC's settlement guaranty in respect of those transactions ends and NSCC's settlement guaranty begins.

The Existing Accord allows for a scenario in which NSCC could choose not to guarantee the settlement of such securities arising out of E&A/Delivery Transactions. Specifically, NSCC is not obligated to guarantee settlement until its member has met its collateral requirements at NSCC. If NSCC chooses not to guarantee settlement, OCC would engage in an alternate method of settlement outside of NSCC. This scenario presents two primary problems. First, the cash required for OCC and its Clearing Members in certain market conditions to facilitate settlement outside of NSCC could be significantly more than the amount required if NSCC were to guarantee the relevant transactions. This is because settlement of the transactions in the underlying equity securities outside of NSCC would mean that they would no longer receive the benefit of netting through the facilities of NSCC. In such a scenario, the additional collateral required from Clearing Members to support OCC's continuing settlement guarantee would also have to be sufficiently liquid to properly manage the risks associated with those transactions being due on the second business day following the option exercise or the relevant futures contract maturity date.

Based on an analysis of scenarios using historical data where it was assumed that OCC could not settle transactions through the facilities of NSCC, the worst-case outcome resulted in extreme liquidity demands of over $300 billion for OCC to effect settlement via an alternative method, *e.g.,* by way of gross broker-to-broker settlement, as discussed in more detail below. OCC Clearing Members, by way of their contributions to the OCC Clearing Fund, would bear the brunt of this demand. Furthermore, there is no guarantee that OCC Clearing Members could fund the entire amount of any similar real-life scenarios. By contrast, projected Guaranty Substitution Payments, defined below, identified during the study ranged from approximately $419 million to over $6 billion, also as discussed in more detail below.

The second primary problem relates to the significant operational complexities if settlement occurs outside of NSCC. More specifically, netting through NSCC reduces the volume and value of settlement obligations. For example, in 2022 it is estimated that netting through NSCC's continuous net settlement (''CNS'') accounting system[9] reduced the value of CNS settlement obligations by approximately 98% or $510 trillion from $519 trillion to $9 trillion. If settlement occurred outside of NSCC, on a broker-to-broker basis between OCC Clearing Members, for example, shares would not be netted and Clearing Members would have to coordinate directly with each other to settle the relevant transactions. The operational complexities and uncertainty associated with alternate means of settlement would impact every market participant involved in a settlement of OCC-related transactions.

To address these problems, the Clearing Agencies are proposing certain changes as part of Phase 1 to amend and restate the Existing Accord and make related changes to their respective rules that would allow OCC to elect to make a cash payment (the ''Guaranty Substitution Payment'' or ''GSP'') to NSCC following the default of a Common Member[10] that would cause NSCC to guarantee settlement of that Common Member's transactions and, therefore, cause those transactions to be settled through processing by NSCC. In connection with this proposal, OCC also would enhance its daily liquidity stress testing processes and procedures to account for the possibility of OCC making such a payment to NSCC in the event of a Common Member default. By making these enhancements to its stress testing, OCC could include the liquid resources necessary to make the payment in its resource planning. The Clearing Agencies believe that by NSCC accepting such a payment from OCC, the operational efficiencies and reduced costs related to the settlement of transactions through NSCC would limit market disruption following a Common Member default because settlement through NSCC following such a default would be less operationally complex and would be expected to require less liquidity and other collateral from market participants than the processes available to OCC for closing out positions. Additionally, proposed enhancements by OCC to its liquidity stress testing would add assurances that

[7] The term ''physically-settled'' as used throughout the OCC Rules refers to cleared contracts that settle into their underlying interest (*i.e.,* options or futures contracts that are not cash-settled). When a contract settles into its underlying interest, shares of stock are sent, *i.e.,* delivered, to contract holders who have the right to receive the shares from contract holders who are obligated to deliver the shares at the time of exercise/assignment in the case of an option and maturity in the case of a future.

[8] Under the Existing Accord, such options and futures are defined as ''E&A/Delivery Transactions,'' which refers to ''Exercise & Assignment Delivery Transactions.''

[9] *See* Rule 11 (CNS System) and Procedure VII (CNS Accounting Operation) of the NSCC Rules. *See* NSCC's Rules, *available at https://www.dtcc.com/-/media/Files/Downloads/legal/rules/nscc_rules.pdf.*

[10] A firm that is both an OCC Clearing Member and an NSCC Member or is an OCC Clearing Member that has designated an NSCC Member to act on its behalf is referred to herein as a ''Common Member.'' The term ''Clearing Member'' as used herein has the meaning provided in OCC's By-Laws. *See* OCC's By-Laws, *supra,* note 5. The term ''Member'' as used herein has the meaning provided in NSCC's Rules. *See* NSCC's Rules, *supra* note 9.

OCC could make such a payment in the event of a Common Member default. The Clearing Agencies believe that their respective clearing members and all other participants in the markets for which OCC provides clearance and settlement would benefit from OCC's ability to choose to make a cash payment to effect settlement through the facilities of NSCC. This change would provide more certainty around certain default scenarios and would blunt the financial and operational burdens market participants could experience in the case of most clearing member defaults.[11]

Finally, the Clearing Agencies are also proposing certain changes as part of Phase 2 that, if approved, would not be implemented until after the Commission shortens the standardized settlement cycle under Exchange Act Rule 15c6–1(a) from two days after the traded date (''T+2'') to one day after the trade date (''T+1''), which currently is set for May 28, 2024. The Phase 2 changes would address the operational realities concerning the Accord that will result from the Commission's adoption and implementation of a new standard settlement cycle of T+1 pursuant to Rule 15c6–1(a) under the Act. The Phase 2 changes generally are designed to allow OCC to provide certain assurances with respect to OCC's ability to make a GSP in the event of a Common Member default to NSCC that would permit NSCC to begin processing Common Members' E&A/Delivery Transactions in a shortened settlement cycle prior to Guaranty Substitution occurring by introducing new or amended terms and setting out the processes associated therewith.

ii. Background

OCC acts as a central counterparty clearing agency for U.S.-listed options and futures on a number of underlying financial assets including common stocks, currencies and stock indices. In connection with these services, OCC provides the OCC Guaranty pursuant to its By-Laws and Rules. NSCC acts as a central counterparty clearing agency for certain equity securities, corporate and municipal debt, exchange traded funds and unit investment trusts that are eligible for its services. Eligible trading activity may be processed through NSCC's CNS system[12] or through its Balance Order Accounting system,[13] where all eligible compared and recorded transactions for a particular settlement date are netted by issue into one net long (buy), net short (sell) or flat position. As a result, for each day with activity, each Member has a single deliver or receive obligation for each issue in which it has activity at NSCC. In connection with these services, NSCC also provides the NSCC Guaranty pursuant to Addendum K of the NSCC Rules.

OCC's Rules provide that delivery of, and payment for, securities underlying certain exercised stock options and matured single stock futures that are physically settled are generally effected through the facilities of NSCC and are not settled through OCC's facilities.[14] OCC and NSCC executed the Existing Accord to facilitate, via NSCC's systems, the physical settlement of securities arising out of options and futures cleared by OCC. OCC Clearing Members that clear and settle physically settled options and futures transactions through OCC also are required under OCC's Rules[15] to be Members of NSCC or to have appointed or nominated a Member of NSCC to act on its behalf. As noted above, these firms are referred to as ''Common Members'' in the Existing Accord.

iii. Summary of the Existing Accord

The Existing Accord governs the transfer between OCC and NSCC of responsibility for settlement obligations that involve a delivery and receipt of stock in the settlement of physically settled options and futures that are cleared and settled by OCC and for which the underlying securities are eligible for clearing through the facilities of NSCC (''E&A/Delivery Transactions''). It also establishes the time when OCC's settlement guarantee (the ''OCC Guaranty'') ends and NSCC's settlement guarantee (the ''NSCC Guaranty'')[16] begins with respect to E&A/Delivery Transactions. However, in the case of a Common Member default[17] NSCC can reject these settlement obligations, in which case the settlement guaranty would not transfer from OCC to NSCC and OCC would not have a right to settle the transactions through the facilities of NSCC. Instead, OCC would have to engage in alternative methods of settlement that have the potential to create significant liquidity and collateral requirements for both OCC and its non-defaulting Clearing Members.[18] More specifically, this could involve broker-to-broker settlement between OCC Clearing Members.[19] This settlement method is operationally complex because it requires bilateral coordination directly between numerous Clearing Members rather than relying on NSCC to facilitate multilateral netting to settle the relevant settlement obligations. As described above, it also potentially could result in significant liquidity and collateral requirements for both OCC and its non-defaulting Clearing Members because the transactions would not be netted through the facilities of NSCC. Alternatively, where NSCC accepts the E&A/Delivery Transactions from OCC, the OCC Guaranty ends and the NSCC Guaranty takes effect. The transactions are then netted through NSCC's systems, which allows settlement obligations for the same settlement date to be netted into a single deliver or receive obligation. This netting reduces the costs associated with securities transfers by reducing the number of securities movements required for settlement and further reduces operational and market risk. The benefits of such netting by NSCC may be significant with respect to the large volumes of E&A/Delivery Transactions processed during monthly options expiry periods.

Pursuant to the Existing Accord, on each trading day NSCC delivers to OCC a file that identifies the securities, including stocks, exchange-traded funds and exchange-traded notes, that are

[11] OCC provided its analysis of the financial impact of alternate means of settlement as confidential Exhibit 3A to this filing.

[12] *See* Rule 11 (CNS System) and Procedure VII (CNS Accounting Operation) of the NSCC Rules, *supra* note 9.

[13] *See* Rule 8 (Balance Order and Foreign Security Systems) and Procedure V (Balance Order Accounting Operation) of the NSCC Rules, *supra* note 9.

[14] *See* Chapter IX of OCC's Rules (Delivery of Underlying Securities and Payment), *supra* note 5.

[15] *See* OCC Rule 901, *supra* note 5.

[16] *See* Addendum K and Procedure III of the NSCC Rules, *supra* note 9.

[17] A Common Member that has been suspended by OCC or for which NSCC has ceased to act is referred to as a ''Mutually Suspended Member.''

[18] For example, OCC evaluated certain Clearing Member default scenarios in which OCC assumed that NSCC would not accept the settlement obligations under the Existing Accord, including the default of a large Clearing Member coinciding with a monthly options expiration. OCC has estimated that in such a Clearing Member default scenario, the aggregate liquidity burden on OCC in connection with obligations having to be settled on a gross broker-to-broker basis could reach a significantly high level. For example, in January 2022, the largest gross broker-to-broker settlement amount in the case of a larger Clearing Member default would have resulted in liquidity needs of approximately $384,635,833,942. OCC provided the data and analysis as confidential Exhibit 3A to this filing.

[19] In broker-to-broker settlement, Clearing Member parties are responsible for coordinating settlement—delivery and payment—among themselves on a transaction-by-transaction basis. Once transactions settle, the parties also have an obligation to affirmatively notify OCC so that OCC can close out the transactions. If either one of or both of the parties do not notify OCC, the transaction would remain open on OCC's books indefinitely until the time both parties have provided notice of settlement to OCC.

eligible (1) to settle through NSCC and (2) to be delivered in settlement of (i) exercises and assignments of stock options cleared and settled by OCC or (ii) delivery obligations from maturing stock futures cleared and settled by OCC. OCC, in turn, delivers to NSCC a file identifying securities to be delivered, or received, for physical settlement in connection with OCC transactions.[20]

After NSCC receives the list of eligible transactions from OCC, and NSCC has received all required deposits to the NSCC Clearing Fund from all Common Members taking into consideration amounts required to physically settle the OCC transactions, the OCC Guaranty would end and the NSCC Guaranty would begin with respect to physical settlement of the eligible OCC-related transactions.[21] At this point, NSCC is solely responsible for settling the transactions.[22]

Each day, NSCC is required to promptly notify OCC at the time the NSCC Guaranty takes effect. If NSCC rejects OCC's transactions due to an improper submission [23] or if NSCC ''ceases to act'' for a Common Member,[24] NSCC's Guaranty would not take effect for the affected transactions pursuant to the NSCC Rules.

NSCC is required to promptly notify OCC if it ceases to act for a Common Member. Upon receiving such a notice, OCC would not continue to submit to NSCC any further unsettled transactions that involve such Common Member, unless authorized representatives of both OCC and NSCC otherwise consent. OCC would, however, deliver to NSCC a reversal file containing a list of all transactions that OCC already submitted to NSCC and that involve such Common Member. The NSCC Guaranty ordinarily would not take effect with respect to transactions for a Common Member for which NSCC has ceased to act, unless both Clearing Agencies agree otherwise. As such, NSCC does not have any existing contractual obligation to guarantee such Common Member's transactions. To the extent the NSCC Guaranty does not take effect, OCC's Guaranty would continue to apply, and, as described above, OCC would remain responsible for effecting the settlement of such Common Member's transactions pursuant to OCC's By-Laws and Rules.

As noted above, the Existing Accord does provide that the Clearing Agencies may agree to permit additional transactions for a Common Member default (''Defaulted NSCC Member Transactions'') to be processed by NSCC while subject to the NSCC Guaranty. This optional feature, however, creates uncertainty for the Clearing Agencies and market participants about how Defaulted NSCC Member Transactions may be processed following a Common Member default and also does not provide NSCC with the ability to collect collateral from OCC that it may need to close out these additional transactions. While the optional feature would remain in the agreement as part of this proposal, the proposed changes to the Existing Accord, as described below, could significantly reduce the likelihood that it would be utilized.

Proposed Phase 1 Changes

i. Proposed Changes to the Existing Accord

The proposed changes to the Existing Accord would permit OCC to make a cash payment, referred to as the ''Guaranty Substitution Payment'' or ''GSP,'' to NSCC. This cash payment could occur on either or both of the day that the Common Member becomes a Mutually Suspended Member and on the next business day. Upon NSCC's receipt of the Guaranty Substitution Payment from OCC, the NSCC Guaranty would take effect for the Common Member's transactions, and they would be accepted by NSCC for clearance and settlement.[25] OCC could use all Clearing Member contributions to the OCC Clearing Fund [26] and certain Margin Assets [27] of a defaulted Clearing Member to pay the GSP, as described in more detail below.

NSCC would calculate the Guaranty Substitution Payment as the sum of the Mutually Suspended Member's unpaid required deposit to the NSCC Clearing Fund (''Required Fund Deposit'') [28] and the unpaid Supplemental Liquidity Deposit [29] obligation that is attributable to E&A/Delivery Transactions. The proposed changes to the Existing Accord define how NSCC would calculate the Guaranty Substitution Payment.

More specifically, NSCC would first determine how much of the member's unpaid Clearing Fund requirement would be included in the GSP. NSCC would look at the day-over-day change in gross market value of the Mutually Suspended Member's positions as well as day-over-day change in the member's NSCC Clearing Fund requirements. Based on such changes, NSCC would identify how much of the change in the Clearing Fund requirement was attributable to E&A/Delivery Transactions coming from OCC. If 100 percent of the day-over-day change in the NSCC Clearing Fund requirement is attributable to activity coming from OCC, then the GSP would include 100 percent of the member's NSCC Clearing Fund requirement. If less than 100 percent of the change is attributable to activity coming from OCC, then the GSP would include that percent of the member's unpaid NSCC Clearing Fund requirement attributable to activity coming from OCC. NSCC would then determine the portion of the member's unpaid SLD obligation that is attributable to E&A/Delivery Transactions. As noted above, the GSP would be the sum of these two amounts. A member's NSCC Clearing Fund requirement and SLD obligation at NSCC are designed to address the credit and liquidity risks that a member poses to NSCC. The GSP calculation is

[20] Each day that both OCC and NSCC are open for accepting trades for clearing is referred to as an ''Activity Date'' in the Existing Accord. Securities eligible for settlement at NSCC are referred to collectively as ''Eligible Securities'' in the Existing Accord. Eligible securities are settled at NSCC through NSCC's CNS Accounting Operation or NSCC's Balance Order Accounting Operation.

[21] The term ''NSCC Clearing Fund'' as used herein has the same meaning as the term ''Clearing Fund'' as provided in the NSCC Rules. Procedure XV of the NSCC Rules provides that all NSCC Clearing Fund requirements and other deposits must be made within one hour of demand, unless NSCC determines otherwise, *supra* note 9.

[22] This is referred to in the Existing Accord as the ''Guaranty Substitution Time,'' and the process of the substitution of the NSCC Guaranty for the OCC Guaranty with respect to E&A/Delivery Transactions is referred to as ''Guaranty Substitution.''

[23] Guaranty Substitution by NSCC (discussed further below) does not occur with respect to an E&A/Delivery Transaction that is not submitted to NSCC in the proper format or that involves a security that is not identified as an Eligible Security on the then-current NSCC Eligibility Master File.

[24] Under NSCC's Rules, a default would generally be referred to as a ''cease to act'' and could encompass a number of circumstances, such as an NSCC Member's failure to make a Required Fund Deposit in a timely fashion. *See* NSCC Rule 46 (Restrictions on Access to Services), *supra* note 9. An NSCC Member for which it has ceased to act is referred to in the Existing Accord as a ''Defaulting NSCC Member.'' Transactions associated with a Defaulting NSCC Member are referred to as ''Defaulted NSCC Member Transactions'' in the Existing Accord.

[25] Acceptance of such transactions by NSCC would be subject to NSCC's standard validation criteria for incoming trades. *See* NSCC Rule 7, *supra* note 9.

[26] The term ''OCC Clearing Fund'' as used herein has the same meaning as the term ''Clearing Fund'' in OCC's By-Laws, *supra* note 5.

[27] The term ''Margin Assets'' as used herein has the same meaning as provided in OCC's By-Laws, *supra* note 5.

[28] The Required Fund Deposit is calculated pursuant to Rule 4 (Clearing Fund) and Procedure XV (Clearing Fund Formula and Other Matters) of the NSCC Rules, *see supra* note 9.

[29] Under the NSCC Rules, NSCC collects additional cash deposits from those Members who would generate the largest settlement debits in stressed market conditions, referred to as ''Supplemental Liquidity Deposits'' or ''SLD.'' *See* Rule 4A of the NSCC Rules, *supra* note 9.

intended to assess how much of a member's obligations arise out of activity coming from OCC so that the amount paid by OCC is commensurate with the risk to NSCC of guarantying such activity.

To permit OCC to anticipate the potential resources it would need to pay the GSP for a Mutually Suspended Member, each business day, NSCC would provide OCC with (1) Required Fund Deposit and Supplemental Liquidity Deposit obligations, as calculated pursuant to the NSCC Rules, and (2) the gross market value of the E&A/Delivery Transactions and the gross market value of total Net Unsettled Positions (as such term is defined in the NSCC Rules). On options expiry days that fall on a Friday, NSCC would also provide OCC with information regarding liquidity needs and resources, and any intraday SLD requirements of Common Members. Such information would be delivered pursuant to the ongoing information sharing obligations under the Existing Accord (as proposed to be amended) and the Service Level Agreement (''SLA'') to which both NSCC and OCC are a party pursuant to Section 2 of the Existing Accord.[30] The SLA addresses specifics regarding the time, form, and manner of various required notifications and actions described in the Accord and also includes information applicable under the Accord.

NSCC and OCC believe the proposed calculation of the Required Fund Deposit portion of the GSP is appropriate because it is designed to provide a reasonable proxy for the impact of the Mutually Suspended Member's E&A/Delivery Transactions on its Required Fund Deposit. While impact study data did show that the proposed calculation could result in a GSP that overestimates or underestimates the Required Fund Deposit attributable to the Mutually Suspended Member's E&A/Delivery Transactions,[31] current technology constraints prohibit NSCC from performing a precise calculation of the GSP on a daily basis for every Common Member.[32]

Implementing the ability for OCC to make the GSP and cause the E&A/Delivery Transactions to be cleared and settled through NSCC would promote the ability of OCC and NSCC to be efficient and effective in meeting the requirements of the markets they serve. This is because data demonstrates that the expected size of the GSP would be smaller than the amount of cash that would otherwise be needed by OCC and its Clearing Members to facilitate settlement outside of NSCC. More specifically, based on a historical study of alternate means of settlement available to OCC from September 2021 through September 2022, in the event that NSCC did not accept E&A/Delivery Transactions, the worst-case scenario peak liquidity need OCC identified was $384,635,833,942 for settlement to occur on a gross broker-to-broker basis. OCC estimates that the corresponding GSP in this scenario would have been $863,619,056. OCC also analyzed several other large liquidity demand amounts that were identified during the study if OCC effected settlement on a gross broker-to-broker basis.[33] These liquidity demand amounts and the largest liquidity demand amount OCC observed of $384,635,833,942 substantially exceed the amount of liquid resources currently available to OCC.[34] By contrast, projected GSPs identified during the study ranged from $419,297,734 to $6,281,228,428. For each of these projected GSP amounts, OCC observed that the Margin Assets and OCC Clearing Fund contributions that would have been required of Clearing Members in these scenarios would have been sufficient to satisfy the amount of the projected GSPs.

To help address the current technology constraint that prohibits NSCC from performing a precise calculation of the GSP on a daily basis for every Common Member, proposed Section 6(b)(i) of the Existing Accord and related Section 7(d) of the SLA would provide that with respect to a Mutually Suspended Member, either NSCC or OCC may require that the Required Fund Deposit portion of the GSP be re-calculated by calculating the Required Fund Deposit for the Mutually Suspended Member both before and after the delivery of the E&A/Delivery Transactions and utilize the precise amount that is attributable to that activity in the final GSP. If such a recalculation is required, the result would replace the Required Fund Deposit component of the GSP that was initially calculated. The SLD component of the GSP would be unchanged by such recalculation.

As the above demonstrates, the GSP is intended to address the significant collateral and liquidity requirements that could be required of OCC Clearing Members in the event of a Common Member default.

Allowing OCC to make a GSP payment also is intended to allow for settlement processing to take place through the facilities of NSCC to retain operational efficiencies associated with the settlement process. Alternative settlement means such as broker-to-broker settlement add operational burdens, because transactions would need to be settled individually on one-off bases. In contrast, NSCC's netting reduces the volume and value of settlement obligations that would need to be closed out in the market.[35] Because the clearance and settlement of obligations through NSCC's facilities following a Common Member default, including netting of E&A/Delivery Transactions with a Common Member's positions at NSCC, would avoid these potentially significant operational burdens for OCC and its Clearing Members, OCC and NSCC believe that the proposed changes would limit market disruption relating to a Common Member default. NSCC netting significantly reduces the total number of obligations that require the exchange of money for settlement. Allowing more activity to be processed through NSCC's netting systems would minimize risk associated with the close out of those transactions following the default of a Common Member.

Amending the Existing Accord to define the terms and conditions under which Guaranty Substitution may occur, at OCC's election, with respect to Defaulted NSCC Member Transactions after a Common Member becomes a Mutually Suspended Member would also provide more certainty to both the Clearing Agencies and market

[30] OCC provided a draft of the revised SLA to the Commission as confidential Exhibit 3C to this filing.

[31] The impact study was conducted at the Commission's request to cover a three-day period and reviewed the ten Common Members with the largest Required Fund Deposits attributable to the Mutually Suspended Member's E&A/Delivery Transactions. Over the 30 instances in the study, approximately 15 instances resulted in an underestimate of the Required Fund Deposit by an average of approximately $112,900,926, four instances where the proxy calculation was the same as the Required Fund Deposit, and eleven instances of an overestimate of the Required Fund Deposit by an average of approximately $59,654,583. *See* confidential Exhibit 3D to this filing for additional detail related to the referenced study.

[32] OCC and NSCC agreed that performing the necessary technology build during Phase 1 would delay the implementation of Phase 1 of this proposal. NSCC will incorporate those technology updates in connection with Phase 2 of this proposal.

[33] *See* confidential Exhibit 3A to this filing for additional detail related to the referenced study.

[34] As of September 30, 2023, OCC held approximately $12.37 billion in qualifying liquid resources. *See OCC Quantitative Disclosure,* July–September 2023, *available at https://www.theocc.com/risk-management/pfmi-disclosures.*

[35] CNS reduces the value of obligations that require financial settlement by approximately 98%, where, for example $519 trillion in trades could be netted down to approximately $9 trillion in net settlements.

participants generally about how a Mutually Suspended Member's Defaulted NSCC Member Transactions may be processed.

NSCC and OCC have agreed it is appropriate to limit the availability of the proposed provision to the day of the Common Member default and the next business day because, based on historical simulations of cease to act events involving Common Members, most activity of a Mutually Suspended Member is closed out on those days.[36] Furthermore, the benefits of netting through NSCC's systems would be reduced for any activity submitted to NSCC after that time.

To implement the proposed Phase 1 changes to the Existing Accord, OCC and NSCC propose to make the following changes.

Section 1—Definitions

First, new definitions would be added, and existing definitions would be amended in Section 1, which is the Definitions section.

The new defined terms would be as follows.

• The term ''Close Out Transaction'' would be defined to mean ''the liquidation, termination or acceleration of one or more exercised or matured Stock Options [37] or Stock Futures [38] contracts, securities contracts, commodity contracts, forward contracts, repurchase agreements, swap agreements, master netting agreements or similar agreements of a Mutually Suspended Member pursuant to OCC Rules 901, 1006 and 1101 through 1111 (including but not limited to Rules 1104 and 1107) and/or NSCC Rule 18.'' This proposed definition would make it clear that the payment of the Guaranty Substitution Payment and NSCC's subsequent acceptance of Defaulted NSCC Member Transactions for clearance and settlement are intended to fall within the ''safe harbors'' provided in the Bankruptcy Code,[39] the Securities Investor Protection Act,[40] and other similar laws.

• The term ''Guaranty Substitution Payment'' would be defined to mean ''an amount calculated by NSCC in accordance with the calculations set forth in Appendix A [to the Existing Accord (as proposed to be amended)], to include two components: (i) a portion of the Mutually Suspended Member's Required Fund Deposit deficit to NSCC at the time of the cease to act; and (ii) a portion of the Mutually Suspended Member's unpaid Supplemental Liquidity Deposit obligation at the time of the cease to act.''

• The term ''Mutually Suspended Member'' would mean ''any OCC Participating Member [41] that has been suspended by OCC that is also an NSCC Participating Member [42] for which NSCC has ceased to act.''

• The term ''Required Fund Deposit'' would have the meaning ''provided in Rule 4 of NSCC's Rules and Procedures (or any replacement or substitute rule), the version of which, with respect to any transaction or obligation incurred that is the subject of this Agreement, is in effect at the time of such transaction or incurrence of obligation.''

• The term ''Supplemental Liquidity Deposit'' would have the meaning ''provided in Rule 4A of NSCC's Rules and Procedures (or any replacement or substitute rule), the version of which, with respect to any transaction or obligation incurred that is the subject of this Agreement, is in effect at the time of such transaction or incurrence of obligation.''

The defined terms that would be amended in Section 1 of the Existing Accord are as follows.

• The definition for the term ''E&A/Delivery Transaction'' generally contemplates a transaction that involves a delivery and receipt of stock in the settlement of physically settled options and futures that are cleared and settled by OCC and for which the underlying securities are eligible for clearing through the facilities of NSCC. The definition would be amended to make clear that it would apply in respect of a ''Close Out Transaction'' of a ''Mutually Suspended Member'' as those terms are proposed to be defined (described above).

• The definition for the term ''Eligible Securities'' generally contemplates the securities that are eligible to be used for physical settlement under the Existing Accord. The term would be modified to clarify that this may include, for example, equities, exchange-traded funds and exchange-traded notes that are underlying securities for options issued by OCC.

Section 6—Default by an NSCC Participating Member or OCC Participating Member

Section 6 of the Existing Accord provides that NSCC is required to provide certain notice to OCC in circumstances in which NSCC has ceased to act for a Common Member. Currently, Section 6(a)(ii) of the Existing Accord also requires NSCC to notify OCC if a Common Member has failed to satisfy its Clearing Fund obligations to NSCC, but for which NSCC has not yet ceased to act. In practice, this provision would trigger a number of obligations (described below) when a Common Member fails to satisfy its NSCC Clearing Fund obligations for any reason, including those due to an operational delay. Therefore, OCC and NSCC are proposing to remove the notification requirement under Section 6(a)(ii) from the Existing Accord. Under Section 7(d) of the Existing Accord, NSCC and OCC are required to provide each other with general surveillance information regarding Common Members, which includes information regarding any Common Member that is considered by the other party to be in distress. Therefore, if a Common Member has failed to satisfy its NSCC Clearing Fund obligations and NSCC believes this failure is due to, for example, financial distress and not, for example, due to a known operational delay, and NSCC has not yet ceased to act for that Common Member, such notification to OCC would still occur but would be done pursuant to Section 7(d) of the Existing Accord (as proposed to be amended), and not Section 6(a)(ii). Notifications under Section 6 of the Existing Accord (as proposed to be amended) would be limited to instances when NSCC has actually ceased to act

[36] OCC provided data regarding such events in confidential Exhibit 3B to this filing. The information contained therein includes the assumptions and timelines leading up to the declaration of a default for a Common Member and the anticipated timing of OCC's payment of the GSP.

[37] The term ''Stock Options'' is defined in the Existing Accord within the definition of ''Eligible Securities,'' and refers to options issued by OCC.

[38] The term ''Stock Futures'' is defined in the Existing Accord within the definition of ''Eligible Securities,'' and refers to stock futures contracts cleared by OCC.

[39] 11 U.S.C. 101 *et seq.,* including sections 362(b)(6), (7), (17), (25) and (27) (exceptions to the automatic stay), sections 546(e)–(g) and (j) (limitations on avoiding powers), and sections 555–556 and 559–562 (contractual right to liquidate, terminate or accelerate certain contracts).

[40] 15 U.S.C. 78aaa–lll, including section 78eee(b)(2)(C) (exceptions to the stay).

[41] The term ''OCC Participating Member'' is defined in the Existing Accord to mean ''(i) a Common Member; (ii) an OCC Clearing Member that is an 'Appointing Clearing Member' (as defined in Article I of OCC's By-Laws) and has appointed an Appointed Clearing Member that is an NSCC Member to effect settlement of E&A/Delivery Transactions through NSCC on the Appointing Clearing Member's behalf; (iii) an OCC Clearing Member that is an Appointed Clearing Member; or (iv) a Canadian Clearing Member.'' No changes are proposed to this definition.

[42] The term ''NSCC Participating Member'' is defined in the Existing Accord to mean ''(i) a Common Member; (ii) an NSCC Member that is an 'Appointed Clearing Member' (as defined in Article I of OCC's By-Laws); or (iii) [Canadian Depository for Securities Limited or ''CDS'']. For the avoidance of doubt, the Clearing Agencies agree that CDS is an NSCC Member for purposes of this Agreement.'' No changes are proposed to this definition.

for a Common Member pursuant to the NSCC Rules.[43]

Following notice by NSCC that it has ceased to act for a Common Member, OCC is obligated in turn to deliver to NSCC a list of all E&A/Delivery Transactions (excluding certain transactions for which Guaranty Substitution does not occur) involving the Common Member.[44] This provision would be amended to clarify that it applies in respect of such E&A/Delivery Transactions for the Common Member for which the NSCC Guaranty has not yet attached—meaning that Guaranty Substitution has not yet occurred.

As described above in the summary of the Existing Accord, where NSCC has ceased to act for a Common Member, the Existing Accord refers to the Common Member as the Defaulting NSCC Member and also refers to the relevant E&A/Delivery Transactions in connection with that Defaulting NSCC Member for which a Guaranty Substitution has not yet occurred as Defaulted NSCC Member Transactions.

If the Defaulting NSCC Member is also suspended by OCC, it would be covered by the proposed definition that is described above for a Mutually Suspended Member. For such a Mutually Suspended Member, the proposed changes in Section 6(b) would provide that NSCC, by a time agreed upon by the parties, would provide OCC with the amount of the Guaranty Substitution Payment as calculated by NSCC and related documentation regarding the calculation. The Guaranty Substitution Payment would be calculated pursuant to NSCC's Rules as that portion of the unmet Required Fund Deposit [45] and Supplemental Liquidity Deposit [46] obligations of the Mutually Suspended Member attributable to the Defaulted NSCC Member Transactions. By a time agreed upon by the parties,[47] OCC would then be required to either notify NSCC of its intent to make the full amount of the Guaranty Substitution Payment to NSCC or notify NSCC that it will not make the Guaranty Substitution Payment. If OCC makes the full amount of the Guaranty Substitution Payment, NSCC's guaranty would take effect at the time of NSCC's receipt of that payment and the OCC Guaranty would end.

The proposed changes would further provide that if OCC does not suspend the Common Member (such that the Common Member would therefore not meet the proposed definition of a Mutually Suspended Member) or if OCC elects to not make the full amount of the Guaranty Substitution Payment to NSCC, then all of the Defaulted NSCC Member Transactions would be exited from NSCC's CNS Accounting Operation and/or NSCC's Balance Order Accounting Operation, as applicable, and Guaranty Substitution would not occur in respect thereof. Therefore, NSCC would continue to have no obligation to guarantee or settle the Defaulted NSCC Member Transactions, and the OCC Guaranty would continue to apply to them pursuant to OCC's By-Laws and Rules.[48]

Proposed changes to the Existing Accord would also address the application of any Guaranty Substitution Payment by NSCC. Specifically, new Section 6(d) would provide that any Guaranty Substitution Payment made by OCC may be used by NSCC to satisfy any liability or obligation of the Mutually Suspended Clearing Member to NSCC on account of transactions involving the Mutually Suspended Clearing Member for which the NSCC Guaranty applies and to the extent that any amount of assets otherwise held by NSCC for the account of the Mutually Suspended Member (including any Required Fund Deposit or Supplemental Liquidity Deposit) are insufficient to satisfy its obligations related to transactions for which the NSCC Guaranty applies. Proposed changes to Section 6(d) would further provide for the return to OCC of any unused portion of the GSP. With regard to the portion of the Guaranty Substitution Payment that corresponds to a member's Supplemental Liquidity Deposit obligation, NSCC must return any unused amount to OCC within fourteen (14) days following the conclusion of NSCC's settlement, close-out and/or liquidation. With regard to the portion of the Guaranty Substitution Payment that corresponds to a Required Fund Deposit, NSCC must return any unused amount to OCC under terms agreed to by the parties.[49]

Other Proposed Changes as Part of Phase 1

Certain other technical changes are also proposed to the Existing Accord to conform it to the proposed changes described above. For example, the preamble and the ''whereas'' clauses in the Preliminary Statement would be amended to clarify that the agreement is an amended and restated agreement and to summarize that the agreement would be modified to contemplate the Guaranty Substitution Payment structure. Section 1(c), which addresses the terms in the Existing Accord that are defined by reference to NSCC's Rules and Procedures and OCC's By-Laws and Rules would be modified to state that such terms would have the meaning then in effect at the time of any transaction or obligation that is covered by the agreement rather than stating that such terms have the meaning given to them as of the effective date of the agreement. This change is proposed to help ensure that the meaning of such terms in the agreement will not become inconsistent with the meaning in the NSCC Rules and/or OCC By-Laws and Rules, as they may be modified through proposed rule changes with the Commission.

Technical changes would be made to Sections 3(d) and (e) of the Existing Accord to provide that those provisions would not apply in the event new Section 6(b) described above, is triggered. Section 3(d) generally provides that OCC will no longer submit E&A/Delivery Transactions to NSCC involving a suspended OCC Participating Member.[50] Similarly, Section 3(e) generally provides that OCC will no longer submit E&A/Delivery Transactions to NSCC involving an NSCC Participating Member [51] for which NSCC has ceased to act. A proposed change would also be made to Section 5 of the Existing Accord to modify a reference to Section 5 of Article VI of OCC's By-Laws to instead provide that the updated cross-reference should be to Chapter IV of OCC's Rules.

Section 5 would also be amended to clarify that Guaranty Substitution

[43] *See* Rule 46 (Restrictions on Access to Services) of the NSCC Rules, *supra* note 9.

[44] The section of the Existing Accord that addresses circumstances in which NSCC ceases to act and/or an NSCC Member defaults is currently part of Section 6(a). It would be re-designated as Section 6(b) for organizational purposes.

[45] The Required Fund Deposit is calculated pursuant to Rule 4 (Clearing Fund) and Procedure XV (Clearing Fund Formula and Other Matters) of the NSCC Rules, *see supra* note 9.

[46] The Supplemental Liquidity Deposit is calculated pursuant to Rule 4A (Supplemental Liquidity Deposits) of the NSCC Rules, *see supra* note 9.

[47] The time by which OCC would be required to notify NSCC of its intent would be defined in the Service Level Agreement. As of the time of this filing, the parties intend to set that time as one hour after OCC's receipt of the calculated Guaranty Substitution Payment from NSCC.

[48] Under the current and proposed terms of the Existing Accord, NSCC would be permitted to voluntarily guaranty and settle the Defaulted NSCC Member Transactions.

[49] Such amounts would be returned to OCC as appropriate and in accordance with a Netting Contract and Limited Cross-Guaranty, by and among The Depository Trust Company, Fixed Income Clearing Corporation, NSCC and OCC, dated as of January 1, 2003, as amended.

[50] *See supra* note 41 defining OCC Participating Member.

[51] *See supra* note 42 defining NSCC Participating Member.

occurs when NSCC has received both the Required Fund Deposit and Supplemental Liquidity Deposit, as calculated by NSCC in its sole discretion, from Common Members. The addition of the collection of the Supplemental Liquidity Deposit to the definition of the Guaranty Substitution Time in this Section 5 would reflect OCC and NSCC's agreement that both amounts are components of the Guaranty Substitution Payment (as described above) and would make this definition consistent with that agreement.

In Section 7 of the Existing Accord, proposed changes would be made to provide that NSCC would provide to OCC information regarding a Common Member's Required Fund Deposit and Supplemental Liquidity Deposit obligations, to include the Supplemental Liquidity Deposit obligation in this notice requirement, and additionally that NSCC would provide OCC with information regarding the potential Guaranty Substitution Payment for the Common Member. On an options expiration date that is a Friday, NSCC would, by close of business on that day, also provide to OCC information regarding the intra-day liquidity requirement, intra-day liquidity resources and intra-day calls for a Common Member that is subject to a Supplemental Liquidity Deposit at NSCC.

Finally, Section 14 of the Existing Accord would be modernized to provide that notices between the parties would be provided by email rather than by hand, overnight delivery service or first-class mail.

ii. Proposed Changes to OCC By-Laws and Rules as Part of Phase 1

General Description

OCC is also proposing certain changes to its By-Laws and Rules that are designed to complement the proposed changes described above regarding the Existing Accord. These proposed changes to the By-Laws and Rules are described below, and they generally cover the following four areas. First, the proposed changes would define Guaranty Substitution Payment. Second, the proposed changes would describe the circumstances under which OCC could make a Guaranty Substitution Payment to NSCC. Third, the proposed changes would specify what financial resources could be used by OCC to make the Guaranty Substitution Payment.[52] Fourth, the proposed changes to OCC's Comprehensive Stress Testing and Clearing Fund Methodology, and Liquidity Risk Management Description would outline enhanced stress testing incorporating the GSP and OCC's ability to call for additional resources from Clearing Members. OCC also is proposing changes to OCC's Liquidity Risk Management Framework to account for OCC's ability to make the GSP.

Article I—Definitions

OCC proposes to add ''Guaranty Substitution Payment'' as a new defined term under Article I of OCC's By-Laws, which is the Definitions section. The term ''Guaranty Substitution Payment'' would be defined to mean: ''a payment that may be made by [OCC] to [NSCC] under the terms of an agreement between them, as described in Rule 901, so that [NSCC] will not reject settlement obligations for CCC-eligible[53] securities that are directed by [OCC] for settlement through the facilities of [NSCC] on account of a Clearing Member that has been suspended, as described in Rule 1102, and for which [NSCC] has ceased to act.''

Chapter IX—Delivery of Underlying Securities and Payment

Certain changes are also proposed to Chapter IX of OCC's Rules. OCC proposes to add parenthetical language to the Introduction section of Chapter IX of OCC's Rules. It would specify that a Guaranty Substitution Payment could be made by OCC to NSCC in connection with OCC's general policy that to the extent a security to be delivered and received is CCC-eligible, OCC will direct the delivery and payment obligations to be settled through the facilities of NSCC where the obligations are physically-settled and arise out of the exercise of stock option contracts or the maturity of stock futures contracts.

Next, OCC proposes to delete certain provisions from Rule 901(b) regarding when a Guaranty Substitution occurs. Specifically, Rule 901(b) currently provides that unless otherwise agreed between OCC and NSCC, a Guaranty Substitution with respect to settlement obligations for CCC-eligible securities that settle ''regular way'' under NSCC's Rules and Procedures will occur if: (i) the applicable settlement obligations are reported to and are not rejected by NSCC; (ii) NSCC has not notified OCC that it has ceased to act for the relevant Clearing Member or Appointed Clearing Member; and (iii) the NSCC Clearing Fund requirements of the relevant Clearing Member or Appointed Clearing Member owing to NSCC, as determined in accordance with NSCC's Rules and Procedures, are received by NSCC. These considerations regarding when a Guaranty Substitution occurs are addressed under the terms of the Existing Accord, and they would continue to be relevant considerations regarding when a Guaranty Substitution occurs under the changes that OCC and NSCC are proposing to the Existing Accord. However, because additional considerations would be added to the Guaranty Substitution process in connection with the proposed ability for OCC in certain circumstances to make a Guaranty Substitution Payment to NSCC and also to eliminate the potential for a description of the Guaranty Substitution process in OCC's Rules to become inconsistent with the process that OCC and NSCC have agreed to in the Existing Accord, as it would be amended, OCC is proposing to delete the discussion of these considerations in Rule 901(b) in favor of instead simply cross referencing the terms of the agreement.[54]

In addition, OCC proposes to add a new paragraph to the end of Rule 901(b) to provide that pursuant to the proposed changes to the Existing Accord, OCC would be permitted to make a Guaranty Substitution Payment to NSCC. The proposed changes would also describe the circumstances in which OCC may make a Guaranty Substitution Payment in connection with settlement obligations of a suspended Clearing Member, and that the amount of the Guaranty Substitution Payment under the terms of the Existing Accord, as amended, would be the amount required by NSCC to satisfy its deficit(s) regarding such Clearing Member's ''Required Fund Deposit'' and ''Supplemental Liquidity Deposit'' as those terms are defined in NSCC's Rules

[52] OCC would be permitted to borrow from the Clearing Fund and margin of a suspended Clearing Member, over which OCC has a general lien, where that Clearing Member is a Mutually Suspended Member. The change would merely expand the circumstances under which OCC's current By-Laws and Rules permit OCC to borrow Clearing Fund and margin. The change would not affect the treatment of such borrowing under OCC's default waterfall that determines how OCC allocates losses against available financial resources. The Mutually Suspended Member's margin and Clearing Fund collateral would remain first in line to absorb losses.

[53] The term ''CCC-Eligible'' as used herein has the meaning provided in OCC's By-Laws, *supra* note 5.

[54] For purposes of the proposed rule change process under Exchange Act Section 19(b), the agreement is treated as a rule of a clearing agency under Exchange Act Section 3(a)(27) and therefore any proposed changes to it by OCC are subject to the related rule change process and public notice and comment. OCC therefore believes that addressing the terms in the agreement and cross-referencing the agreement in OCC Rule 901 would not deprive the Commission or the public of notice regarding any future proposed changes.

and Procedures.[55] The changes would provide that any amount of a Guaranty Substitution Payment that NSCC does not use pursuant to its Rules and Procedures would subsequently be returned to OCC under such terms and within such times as are agreed by OCC and NSCC. OCC believes that it is useful to include this description of the proposed process for the Guaranty Substitution Payment and the circumstances in which it may be made so that a user of OCC's publicly available By-Laws and Rules would have sufficient information to understand the existence of the Guaranty Substitution Payment mechanism, the general circumstances in which it may be made and the role that a Guaranty Substitution Payment would play in causing NSCC to accept obligations for CCC-eligible securities for clearance and settlement.

Chapters X and XI—Clearing Fund Contributions and Suspension of a Clearing Member

As generally described above, the proposed changes would also provide that OCC would be permitted to borrow from the OCC Clearing Fund, and also against certain Margin Assets, of a Clearing Member that has been suspended by OCC where that Clearing Member is a Mutually Suspended Member. To implement these changes, OCC is proposing the following amendments to OCC Rule 1006 and Rule 1104.

OCC Rule 1006 addresses the purpose and permitted uses of the OCC Clearing Fund. OCC proposes to make amendments to paragraphs (a) and (f) to permit OCC to utilize assets in the Clearing Fund as a liquidity resource in connection with making a Guaranty Substitution Payment. Currently, OCC Rule 1006(a) states the conditions for use of the OCC Clearing Fund. These provide that the OCC Clearing Fund may be used for borrowings pursuant to OCC Rule 1006(f) or to make good losses or expenses suffered by OCC including: (i) as a result of the failure of any Clearing Member to discharge duly any obligation on or arising from any confirmed trade accepted by OCC, (ii) as a result of the failure of any Clearing Member (including any Appointed Clearing Member) or of CDS (Canada's national securities depository) to perform its obligations under any contract or obligation issued, undertaken, or guaranteed by OCC or in respect of which OCC is otherwise liable, (iii) as a result of the failure of any Clearing Member to perform any of its obligations to OCC in respect of the stock loan and borrow positions of such Clearing Member, (iv) in connection with any liquidation of a Clearing Member's open positions, (v) in connection with protective transactions effected for the account of OCC pursuant to Chapter XI of OCC's Rules (delivery of underlying securities and payment), (vi) as a result of the failure of any Clearing Member to make any other required payment or render any other required performance or (vii) as a result of the failure of any bank, securities or commodities clearing organization, or investment counterparty, to perform its obligations to OCC for certain specified reasons.[56]

OCC proposes to renumber clauses (iii) through (vii) in paragraph (a) as (iv) through (viii), and to insert as new clause (iii) a provision that the OCC Clearing Fund may be used ''regarding any Guaranty Substitution Payment that [OCC] may make to [NSCC] under an agreement between them, as described in [OCC] Rule 901, so that [NSCC] will not reject settlement obligations for CCC-eligible securities involving a Clearing Member for which [NSCC] has ceased to act and that [OCC] directs to [NSCC] for settlement through its facilities.'' [57] OCC also proposes to add parenthetical language to paragraphs (f)(1)(A) and (f)(2)(A)(ii) to further clarify that contributions to the OCC Clearing Fund may be borrowed by OCC for use in connection with making a Guaranty Substitution Payment to NSCC. Any borrowing from the OCC Clearing Fund by OCC to make a Guaranty Substitution Payment to NSCC would be subject to the existing terms of OCC Rule 1006(f)(3) that provide that irrespective of how any such borrowings from the OCC Clearing Fund are applied by OCC, the borrowing for a period not to exceed thirty (30) days will not be deemed to result in charges against the OCC Clearing Fund under OCC's default waterfall for allocating actual losses. For purposes of determining whether a loss resulting from a Guaranty Substitution Payment has occurred, OCC Rule 1006(f)(3) would be amended to provide that the Guaranty Substitution Payment is deemed to be repaid by OCC at such time as under the Accord that it is NSCC's obligation to return any portion of the Guaranty Substitution Payment that NSCC does not use pursuant to its rules. If, subsequent to the borrowing, OCC determines that the borrowing represents an actual loss or all or any part of the borrowing remains outstanding after thirty (30) days (or on the first Business Day thereafter if the thirtieth calendar day is not a Business Day) then the amount of OCC Clearing Fund assets used in the outstanding borrowing would be an actual loss that OCC would be required to immediately allocate under its By-Laws and Rules.[58] As noted above, losses resulting from the borrowing of Clearing Fund or Margin Assets as a liquidity resource to facilitate OCC making a Guaranty Substitution Payment would be allocated in the same sequence as any other losses charged to the default waterfall.

Consistent with these changes to permit OCC to use the OCC Clearing Fund as a borrowing resource to make a Guaranty Substitution Payment to NSCC, OCC is also proposing similar changes to OCC Rule 1104 that would permit OCC to borrow certain Margin Assets of a Clearing Member that has been suspended by OCC where that Clearing Member is a Mutually Suspended Member and OCC has a general lien [59] over the Margin Assets.

Specifically, OCC proposes to add a new paragraph (g) to OCC Rule 1104 that would provide that OCC may use specified Margin Assets of a suspended Clearing Member as a borrowing in order to use such borrowed Margin Assets to make a Guaranty Substitution Payment to NSCC. OCC would be permitted to use Margin Assets from the following accounts of a suspended Common Member: firm lien account and firm non-lien account; separate Market-Maker's account; combined Market-Maker's account; and JBO Participants' account.[60] OCC is not proposing at this time to have authority to borrow Margin Assets from other types of accounts over

[55] *See* NSCC Rules 4 (defining ''Required Fund Deposit'') and 4A (defining ''Supplemental Liquidity Deposit''), *supra* note 9.

[56] The terms ''Clearing Member'' and ''Appointed Clearing Member'' as used herein have the meanings provided in OCC's By-Laws, *supra* note 5.

[57] In connection with these amendments, the reference in Rule 1006(b) to ''clauses (i) through (vi) of paragraph (a)'' would be changed to ''clauses (i) through (vii) of paragraph (a).''

[58] If the defaulting OCC Clearing Member's Margin Assets and OCC Clearing Fund contribution were insufficient to cover the associated losses, OCC would next look to certain OCC financial resources that are available for that purpose (*e.g.,* OCC's corporate contribution and Clearing Fund contributions of non-defaulting OCC Clearing Members).

[59] Article I, Section 1.G.(1) of OCC's By-Laws states that the ''term 'general lien' means a security interest of [OCC] in all or specified assets in a Clearing Member account as security for all of the Clearing Member's obligations to [OCC] regardless of the source or nature of such obligations.'' *See* OCC By-Laws, *supra* note 5.

[60] The Clearing Member accounts referenced herein are described in subparagraphs (a), (b), (c) and (h) of Article VI, Section 3 of OCC's By-Laws. *See* OCC's By-Laws, *supra* note 5.

which OCC has a restricted lien [61] and for which the Margin Assets are security for the particular restricted lien accounts because of additional complexity that OCC believes would be associated with tracking NSCC's use of Margin Assets associated with those accounts and also due to certain regulatory requirements under Commission Rule 15c3–3 that apply to broker-dealer Clearing Members and prohibit the use of customer property of the broker-dealer to support non-customer activities.[62]

As with the terms that currently apply to any borrowing from the OCC Clearing Fund pursuant to OCC Rule 1006(f), new paragraph (g) in OCC Rule 1104 would further provide that Margin Assets borrowed by OCC to make a Guaranty Substitution Payment to NSCC would not be deemed to be charges against the margin assets for the relevant account(s) for up to thirty (30) days; however, if all or a part of such borrowing were to be determined by OCC, in its discretion, to represent an actual loss, or if all or a part of the borrowing were to remain outstanding after such thirty (30)-day period, OCC would consider the amount of margin assets used to support OCC's obligations under the outstanding borrowing or transaction as an actual loss and immediately allocate the loss in accordance with OCC's By-Laws and Rules.

OCC anticipates that in a scenario in which it would be permitted make a Guaranty Substitution Payment to NSCC under the proposed changes to the Existing Accord and OCC's By-Laws and Rules, OCC would generally expect to borrow from the Clearing Fund as a primary liquidity resource. OCC could also borrow Margin Assets of the suspended Clearing Member that is a Common Member under the proposed terms described above. OCC is not proposing changes that would require a specific borrowing sequence because OCC believes that it is more appropriate to preserve flexibility to borrow from the available OCC Clearing Fund or Margin Assets as OCC determines appropriate under the circumstances.

In addition, OCC proposes to specify in OCC Rule 1107(a)(1) that exercised option contracts and matured, physically-settled stock futures to which the suspended Clearing Member is a party may be settled in accordance with the terms of any agreement between OCC and NSCC governing the settlement of exercised option contracts and matured, physically-settled stock futures of a suspended Clearing Member. In such an event, settlement will be governed by and subject to the agreement between OCC and NSCC and the rules of NSCC.

The purpose of the proposed changes to create the Guaranty Substitution Payment mechanism is to provide OCC and NSCC with an additional default management tool to help manage liquidity and settlement risks that OCC believes would be presented to each covered clearing agency in connection with a Mutually Suspended Member. OCC believes that having the ability to make a Guaranty Substitution Payment to NSCC in regard to any unmet Required Fund Deposit or Supplemental Liquidity Deposit obligations of a Mutually Suspended Member would promote prompt and accurate clearance and settlement in the national system for the settlement of securities transactions by causing NSCC to guarantee certain securities settlement obligations that result from exercised options and matured futures contracts that are cleared and settled by OCC. In the following ways, OCC believes that this would be beneficial to and protective of OCC, NSCC, their participants, and the markets they serve.

First, OCC's ability to make the Guaranty Substitution Payment would ensure that the relevant securities settlement obligations would be accepted by NSCC for clearance and settlement and therefore the size of the related settlement obligations could be decreased from netting through NSCC's CNS Accounting Operation and/or NSCC's Balance Order Accounting Operation. Second, this outcome would avoid a scenario in which OCC's Guaranty would continue to apply and the settlement obligations would be settled on a broker-to-broker basis between OCC Clearing Members pursuant to the applicable provisions in Chapter IX of OCC's Rules. As noted above, OCC believes that such a broker-to-broker settlement scenario could result in substantial collateral and liquidity requirements for OCC Clearing Members. OCC believes that these potential collateral and liquidity consequences would be due to the lost benefit of netting of the settlement obligations through NSCC's facilities and also due to the short time (*i.e.,* the T+2 standard settlement cycle) between a rejection by NSCC of the settlement obligations for clearing and the associated settlement date on which settlement would be otherwise required to be made bilaterally by OCC Clearing Members. This scenario also raises the potential for procyclical liquidity demands on OCC Clearing Members and participants during stressed market conditions. Third, OCC will plan to size its liquidity resource requirements to reasonable expectations with a high probability of making a Guaranty Substitution Payment in order to facilitate the settlement of a Mutually Suspended Member's obligations through NSCC. Accounting for net liquidity demands from a Mutually Suspended Member's settlement obligations at the central counterparty-level enhances liquidity in the financial system and promotes the efficient use of capital by reducing the demand for liquidity associated with gross settlement of obligations and enabling the application of resources at both clearing agencies to satisfy the Member's obligation. Fourth, OCC believes that the potential for the size of the settlement obligations to be comparatively larger than the Guaranty Substitution Payment coupled with the short time remaining to settlement could also increase the risk of default by the affected OCC Clearing Members at a time when a Common Member has already been suspended. Therefore, OCC believes that the proposed changes to implement the ability for OCC to make a Guaranty Substitution Payment to NSCC would allow OCC to avoid these risks by causing NSCC to accept the relevant obligations arising from exercised options and matured futures cleared and settled by OCC, as it ordinarily would, and guarantee their settlement, upon OCC making a Guaranty Substitution Payment to NSCC in accordance with the revised Accord.

[61] Article I, Section 1.R.(8) of OCC's By-Laws states that the ''term 'restricted lien' means a security interest of [OCC] in specified assets (including any proceeds thereof) in an account of a Clearing Member with [OCC] as security for the Clearing Member's obligations to [OCC] arising from such account or, to the extent so provided in the By-Laws or Rules, a specified group of accounts that includes such account including, without limitation, obligations in respect of all confirmed trades effected through such account or group of accounts, and exercise notices assigned to such account or group of accounts.'' *See* OCC's By-Laws, *supra* note 5.

[62] For example, under the broker-dealer customer reserve account formula to SEC Rule 15c3–3 the broker-dealer takes a debit in the formula under Item 13 for margin that is ''required and on deposit with OCC for all option contracts written or purchased in customer accounts.'' This means that such margin in turn can be used by the broker-dealer Clearing Member as Margin Assets to support the securities customers' account at OCC.

iii. Proposed Changes to Comprehensive Stress Testing & Clearing Fund Methodology, and Liquidity Risk Management Description and Liquidity Risk Management Framework as Part of Phase 1

Comprehensive Stress Testing & Clearing Fund Methodology, and Liquidity Risk Management Description

OCC proposes to revise the OCC Comprehensive Stress Testing & Clearing Fund Methodology, and Liquidity Risk Management Description to include the GSP in its liquidity risk management practices. Overall, the proposed changes would reflect that the GSP functions as an additional liquidity demand type at the Clearing Member Organization (''CMO'') Group level.[63]

OCC would include additional specifics to address the potential increased demand that the inclusion of the GSP may cause in its liquidity risk management practices in the Liquidity Risk Management section of the Comprehensive Stress Testing & Clearing Fund Methodology, and Liquidity Risk Management Description. Specifically, OCC proposes to amend the Liquidity Demand for Positions Rejected by NSCC subsection, which describes the Existing Accord, including the scenario in which NSCC could choose not to guaranty certain securities settlement obligations arising out of transactions cleared by OCC. This subsection would be retitled as the Liquidity Demand Associated with NSCC Performance of Physical Settlement Activities subsection to more clearly describe its content and incorporate the GSP, as further detailed below. Consistent with the changes to the Existing Accord described above, OCC proposes to clarify that the Accord allows NSCC to reject such obligations if OCC elects to not make a GSP.

OCC proposes a new subsection, titled the Liquidity Demand GSP, to describe the GSP, which NSCC would calculate as defined in the proposed amendments to the Existing Accord. OCC would describe a GSP as a firm specific liquidity demand (*i.e.,* the amount of cash OCC needs to pay NSCC on behalf of the defaulting Common Member). OCC would describe the components of the GSP under the Accord. OCC would explain how it accounts for the liquidity demand associated with a potential GSP. Specifically, OCC would apply an amount to account for a potential GSP obligation for every day on which option expirations occur. This amount would be based on peak GSP amounts from the prior 12 months in a given expiration category for the specific CMO Group for each forecasted liquidity demand calculation. OCC will use a one-year lookback time period to determine the appropriate GSP amount to apply. The one-year lookback allows for the best like-to-like application of a historical GSP as there is a cyclical nature to option standard expirations with quarterly (*i.e.,* March, June, September, and December) and January generally being more impactful than non-quarterly expirations. The one-year lookback also allows behavior changes of a Clearing Member to be recognized within an annual cycle. OCC proposes to utilize a historical GSP based on current system capabilities and data that will be supplied by NSCC.

OCC would use the total amount of Clearing Fund and SLD deficits at NSCC in its calculation to account for its obligation. However, in the event of a default, OCC would be responsible for a proportionate share of both NSCC Clearing Fund deficits (which are analogous to OCC margin deficits) and SLDs that are attributable to OCC E&A activity transmitted to NSCC for settlement, whereas NSCC will be responsible for the portion of the Clearing Fund and SLD deficits associated with activity that NSCC clears that is not transmitted by OCC.

The amount of notional activity sent by OCC to NSCC informs the likelihood of a GSP. Namely, the potential amount of NSCC Clearing Fund and SLD deficits that are allocable to OCC increases as the amount of activity OCC sends to NSCC increases. Since not all types of expirations are the same with respect to the notional amount of activity sent by OCC to NSCC, OCC proposes to use five separate categories of expirations with potentially different GSP amounts to apply. Each day on which expirations occur would fall into one of five categories as follows:

- Standard Monthly Expiration: typically the third Friday of each month from the previous twelve months;
- Non-Standard Monthly Expiration Fridays (''End of Week Expirations''): the last business day of every week, typically a Friday, excluding the third Friday of each month from the previous twelve months;
- End of Month Expirations: the last trading day of every month from the previous twelve months;
- Expirations falling on Bank Holidays where Markets Are Open (''Bank Holiday Expirations''): days where banks are closed but the markets are open from the previous twelve months;[64]
- Remaining Expiration Days (''Daily Expirations''): All other days with an expiration from the previous twelve months that do not fall into any of the categories above (typically most Mondays through Thursdays) from the previous twelve months.

OCC believes these five categories are appropriate after an analysis of notional activity sent to NSCC by OCC.[65] More specifically, the standard Friday monthly expiration far exceeds the needs associated with any other category.[66] The remaining categories are intended to capture like time periods that will appropriately account for the GSP.

OCC would apply the peak GSP amounts from the prior twelve months in a given expiration category for the specific CMO Group for each forecasted liquidity demand calculation by adding the GSP amounts to the CMO Group's other forecasted liquidity demands for the relevant expiration day.[67] If a Clearing Member defaults, OCC may have to pay a GSP to NSCC on two successive days to facilitate the close-out of the defaulted Clearing Member's positions. To account for this possibility in its liquidity risk management process, OCC contemplates the payment of a GSP on expirations that result in settlements on the first and second days of the default management process. As described above, this GSP amount may

[63] A Clearing Member Group is composed of a set of affiliated OCC Clearing Members.

[64] The Bank Holiday category recognizes that for Veterans Day and Columbus Day, the equity and equity derivative markets are open for trading, but the banking system is closed for the day. Since the banking system is closed while the aforementioned markets are open, settlement at NSCC encompasses two days of equity trading and equity derivative E&A activity. As OCC is using NSCC deficit numbers without regard for allocation, there is a possibility of a significant outlying GSP requirement due to the settlement of two days of activity simultaneously. Prudence dictates retaining the capability to risk manage a day with such disparate characteristics differently. Additional supporting data in support of the creation of the Bank Holiday Expiration category is included as confidential Exhibit 3E to this filing.

[65] OCC provided its analysis of notional activity sent to NSCC by OCC in support of the creation of the five categories as confidential Exhibit 3E to this filing. This Exhibit 3E sets forth data related to OCC's liquidity stress testing, including Available Liquidity Resources, Minimum Cash Requirement thresholds, and/or liquidity breaches, for Sufficiency and Adequacy scenarios with and without the inclusion of the GSP.

[66] For example, the average notional transfer for Remaining Expiration Days is approximately 10% the size of Standard Expiration.

[67] As an example, if the applicable GSP is $100 and the (current) stressed liquidity demand is $150 for a Clearing Member Group, the result after the application of the GSP for that Clearing Member Group would be a combined liquidity requirement of $250 versus $150 currently.

serve to only increase liquidity demands.[68]

Furthermore, as stated in the new Liquidity Demand GSP subsection, OCC would apply a floor to certain expirations. At a minimum, the GSPs applied to the End of Week, End of Month, and Bank Holiday Expirations will be no lower than the peak of the Daily Expirations category. If a GSP pertaining to the End of Week, End of Month, and Bank Holiday Expiration category is higher than the peak of the Daily Expirations category, then OCC will apply that higher GSP. Standard Monthly Expirations will be floored by End of Week, End of Month, and Daily Expirations. If a GSP pertaining to any of these categories is higher than the Standard Monthly Expiration category, then OCC will apply that higher GSP. OCC would set out formulas representing the floors for the Standard Monthly, End of Week, End of Month, and Bank Holiday Expirations. Finally, OCC also proposes a minor change to clarify that it would attempt to effect alternative settlement if OCC elected not to make a GSP.[69]

Liquidity Risk Management Framework

OCC proposes changes to the Liquidity Risk Management Framework to incorporate the GSP. In the Liquidity Risk Identification section, OCC would specify that, in the situation where a member defaults immediately preceding, or during the expiration, of physically-settled E&A activity, OCC may elect to make a GSP to NSCC to compel NSCC to accept and process the E&A activity. If OCC elects to not make a GSP, OCC would complete settlement of the defaulted Clearing Member's E&A transactions through its current process. Relatedly, OCC would include a minor clarification to a footnote in this section to note that NSCC is not acting on behalf of a defaulting Clearing Member ''in this situation.''

Proposed Phase 2 Changes

On February 15, 2023, the Commission adopted amendments to Rule 15c6–1(a) under the Act[70] to shorten the standard settlement cycle for most broker-dealer transactions in securities from T+2 to T+1. In doing so, the Commission stated that a shorter settlement cycle ''can promote investor protection, reduce risk, and increase operational and capital efficiency.''[71] Moreover, the Commission stated that delaying the move to a shorter settlement cycle would ''allow undue risk to continue to exist in the U.S. clearance and settlement system''[72] and that it ''believes that the May 28, 2024, compliance date will help ensure that market participants have sufficient time to implement the changes necessary to reduce risk, such as risks associated with the potential for increases in settlement fails.''[73] The Phase 2 changes proposed herein serve those risk reduction objectives related to securities settlements by endeavoring to limit market disruption following a Common Member default. The proposed changes would allow OCC to provide certain assurances with respect to its ability to make a GSP in the event of a Common Member default to NSCC in a shortened settlement cycle, which would permit NSCC to begin processing E&A/Delivery Transactions prior to Guaranty Substitution occurring. This, in turn, would promote settlement through NSCC that is less operationally complex and would be expected to require less collateral and liquidity from market participants than if OCC engaged in the alternative settlement processes discussed above.

To address the operational realities concerning the Accord that will result from the Commission's adoption and implementation of a new standard settlement cycle of T+1 pursuant to Rule 15c6–1(a) under the Act, OCC and NSCC are proposing Phase 2 changes to further modify the Accord after the T+1 settlement cycle becomes effective. As described in greater detail below, the Phase 2 changes would allow the GSP and other changes that are part of the Phase 1 changes to continue to function appropriately and efficiently in the new T+1 settlement environment. Because of the phased approach, a separate mark-up is provided in confidential Exhibit 5C to this filing of the Phase 2 changes against the Accord as modified through the Phase 1 changes.

As described in more detail below, shortening the settlement cycle to T+1 will require NSCC to process stock settlement obligations arising from E&A Delivery Transactions one day earlier, *i.e.,* on the day after the trade date, than is currently the case. Moving processing times ahead by a full day will require processing to occur before the guaranty transfers from OCC to NSCC.[74] In this new T+1 processing environment, the Phase 2 changes would limit market disruption following a Common Member default because the Phase 2 changes would allow OCC to provide certain assurances with respect to its ability to make a GSP in the event of a Common Member default to NSCC that would permit NSCC to begin processing the defaulting Common Member's E&A/Delivery Transactions prior to Guaranty Substitution occurring. This, in turn, will promote settlement through NSCC that is less operationally complex and would be expected to require less collateral and liquidity from market participants than if OCC engaged in alternative settlement processes. The specific changes included in Phase 2 are described below. The changes would facilitate the continued ability of the GSP to function in an environment with a shorter settlement cycle. These changes are generally designed to allow OCC to provide certain assurances with respect to its ability to make a GSP in the event of a Common Member default to NSCC that would permit NSCC to begin processing E&A/Delivery Transactions prior to Guaranty Substitution occurring by introducing new or amended terms and setting out the processes associated therewith. All of the descriptions below explain the changes to the Accord as they would be made after the Accord has already been modified through prior implementation of the proposed Phase 1 changes.

Section 1—Definitions

First, new definitions would be added, and existing definitions would be amended or removed in Section 1.

The new defined terms would be as follows.

- The term ''GSP Monitoring Data'' would be defined to mean a set of margin and liquidity-related data points provided by NSCC on each Activity Date prior to the submission of E&A/Delivery Transactions by OCC to be used for informational purposes at OCC and NSCC.
- The term ''Final Guaranty Substitution Payment'' would be defined to mean an amount calculated by NSCC for each Settlement Date in accordance with Appendix A to the Accord, to include two components: (i) a portion of the NSCC Participating

[68] OCC provided its analysis of the impact of the GSP, including with respect to calls for collateral and liquidity demands as confidential Exhibit 3E to this filing.

[69] This clarification would maintain OCC's current process for settling transactions not processed through NSCC and does not represent the adoption of a new process or settlement method.

[70] 17 CFR 240.15c6–1.

[71] Securities Exchange Act Release No. 96930 (Feb. 15, 2023), 88 FR 13872, 13873 (Mar. 6, 2023).

[72] *Id.* at 13881.

[73] *Id.* at 13917.

[74] Given the reduction in the settlement cycle and existing processes that must be completed for settlement, it is OCC's understanding that the NSCC would not be able to safely compress its processing times further to allow processing to occur after the guaranty transfers from OCC to NSCC. OCC provided proposed processing timelines in confidential Exhibit 3G to this filing.

Member's [75] Required Fund Deposit deficit to NSCC calculated as a difference between the Required Fund Deposit deficit calculated on the NSCC Participating Member's entire portfolio and the Required Fund Deposit deficit calculated on the NSCC Participating Member's portfolio prior to submission of the E&A/Delivery Transactions; and (ii) the portion of the NSCC Participating Member's unpaid Supplemental Liquidity Deposit obligation attributable to the additional activity to be guaranteed.

• The term ''Historical Peak Guaranty Substitution Payment'' would be defined to mean the largest Final Guaranty Substitution Payment for an NSCC Participating Member and its affiliates that are also NSCC Participating Members over the 12 months immediately preceding the Activity Date, to include two components: (i) the Required Fund Deposit deficits associated with E&A/Delivery Transactions based on peak historical observations of the largest NSCC Participating Member and its affiliates that are also NSCC Participating Members; and (ii) the Supplemental Liquidity Deposit obligations associated with E&A/Delivery Transactions based on peak historical observations as calculated in accordance with applicable NSCC or OCC Rules and procedures.

• The term ''Qualifying Liquid Resources'' would be defined to have the meaning provided by Rule 17Ad-22(a)(14) of the Exchange Act, 17 CFR 240.17Ad–22(a)(14), or any successor Rule under the Exchange Act.

• The term ''Settlement Date'' would be defined to mean the date on which an E&A/Delivery Transaction is designated to be settled through payment for, and delivery of, the Eligible Securities underlying the exercised Stock Option [76] or matured Stock Future,[77] as the case may be.

• The term ''Weekday Expiration'' would be defined to mean any expiration for which the options expiration date occurs on a date other than a Friday or for which the Settlement Date is any date other than the first business date following a weekend.

• The term ''Weekend Expiration'' would be defined to mean any expiration for which the options expiration date occurs on a Friday or for which the Settlement Date is the first business date following a weekend.

[75] *See supra* note 42.

[76] *See supra* note 37.

[77] *See supra* note 38.

The defined term that would be removed in Section 1 is as follows.

• ''Guaranty Substitution Payment,'' which would be replaced by the new defined terms ''Final Guaranty Substitution Payment'' and ''Historical Peak Guaranty Substitution Payment.''

The defined terms that would be amended in Section 1 are as follows.

• The definition for the term ''Eligible Securities'' generally contemplates the securities that are eligible to be used for physical settlement under the Existing Accord. In Phase 2, the term will be modified to exclude any transactions settled through NSCC's Balance Order System and any security undergoing a voluntary corporate action that is being supported by NSCC's CNS system. This is because the processing of E&A/Delivery Transactions and potential reversals of such transactions under the Phase 2 changes would not be feasible under the anticipated operation of NSCC's CNS and Balance Order Accounting Operations under the shortened T+1 settlement cycle.

Section 3—Historical Peak Guaranty Substitution Payment

A new Section 3 would be added to describe the process by which OCC would send to NSCC evidence of sufficient funds to cover the Historical Peak Guaranty Substitution Payment. In particular, Section 3(a) would provide that on each Activity Date, at or before a time agreed upon by the Clearing Agencies (which may be modified on any given Activity Date with the consent of an authorized representative of OCC), NSCC will communicate to OCC the amount of the Historical Peak Guaranty Substitution Payment amount and the GSP Monitoring Data, which are to be used for informational purposes at OCC. The Historical Peak Guaranty Substitution Payment would reflect the largest GSP of the NSCC Participating Member and its affiliates over the prior twelve months and would be calculated based on the sum of the Required Fund Deposit deficits and Supplemental Liquidity Deposit associated with E&A/Delivery Transactions. Section 3(b) would provide that OCC would then submit to NSCC an acknowledgement of the Historical Peak Guaranty Substitution Payment amount and evidence that OCC has sufficient cash resources in the OCC Clearing Fund to cover the Historical Peak Guaranty Substitution Payment.

Section 3(c) would provide that if OCC does not provide NSCC with evidence within the designated time period that it has sufficient cash resources in the OCC Clearing Fund to cover the Historical Peak Guaranty Substitution Payment on the Activity Date, OCC will immediately contact NSCC to escalate discussions to discuss potential exposures and determine, among other things, whether OCC has other qualifying liquidity resources available to satisfy such amount.

As described above, the Historical Peak Guaranty Substitution Payment is designed to serve as a reasonable proxy for the largest potential Final Guaranty Substitution Payment. Its purpose is to allow OCC to provide evidence that it likely will be able to satisfy the Final Guaranty Substitution Payment in the event of a Common Member default, which will provide NSCC with reasonable assurances such that NSCC can begin processing E&A/Delivery Transactions upon receipt and prior to the Guaranty Substitution occurring, which will minimize the probability of reversals in a default event in light of the shortened settlement cycle. The Historical Peak Guaranty Substitution Payment amount also will provide OCC with information that will allow OCC to include the amount of a potential GSP in its liquidity resource planning.

Section 6—Final Guaranty Substitution Payment; OCC's Commitment

A new Section 6 would be added to provide the process by which NSCC would communicate the amount of, and OCC would commit to pay, the Final Guaranty Substitution Payment. In particular, Section 6(a) would provide that on each Settlement Date (or each Saturday for Weekend Expirations), by no later than the time(s) agreed upon by NSCC and OCC, NSCC will communicate to OCC the Final Guaranty Substitution Payment for each Common Member calculated by NSCC. NSCC would make such calculation according to a calculation methodology described in a new Appendix A to the Accord. This calculation would represent the sum of the Required Fund Deposit [78] and the Supplemental Liquidity Deposit [79] for the Common Member. As with the Phase 1 Accord, payment of the Final Guaranty Substitution Payment would be contingent on the mutual

[78] The Required Fund Deposit is the portion of the defaulted Common Member's Required Fund Deposit deficit to NSCC, calculated as a difference between the Required Fund Deposit deficit calculated on the entire portfolio and the Required Fund Deposit deficit calculated on the Common Member's portfolio prior to the submission of E&A/Delivery Transactions. The Phase 2 changes would refine the existing calculation methodology for the Required Fund Deposit in order to provide for a more accurate amount.

[79] If NSCC calculates a liquidity shortfall with respect to a defaulted Common Member, the Supplemental Liquidity Deposit is the portion of that shortfall that is attributable to the additional activity to be guaranteed.

suspension of the Common Member and payment of the Final Guaranty Substitution Payment would continue to be the means by which Guaranty Substitution may occur.

Section 6(b) would provide that, following NSCC's communication of the Final Guaranty Substitution Payment for each Common Member to OCC, and by no later than the agreed upon time, OCC must either (i) commit to NSCC that it will pay the Final Guaranty Substitution Payment in the event of a mutual suspension of a Common Member,[80] or (ii) notify NSCC that it will not have sufficient cash resources to pay the largest Final Guaranty Substitution Payment calculated for every Common Member. Section 6(b)(i) would further provide that for Weekday Expirations, OCC's submission of E&A/Delivery Transactions to NSCC would constitute OCC's commitment to pay the Final Guaranty Substitution Payment on the Settlement Date in the event of a mutual suspension of a Common Member.

Section 6(c) would provide that if OCC notifies NSCC that it will not have sufficient cash resources to pay the Final Guaranty Substitution Payment, NSCC may, in its sole discretion (i) reject or reverse all E&A/Delivery Transactions, or (ii) voluntarily accept E&A/Delivery Transactions subject to certain terms and conditions mutually agreed upon by NSCC and OCC.[81] Section 6(c) would also provide that any necessary reversals of E&A/Delivery Transactions shall be delivered by NSCC to OCC at such time and in such form as the Clearing Agencies agree.

Section 6(d) would provide that if, at any time after OCC has acknowledged the Historical Peak Guaranty Substitution Payment in accordance with proposed Section 3(b) of the Accord or committed to pay the Final Guaranty Substitution Payment in accordance with proposed Section 6(b) of the Accord, OCC has a reasonable basis to believe it will be unable to pay the Final Guaranty Substitution Payment, OCC will immediately notify NSCC.

[80] If OCC does not have sufficient cash to pay the Final GSP, then it must confirm for NSCC the availability of other qualifying liquid resources and the expected timeline for converting such resources to cash.

[81] Such terms and conditions may include, but would not be limited to, OCC's agreement to (i) pay NSCC available cash resources in partial satisfaction of the Final Guaranty Substitution Payment; (ii) collect or otherwise source additional resources that would constitute NSCC Qualifying Liquid Resources to pay the full Final Guaranty Substitution Payment amount; and/or (iii) reimburse NSCC for any losses associated with closing out such E&A/Delivery Transactions.

Section 8—Default by an NSCC Participating Member or OCC Participating Member

Section 6(b)(i), which would be renumbered as Section 8(b)(i), would be amended to reflect the modified use of the Final Guaranty Substitution Payment in the event of a mutual suspension of a Common Member. Section 8(b)(i) would also be revised to remove the ability for OCC or NSCC to require that the Guaranty Substitution Payment be re-calculated in accordance with an alternative methodology. This will not be necessary under the calculation methodology used in the Phase 2 changes because the proposed methodology would result in a more accurate calculation. Section 8(b)(i) would further amend the Accord by providing NSCC with discretion to voluntarily accept Defaulted NSCC Member Transactions and assume the guaranty for such transactions, subject to certain terms and conditions mutually agreed upon by NSCC and OCC. The only remaining change to the Guaranty Substitution process from its operation under the Accord would be the shortened time duration under which OCC would elect (by way of its commitment) to make the Final Guaranty Substitution Payment and the timing under which the Guaranty Substitution will be processed in order to function in a T+1 environment.

In particular, Section 8(b)(i) would provide that, with respect to a Mutually Suspended Member, if OCC has committed to make the Final Guaranty Substitution Payment, it will make such cash payment in full by no later than the agreed upon time(s). Upon NSCC's receipt of the full amount of the Final Guaranty Substitution Payment, NSCC's Guaranty would attach (and OCC's Guaranty will no longer apply) to the Defaulted NSCC Member Transactions. NSCC would have no obligation to accept a Final Guaranty Substitution Payment and attach the NSCC Guaranty to any Defaulted NSCC Member Transactions for more than the Activity Date on which it has ceased to act for that Mutually Suspended Member and one subsequent Activity Date. If NSCC does not receive the full amount of the Final Guaranty Substitution Payment in cash by the agreed upon time, the Guaranty Substitution Time would not occur with respect to the Defaulted NSCC Member Transactions and Section 8(b)(ii), described below, would apply. NSCC would, however, have discretion to voluntarily accept Defaulted NSCC Member Transactions and assume the guaranty for such transactions, subject to certain terms and conditions mutually agreed upon by NSCC and OCC.

Section 6(b)(ii), which would be renumbered as Section 8(b)(ii), would also be amended to reflect the modified use of the Final Guaranty Substitution Payment in the event OCC continues to perform or does not make the Final Guaranty Substitution Payment. In particular, Section 8(b)(ii) would add an additional criterion of OCC not satisfying any alternative agreed upon terms for Guaranty Substitution to reflect this as an additional option under the Phase 2 changes. As amended, Section 8(b)(ii) would provide that if OCC does not suspend an OCC Participating Member for which NSCC has ceased to act, OCC does not commit to make the Final Guaranty Substitution Payment, NSCC does not receive the full amount of the Final Guaranty Substitution Payment in cash by the agreed upon time, or OCC does not satisfy any alternative agreed upon terms for Guaranty Substitution, Guaranty Substitution with respect to all Defaulted NSCC Member Transactions for that Activity Date will not occur, all Defaulted NSCC Member Transactions for that Activity Date will be reversed and exited from NSCC's CNS accounting system, and NSCC will have no obligation to guaranty or settle such Defaulted NSCC Member Transactions. NSCC may, however, exercise its discretion to voluntarily accept the Defaulted NSCC Member Transactions, and assume the guaranty for such transactions, subject to certain agreed upon terms and conditions.

Section 8(b) would also be modified to provide for escalated discussion between the Clearing Agencies in the event of an intraday NSCC Cease to Act and/or NSCC Participating Member Default, particularly to confirm that OCC has sufficient qualifying liquid resources to pay the projected Final Guaranty Substitution Payment for the Defaulting NSCC Member's projected E&A/Delivery Transactions based on information provided in GSP Monitoring Data for such Defaulting NSCC Member.

Conforming changes would also be made to Section 8(d) to reflect the use of the new defined term ''Final Guaranty Substitution Payment.''

Other Proposed Changes as Part of Phase 2

Certain other technical changes are also proposed as part of the Phase 2 changes, including to conform the Accord to the proposed changes described above. For example, Section 9(c) would be revised regarding information sharing to reflect the

introduction of the Historical Peak and Final Guaranty Substitution Payments and the GSP Monitoring Data; Section 4(c)(ix) would be conformed to reflect the addition of ''Settlement Date'' as a defined term in Section 1; various sections would be renumbered and internal cross-references would be adjusted to reflect the addition of new sections proposed herein; correct current references throughout the Accord to ''NSCC Rules and Procedures'' would be changed to simply read ''the NSCC Rules;'' and various non-substantive textual changes would be made to increase clarity.

Section 4(a) would also be modified to reflect that the Eligibility Master Files referenced in that paragraph, which identify Eligible Securities to OCC, are described in the SLA between OCC and NSCC. Section 9(b) would be modified to include OCC's available liquidity resources, including Clearing Fund cash balances in the information OCC provides to NSCC, and to specify that information will be provided on each Activity Date at an agreed upon time and in an agreed upon form by the Clearing Agencies. Finally, Section 16(b) would be modified to provide the correct current delivery address information for NSCC.

The Phase 2 changes would also include an Appendix A that would describe in detail the calculation methodology for the Guaranty Substitution Payment. This would provide the detailed technical calculation to determine each of the Mutually Suspended Member's Required Fund Deposit deficit and liquidity shortfall to NSCC. The full text of Appendix A is filed confidentially with the Commission as Exhibit 5 to this filing.

Phase 2 Guaranty Substitution Process Changes

As described above, the Phase 2 changes would modify the Guaranty Substitution process to reflect the shortened time duration under which the Guaranty Substitution will be processed in order to function in a T+1 environment. Below is a description of how that process would operate. The actual process would be implemented pursuant to a modified SLA between the Clearing Agencies.[82] All times provided below are in Eastern Time and represent the latest time by which the specified action must occur, unless otherwise agreed by the Clearing Agencies.

Weekend Expirations: On Friday (the Activity Date), NSCC would provide OCC with the Historical Peak GSP amount by 8:00 a.m. By 5:00 p.m. on Friday, OCC must acknowledge the Historical Peak GSP and provide evidence of OCC's Clearing Fund cash resources sufficient to cover that amount, following which NSCC would provide the Eligibility Master File by 5:45 p.m. By 1:00 a.m. on Saturday, OCC would then provide NSCC with the E&A/Delivery Transactions file and by 8:00 a.m. NSCC would provide OCC with the Final GSP, which OCC must commit to pay by 9:00 a.m. in the event of a mutual suspension of a Common Member.[83] By 8:00 a.m. Monday (the Settlement Date), if a cease to act is declared over the weekend (or the later of 10:00 a.m. or one hour after the cease to act is declared if declared on Monday), OCC must pay the Final GSP if there has been a mutual suspension of a Common Member. Finally, by 1:00 p.m. on Monday, OCC must provide reversals for the defaulted member's E&A/Delivery Transactions if OCC has not satisfied (or will not satisfy) the Final GSP.

Weekday Expirations: On the Activity Date, NSCC would provide OCC with the Historical Peak GSP amount by 8:00 a.m. By 5:00 p.m. on the Activity Date, OCC must acknowledge the Historical Peak GSP and provide evidence of its cash resources in the OCC Clearing Fund sufficient to cover that amount, following which NSCC would provide the Eligibility Master File by 5:45 p.m. By 1:00 a.m. on the Settlement Date (the day after the Activity Date in the T+1 environment), OCC would then provide NSCC with the E&A/Delivery Transactions file, which also constitutes OCC's commitment to pay the Final GSP. By 8:00 a.m. NSCC would provide OCC with the Final GSP. By the later of 10:00 a.m. on the Settlement Date or one hour after a cease to act is declared, OCC must pay the Final GSP if there has been a mutual suspension of a Common Member. Finally, by 1:00 p.m. on the Settlement Date, OCC must provide reversals for the defaulted member's E&A/Delivery Transactions if OCC has not satisfied (or will not satisfy) the Final GSP.

For both Weekend Expirations and Weekday Expirations, Guaranty Substitution will take place only after the Common Members meet their start of day margin funding requirements at NSCC, if any. In a Common Member default event, the Guaranty Substitution will take place when OCC pays the Final GSP to NSCC.

The Clearing Agencies note that the Phase 2 changes described above are designed to change the process by which the GSP is implemented such that the use of the GSP as a mechanism to facilitate the acceptance of settlement obligations by NSCC can continue to operate within the condensed timing for clearance and settlement in a T+1 environment. However, the ultimate use of the GSP, its purpose, and its substantive import would remain consistent with the Phase 1 changes.

Proposed Liquidity Risk Management Framework Changes

OCC proposes changes to the Liquidity Risk Management Framework to incorporate the Phase 2 changes into its liquidity risk management practices. In the Contingency Funding Plan section, OCC would specify that it endeavors to maintain sufficient cash resources to cover its projected settlement demands. Projected settlement demands may include settlements associated with option exercise & assignment activity that create obligations for OCC under the Accord (*e.g.,* Final GSP, Historical Peak GSP). Final and Historical Peak GSP would be defined in the Definitions section. OCC proposes a footnote referencing the proposed Phase 1 changes to the Comprehensive Stress Testing & Clearing Fund Methodology, and Liquidity Risk Management Description with respect to the Final GSP. Namely, to account for the liquidity demand associated with the potential payment of a Final GSP, OCC would include the peak amount of the entire actual NSCC Required Fund Deposit deficits and SLD start-of-day obligations, without regard to allocation between NSCC and OCC, specific to each CMO Group for the relevant type of expiration on a rolling twelve-month lookback. Moreover, OCC may require the deposit of cash by a Clearing Member pursuant to its current Rules if projected settlement demands exceed OCC liquidity resources available to make settlement in the event of a Clearing Member default.

OCC also proposes related and clarifying changes in the document. For example, OCC would include a minor clarifying change to the Liquidity Risk Identification section to define GSP as a firm-specific liquidity demand. OCC would also amend the Stress Testing

[82] OCC provided a draft of the SLA illustrating such changes to the Commission as confidential Exhibit 3F to this filing.

[83] If OCC does not have sufficient cash resources to pay the Final GSP and the Clearing Agencies are unable to reach an agreement on additional terms for NSCC to accept E&A/Delivery Transactions, OCC must submit a reversal file by 12:30 a.m. on Monday so that NSCC can remove the E&A/Delivery Transactions from CNS prior to the start of NSCC's overnight processing. *See* confidential Exhibit 3H to this filing for additional details on action deadlines and processing times.

and Liquidity Resource Sizing section to incorporate information pertaining to GSP obligations into the annual analysis presented to the Board on projected liquidity demands that OCC may face under a variety of scenarios.

Proposed By-Law Changes

OCC proposes to update its By-Laws to conform with the revised Accord. OCC proposes to remove a reference to Balance Order Accounting Operation to align with the exclusion of transactions settled through NSCC's Balance Order System under the amended definition of Eligible Securities in the Phase 2 Accord.

Implementation Framework

The proposed Phase 1 and Phase 2 changes will be implemented as follows:

- Phase 1: Within 120 days after the date OCC and NSCC receive all necessary regulatory approvals for these proposed changes to the Accord, OCC will implement all Phase 1 changes. OCC would announce the implementation date by an Information Memorandum posted to its public website at least seven days prior to implementation.
- Phase 2: On the compliance date with respect to the final T+1 amendments to Exchange Act Rule 15c6–1(a) established by the SEC, OCC will implement all Phase 2 changes, keep in place any applicable Phase 1 changes that carry over to Phase 2, and decommission all Phase 1 changes that do not apply to Phase 2.[84]

Anticipated Effect on and Management of Risk

OCC believes that the proposed changes would reduce the nature and level of risk presented by OCC because the purpose of the proposed changes to enhance its stress testing processes and create the Guaranty Substitution Payment mechanism is to provide OCC and NSCC with additional default management tools to help manage liquidity and settlement risks that OCC believes would be presented to each covered clearing agency in connection with a Mutually Suspended Member. As described above in the Phase 1 changes, OCC believes that having the ability to make a Guaranty Substitution Payment to NSCC in regard to any unmet Required Fund Deposit or Supplemental Liquidity Deposit obligations of a Mutually Suspended Member would promote prompt and accurate clearance and settlement in the national system for the settlement of securities transactions by causing NSCC to guarantee certain securities settlement obligations that result from exercised options and matured futures contracts that are cleared and settled by OCC. OCC further believes that enhancing its stress testing processes will help to ensure that it maintains the resources to make such a payment. The Phase 2 changes would also promote prompt and accurate clearance and settlement in the national system for the settlement of securities transactions because, as described above, they would facilitate implementation of the new settlement cycle and support the Commission's stated goal of implementing necessary risk reducing changes in connection with the move to T+1 settlement, currently set for May 28, 2024. The Phase 2 changes would further enable OCC to provide certain assurances that would permit NSCC to begin processing E&A/Delivery Transactions prior to guaranty substitution occurring—thereby promoting the continued effectiveness of the guaranty substitution process in an environment with a shorter settlement cycle. In the following ways, OCC believes that this proposal would be beneficial to and protective of OCC, NSCC, their participants, and the markets they serve.

First, OCC's ability to make the Guaranty Substitution Payment would ensure that the relevant securities settlement obligations would be accepted by NSCC for clearance and settlement and therefore the size of the related settlement obligations could be decreased from netting through NSCC's CNS Accounting Operation and/or NSCC's Balance Order Accounting Operation. Second, this outcome would avoid a scenario in which OCC's Guaranty would continue to apply and the settlement obligations would be settled on a broker-to-broker basis between OCC Clearing Members pursuant to the applicable provisions in Chapter IX of OCC's Rules. As noted above, OCC believes that such a broker-to-broker settlement scenario could result in substantial collateral and liquidity requirements for OCC Clearing Members. OCC believes that these potential collateral and liquidity consequences would be due to the lost benefit of netting of the settlement obligations through NSCC's facilities and also due to the short time between a rejection by NSCC of the settlement obligations for clearing and the associated settlement date on which settlement would be otherwise required to be made bilaterally by OCC Clearing Members. This scenario also raises the potential for procyclical liquidity demands on OCC Clearing Members and participants during stressed market conditions. Third, OCC will plan to size its liquidity resource requirements to reasonable expectations with a high probability of making a Guaranty Substitution Payment in order to facilitate the settlement of a Mutually Suspended Member's obligations through NSCC. Accounting for net liquidity demands from a Mutually Suspended Member's settlement obligations at the central counterparty-level enhances liquidity in the financial system and promotes the efficient use of capital by reducing the demand for liquidity associated with gross settlement of obligations and enabling the application of resources at both clearing agencies to satisfy the Member's obligation. Fourth, OCC believes that the potential for the size of the settlement obligations to be comparatively larger than the Guaranty Substitution Payment coupled with the short time remaining to settlement could also increase the risk of default by the affected OCC Clearing Members at a time when a Common Member has already been suspended. Therefore, OCC believes that the proposed changes to implement the ability for OCC to make a Guaranty Substitution Payment to NSCC would allow OCC to avoid these risks by causing NSCC to accept the relevant obligations arising from exercised options and matured futures cleared and settled by OCC, as it ordinarily would, and guarantee their settlement, upon OCC making a Guaranty Substitution Payment to NSCC in accordance with the revised Accord.

Consistency With the Payment, Clearing and Settlement Supervision Act

The stated purpose of the Clearing Supervision Act is to mitigate systemic risk in the financial system and promote financial stability by, among other things, promoting uniform risk management standards for systemically important financial market utilities and strengthening the liquidity of systemically important financial market utilities.[85] Section 805(a)(2) of the Clearing Supervision Act[86] also authorizes the Commission to prescribe risk management standards for the payment, clearing and settlement activities of designated clearing entities, like OCC, for which the Commission is the supervisory agency. Section 805(b) of the Clearing Supervision Act[87] states

[84] If, due to the timing of regulatory approval, the implementation dates for Phase 1 and Phase 2 overlap, OCC would implement only the Phase 2 changes and Phase 1 changes that carry over to Phase 2.

[85] 12 U.S.C. 5461(b).

[86] 12 U.S.C. 5464(a)(2).

[87] 12 U.S.C. 5464(b).

that the objectives and principles for risk management standards prescribed under Section 805(a) shall be to:

- promote robust risk management;
- promote safety and soundness;
- reduce systemic risks; and
- support the stability of the broader financial system.

The Commission has adopted risk management standards under Section 805(a)(2) of the Clearing Supervision Act and the Exchange Act in furtherance of these objectives and principles.[88] Rule 17Ad–22 requires registered clearing agencies, like OCC, to establish, implement, maintain, and enforce written policies and procedures that are reasonably designed to meet certain minimum requirements for their operations and risk management practices on an ongoing basis.[89] Therefore, the Commission has stated [90] that it believes it is appropriate to review changes proposed in advance notices against Rule 17Ad–22 and the objectives and principles of these risk management standards as described in Section 805(b) of the Clearing Supervision Act.[91]

OCC believes the proposed changes are consistent with Section 805(b)(1) of the Clearing Supervision Act [92] because they would promote the reduction of risks to OCC, its Clearing Members and the markets OCC serves. As described above in the Phase 1 changes, OCC believes that the proposed enhancements to its stress testing processes and having the ability to make a Guaranty Substitution Payment to NSCC with respect to any unmet obligations of a Mutually Suspended Member would promote the reduction of risk because it would ensure that OCC maintains sufficient liquidity resources and that the relevant securities settlement obligations would be accepted by NSCC for clearance and settlement and therefore the size of the related settlement obligations for both the Mutually Suspended Member and its assigned delivery counterparties could be decreased from netting through NSCC's CNS Accounting Operation and/or NSCC's Balance Order Accounting Operation. This would also avoid a scenario in which OCC's Guaranty would continue to apply and the settlement obligations would be settled on a broker-to-broker basis between OCC Clearing Members, which OCC believes could result in substantial collateral and liquidity requirements for OCC Clearing Members and that, in turn, could also increase a risk of default by the affected OCC Clearing Members at a time when a Common Member has already been suspended. Additionally, the Phase 2 changes would facilitate implementation of the new settlement cycle and support the Commission's stated goal of implementing necessary risk reducing changes in connection with the move to T+1 settlement. The Phase 2 changes would further enable OCC to provide certain assurances that would permit NSCC to begin processing E&A/Delivery Transactions prior to guaranty substitution occurring—thereby promoting the continued effectiveness of the guaranty substitution process in an environment with a shorter settlement cycle. For these reasons, OCC believes that the proposed changes: (i) are designed to promote robust risk management; (ii) are consistent with promoting safety and soundness; and (iii) are consistent with reducing systemic risks and promoting the stability of the broader financial system.

OCC believes that the proposed changes are also consistent with the SEC rules that apply to OCC as a covered clearing agency.[93] In particular, SEC Rule 17Ad–22(e)(20) requires OCC to establish, implement, maintain and enforce written policies and procedures reasonably designed to identify, monitor and manage risks related to any link that OCC establishes with one or more other clearing agencies, financial market utilities, or trading markets.[94] As described in OCC's publicly available disclosure framework for financial market infrastructures,[95] the Existing Accord between OCC and NSCC is one such link. As described above, OCC believes (i) the proposed modifications to OCC's stress testing procedures that are designed to enhance its ability to call for additional liquidity resources, and (ii) the implementation of the ability for OCC to make a Guaranty Substitution Payment to NSCC in the relevant circumstances involving a Mutually Suspended Member would help manage the risks presented to OCC and its Clearing Members by the settlement link with NSCC because the Guaranty Substitution Payment would ensure that the relevant securities settlement obligations would be accepted by NSCC for clearance and settlement and therefore the size of the related settlement obligations could be decreased from netting through NSCC's CNS Accounting Operation and/or NSCC's Balance Order Accounting Operation.

For this same reason, OCC also believes that the proposed changes are consistent with the requirements of SEC Rules 17Ad–22(e)(3) and (7).[96] SEC Rule 17Ad–22(e)(3) requires OCC to establish, implement, maintain and enforce written policies and procedures reasonably designed to maintain a sound risk management framework for comprehensively managing, among other things, liquidity, credit and other risks that arise in or are borne by OCC.[97] SEC Rule 17Ad–22(e)(7) requires OCC, in relevant part, to establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively measure, monitor and manage the liquidity risk that arises in or is borne by OCC and to, among other things, address foreseeable liquidity shortfalls that would not be covered by OCC's liquid resources.[98] As noted, OCC believes the proposed stress testing enhancements and the ability to make a Guaranty Substitution Payment to NSCC would allow OCC to better manage liquidity and credit risks related to the settlement link with NSCC by ensuring that the relevant securities settlement obligations would be accepted by NSCC for clearance and settlement. It would avoid a scenario in which OCC's Guaranty would continue to apply and the settlement obligations would be settled on a broker-to-broker basis between OCC Clearing Members, which OCC believes could result in substantial collateral and liquidity requirements for OCC Clearing Members that, in turn, could also increase a risk of default by the affected OCC Clearing Members, particularly in circumstances where the prior suspension of a Mutually Suspended Member relates to broader stress in the financial system. Moreover, the incorporation of the Guaranty Substitution Payment into OCC's liquidity risk management practices would enhance OCC's ability to maintain additional liquidity resources to effect the settlement of exercise and assignment activity in the event of a

[88] 17 CFR 240.17Ad–22. *See* Securities Exchange Act Release Nos. 68080 (October 22, 2012), 77 FR 66220 (November 2, 2012) (S7–08–11) (''Clearing Agency Standards''); 78961 (September 28, 2016), 81 FR 70786 (October 13, 2016) (S7 17 CFR 240.17Ad–22. See Securities Exchange Act Release Nos. 68080 (October 22, 2012), 77 FR 66220 (November 2, 2012) (S7–08–11) (''Clearing Agency Standards''); 78961 (September 28, 2016), 81 FR 70786 (October 13, 2016).

[89] 17 CFR 240.17Ad–22.

[90] *See, e.g.,* Exchange Act Release No. 89039, 85 FR at 36446.

[91] 12 U.S.C. 5464(b).

[92] 12 U.S.C. 5464(b)(1).

[93] 17 CFR 240.17Ad–22(a)(5).

[94] 17 CFR 240.17Ad–22(e)(20).

[95] *See* The Options Clearing Corporation Disclosure Framework for Financial Market Infrastructures, pg. 105, (2023), *available at https://www.theocc.com/risk-management/pfmi-disclosures.*

[96] 17 CFR 240.17Ad–22(e)(3), (7).

[97] 17 CFR 240.17Ad–22(e)(3).

[98] 17 CFR 240.17Ad–22(e)(7).

Common Member default, and therefore, potentially increase the promotion of market stability. Regarding the Phase 2 changes, OCC believes that the continued ability in a T+1 environment to make a Guaranty Substitution Payment to NSCC would allow OCC to better manage liquidity and credit risks related to the settlement link with NSCC by ensuring that the relevant securities settlement obligations would be accepted by NSCC for clearance and settlement.

III. Date of Effectiveness of the Advance Notice and Timing for Commission Action

The proposed change may be implemented if the Commission does not object to the proposed change within 60 days of the later of (i) the date that the proposed change was filed with the Commission or (ii) the date that any additional information requested by the Commission is received. The clearing agency shall not implement the proposed change if the Commission has any objection to the proposed change.

The Commission may extend the period for review by an additional 60 days if the proposed change raises novel or complex issues, subject to the Commission or the Board of Governors of the Federal Reserve System providing the clearing agency with prompt written notice of the extension. A proposed change may be implemented in less than 60 days from the date the advance notice is filed, or the date further information requested by the Commission is received, if the Commission notifies the clearing agency in writing that it does not object to the proposed change and authorizes the clearing agency to implement the proposed change on an earlier date, subject to any conditions imposed by the Commission. The clearing agency shall post notice on its website of proposed changes that are implemented.

The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the advance notice is consistent with the Clearing Supervision Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–OCC–2023–801 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to file number SR–OCC–2023–801. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the advance notice that are filed with the Commission, and all written communications relating to the advance notice 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 self-regulatory organization.

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–OCC–2023–801 and should be submitted on or before February 14, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[99]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–01748 Filed 1–29–24; 8:45 am]

BILLING CODE 8011–01–P

[99] 17 CFR 200.30–3(a)(91).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99419; File No. SR–NASDAQ–2023–045]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To List and Trade Shares of the iShares Ethereum Trust Under Nasdaq Rule 5711(d), Commodity-Based Trust Shares

January 24, 2024.

On November 21, 2023, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the iShares Ethereum Trust under Nasdaq Rule 5711(d), Commodity-Based Trust Shares. The proposed rule change was published for comment in the **Federal Register** on December 11, 2023.[3] The Commission has received no comments on the proposal.

Section 19(b)(2) of the Act [4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is January 25, 2024. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change and the issues raised therein. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates March 10, 2024, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 99081 (Dec. 5, 2023), 88 FR 85945.

[4] 15 U.S.C. 78s(b)(2).

[5] 15 U.S.C. 78s(b)(2).

disapprove, the proposed rule change (File No. SR–NASDAQ–2023–045).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–01749 Filed 1–29–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: Publishing in the FR of 1/29/24.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Wednesday, January 31, 2024, at 10:00 a.m.

CHANGES IN THE MEETING: The Open Meeting scheduled for Wednesday, January 31, 2024, at 10:00 a.m., has been changed to Wednesday, January 31, 2024, at 9:00 a.m.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Authority: 5 U.S.C. 552b.

Dated: January 25, 2024.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–01865 Filed 1–26–24; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99424; File No. SR–ISE–2024–04]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Options 7, Section 4

January 24, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 12, 2024, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's Pricing Schedule at Options 7.[3]

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/ise/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's Pricing Schedule at Options 7, Section 4, Complex Order Fees and Rebates, to amend note 9 related to the Complex Order Fee for PIM Orders.[4]

Today, the Exchange assesses a $0.10 per contract Complex Order Fee for PIM Orders to all Non-Priority Customer[5] market participants (Market Makers,[6] Firm Proprietary[7]/Broker Dealers,[8] and Professional Customers,[9]) in Select[10] and Non-Select[11] Symbols. Today, Priority Customers[12] are not assessed Complex Order Fee for PIM Orders in Select and Non-Select Symbols. Today, note 9 to Options 7, Section 4, reduces the $0.10 per contract fee to $0.05 per contract for all Non-Priority Customer orders provided Members execute an average daily volume (''ADV'') of 7,500 or more contracts in the PIM in a given month. Further, the $0.10 per contract Complex Order Fee for PIM Orders is reduced to $0.00 per contract for all Member orders provided the Members execute an ADV of 12,500 or more contracts in the Complex PIM. The Exchange applies the discounted fees retroactively to all eligible Complex PIM volume in that month once the threshold has been reached. Additionally, Complex Order Fees for PIM Orders (including Complex PIM Orders) apply to the originating and contra order.[13]

Proposal

At this time, the Exchange proposes to amend note 9 of Options 7, Section 4 to revise the second sentence to instead provide that ''Other than for Priority Customer orders, Members that execute an ADV of 12,500 or more contracts in a given month in the Complex PIM will be charged a $0.02 per contract fee.'' The Exchange will continue to reduce the Complex Order Fees for PIM Orders from $0.10 to $0.05 per contract for all Non-Priority Customers that execute an ADV of 7,500 or more contracts in the Complex PIM in a given month. At this time, the Exchange would decrease the reduction for Complex Order Fees for Complex PIM Orders for Non-Priority

[6] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed pricing change on January 2, 2024 (SR–ISE–2024–01). On January 12, 2024, the Exchange withdrew that filing and submitted this filing.

[4] The PIM is a process by which an Electronic Access Member can provide price improvement opportunities for a transaction wherein the Electronic Access Member seeks to facilitate an order it represents as agent, and/or a transaction wherein the Electronic Access Member solicited interest to execute against an order it represents as agent. *See* Options 3, Section 13.

[5] ''Non-Priority Customers'' include Market Makers, Non-Nasdaq ISE Market Makers (FarMMs), Firm Proprietary/Broker-Dealers, and Professional Customers. *See* Options 7, Section 1(c).

[6] The term ''Market Makers'' refers to ''Competitive Market Makers'' and ''Primary Market Makers'' collectively. *See* Options 1, Section 1(a)(21).

[7] A ''Firm Proprietary'' order is an order submitted by a member for its own proprietary account. *See* Options 7, Section 1(c).

[8] A ''Broker-Dealer'' order is an order submitted by a member for a broker-dealer account that is not its own proprietary account. *See* Options 7, Section 1(c).

[9] A ''Professional Customer'' is a person or entity that is not a broker/dealer and is not a Priority Customer. *See* Options 7, Section 1(c).

[10] ''Select Symbols'' are options overlying all symbols listed on the Nasdaq ISE that are in the Penny Interval Program. *See* Options 7, Section 1(c).

[11] ''Non-Select Symbols'' are options overlying all symbols excluding Select Symbols. *See* Options 7, Section 1(c).

[12] A ''Priority Customer'' is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in Nasdaq ISE Options 1, Section 1(a)(37). Unless otherwise noted, when used in this Pricing Schedule the term ''Priority Customer'' includes ''Retail'' as defined below. *See* Options 7, Section 1(c).

[13] *See* note 11 of Options 7, Section 4.

Customers that execute an ADV of 12,500 or more contracts in a given month in the Complex PIM. Today, Priority Customers pay no Complex Order Fees for PIM Orders. Today, Members that execute an ADV of 12,500 or more contracts in a given month in the Complex PIM pay no Complex Order Fees for PIM Orders, except for Priority Customers who pay no Complex Order Fees for any PIM Orders. With this change, Non-Priority Customers would pay a $0.02 per contract fee for Complex Order Fees for Complex PIM Orders, provided they execute an ADV of 12,500 or more contracts in a given month in the Complex PIM.

The Exchange proposes to amend note 9 of Options 7, Section 4 to add the words ''Complex Fee for PIM Orders'' in place of ''fee'' to make clear the applicable fee. Today, the Exchange assesses Regular Order [14] and Complex Order [15] PIM Fees. The addition of the words ''Complex Fee for PIM Orders'' clarifies that the fee in note 9 is a Complex Order fee. The Exchange proposes to add the words ''Other than for Priority Customer orders,'' to the beginning of the second sentence, similar to the first sentence, because Priority Customers pay no Complex Order Fee for PIM Orders today and would not have a fee to reduce. Additionally, the Exchange proposes to add the words ''in a given month'' to the second sentence, similar to the first sentence, to make clear the time period in which Members must execute the required ADV. Finally, the Exchange proposes to amend note 9 of Options 7, Section 4 to add the word ''Complex'' before ''PIM'' to make clear the note applies to Complex PIM Orders.

Despite the decrease in the discount, the Exchange will continue to offer Non-Priority Customers an opportunity to pay a lower Complex Order Fees for PIM Orders.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[16] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[17] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange's proposed changes to its Pricing Schedule are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for options securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .'' [18]

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [19]

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for options security transaction services. The Exchange is only one of seventeen options exchanges to which market participants may direct their order flow. Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules. As such, the proposal represents a reasonable attempt by the Exchange to increase its liquidity and market share relative to its competitors.

The Exchange's proposal to amend note 9 of Options 7, Section 4 to decrease the reduction in the Complex Order Fee for PIM Orders for Non-Priority Customers that execute an ADV of 12,500 or more contracts in a given month in the Complex PIM from paying no fee to paying $0.02 per contract is reasonable because, despite the decrease in the discount, the Exchange will continue to offer Non-Priority Customers an opportunity to pay a lower Complex Order Fees for PIM Orders from $0.10 to $0.02 per contract. Additionally, the Exchange will continue to reduce the Complex Order Fees for Complex PIM Orders from $0.10 to $0.05 per contract for all Non-Priority Customers that execute an ADV of 7,500 or more contracts in the Complex PIM in a given month. Unlike other market participants, Priority Customers pay no Complex Order Fee for PIM Orders. The proposed $0.02 per contract Complex Order Fee for PIM Orders for Non-Priority Customers that execute an ADV of 12,500 or more contracts in a given month in the Complex PIM is competitive and remains lower than comparable fees at other options exchanges. BOX Exchange LLC (''BOX'') assesses a $0.05 per contract fee to its Professional Customer or Broker-Dealer and Market Maker for Complex Order Price Improvement Period (''COPIP'') Orders.[20] Additionally, Miami International Securities Exchange, Inc. (''MIAX'') assesses a $0.30 per contract fee to Public Customers that are not a Priority Customer, MIAX Market Maker, Non-MIAX Market Maker, Non-Member Broker-Dealer and Firm in its Complex Price Improvement Mechanism (''cPRIME'').[21]

The Exchange's proposal to amend note 9 of Options 7, Section 4 to decrease the reduction in the Complex Order Fee for PIM Orders for Non-Priority Customers that execute an ADV of 12,500 or more contracts in a given month in the Complex PIM from paying no fee to paying $0.02 per contract is equitable and not unfairly discriminatory because all Non-Priority Customers are eligible for the discount and would uniformly be assessed the lower fee provided they executed the requisite volume in a given month in the Complex PIM. Priority Customers are not eligible for the discount because they pay no Complex Order Fee for PIM Orders. Priority Customer liquidity benefits all market participants by providing more trading opportunities which attracts market makers. An

[14] *See* Options 7, Section 3, Regular Order Fees and Rebates.

[15] *See* Options 7, Section 4, Complex Order Fees and Rebates.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(4) and (5).

[18] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[19] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[20] *See* BOX's Fee Schedule.

[21] *See* MIAX's Fee Schedule.

increase in the activity of these market participants (particularly in response to pricing) in turn facilitates tighter spreads which may cause an additional corresponding increase in order flow from other market participants. Attracting more liquidity from Priority Customers will benefit all market participants that trade on the ISE.

The Exchange's proposal to amend note 9 of Options 7, Section 4 to add the words ''Complex Fee for PIM Orders'' in place of ''fee'' to make clear the applicable fee is reasonable because the addition of these words makes clear that the fees in note 9 are Complex Order fees as compared to Regular Order fees. The Exchange's proposal to add the words ''Other than for Priority Customer orders,'' to the beginning of the second sentence, similar to the first sentence, is reasonable because Priority Customers pay no Complex Order Fee for PIM Orders today and would not have a fee to reduce. The addition of the language makes clear that the fees apply to Non-Priority Customers. The Exchange's proposal to add the words ''in a given month'' to the second sentence, similar to the first sentence, is reasonable because it makes clear the time period in which Members must execute the required ADV. Finally, the Exchange's proposal to amend note 9 of Options 7, Section 4 to add the word ''Complex'' before ''PIM'' is reasonable because it makes clear the note applies to Complex PIM Orders and not Regular PIM Orders. The technical amendments to the rule text of note 9 are intended to clarify the current rule text and do not substantively amend the rule text. The Exchange also believes the aforementioned technical amendments to the rule text of note 9 are equitable and not unfairly discriminatory as the rule text does not impact any Member.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. In sum, if the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

In terms of intra-market competition, the Exchange does not believe that this proposal will place any category of market participant at a competitive disadvantage. The Exchange's proposal to amend note 9 of Options 7, Section 4 to decrease the reduction in the Complex Order Fee for PIM Orders for Non-Priority Customers that execute an ADV of 12,500 or more contracts in a given month in the Complex PIM from paying no fee to paying $0.02 per contract does not impose an undue burden on competition because all Non-Priority Customers are eligible for the discount and would uniformly be assessed the lower fee provided they executed the requisite volume in a given month in the Complex PIM. Unlike other market participants, Priority Customers are not eligible for the discount because they pay no Complex Order Fee for PIM Orders. Priority Customer liquidity benefits all market participants by providing more trading opportunities which attracts market makers. An increase in the activity of these market participants (particularly in response to pricing) in turn facilitates tighter spreads which may cause an additional corresponding increase in order flow from other market participants. Attracting more liquidity from Priority Customers will benefit all market participants that trade on the ISE.

The Exchange's proposal to amend note 9 of Options 7, Section 4 to add the words ''Complex Fee for PIM Orders'' in place of ''fee'' to make clear the applicable fee does not impose an undue burden on competition because the addition of these words makes clear that the fees in note 9 are Complex Order fees as compared to Regular Order fees. The Exchange's proposal to add the words ''Other than for Priority Customer orders,'' to the beginning of the second sentence, similar to the first sentence, does not impose an undue burden on competition because Priority Customers pay no Complex Order Fee for PIM Orders today and would not have a fee to reduce. Further, the addition of the language makes clear that the fees apply to Non-Priority Customers. The Exchange's proposal to add the words ''in a given month'' to the second sentence, similar to the first sentence, does not impose an undue burden on competition because it makes clear the time period in which Members must execute the required ADV. Finally, the Exchange's proposal to amend note 9 of Options 7, Section 4 to add the word ''Complex'' before ''PIM'' does not impose an undue burden on competition because it makes clear the note applies to Complex PIM Orders and not Regular PIM Orders. These technical amendments to the rule text of note 9 are intended to clarify the current rule text. The technical amendments do not substantively amend the rule text and do not impact any Member.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act[22] and Rule 19b–4(f)(2)[23] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–ISE–2024–04 on the subject line.

[22] 15 U.S.C. 78s(b)(3)(A)(ii).

[23] 17 CFR 240.19b–4(f)(2).

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–ISE–2024–04. 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–ISE–2024–04 and should be submitted on or before February 20, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–01750 Filed 1–29–24; 8:45 am]

BILLING CODE 8011–01–P

[24] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99426; File No. SR–OCC–2023–007]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of Amendment No. 2 to Proposed Rule Change by The Options Clearing Corporation Concerning Modifications to the Amended and Restated Stock Options and Futures Settlement Agreement Between the Options Clearing Corporation and the National Securities Clearing Corporation

January 24, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 23, 2024, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') this amendment (''Amendment No. 2'') to the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by OCC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

This Amendment No. 2 to the proposed rule change SR–OCC–2023–007 would (1) modify the Amended and Restated Stock Options and Futures Settlement Agreement dated August 5, 2017 between OCC and National Securities Clearing Corporation (''NSCC,'' and together with OCC, the ''Clearing Agencies'') (''Existing Accord'') [3] to permit OCC to elect to make a cash payment to NSCC following the default of a common clearing participant that would cause NSCC's central counterparty trade guaranty to attach to certain obligations of that participant and to make certain related revisions to OCC By-Laws, OCC Rules,[4] OCC's Comprehensive Stress Testing & Clearing Fund Methodology, and Liquidity Risk Management Description and OCC's Liquidity Risk Management Framework (''Phase 1'') and (2) to improve information sharing between the Clearing Agencies to facilitate the upcoming transition to a T+1 standard securities settlement cycle and allow OCC, after the compliance date under amended Exchange Act Rule 15c6–1(a), to provide certain assurances to NSCC prior to the default of a common clearing participant that would enable NSCC to begin processing E&A/Delivery Transactions (defined below) before the central counterparty trade guaranty attaches to certain obligations of that participant (''Phase 2'').[5] This Amendment No. 2 would amend and replace the Initial Filing and Amendment No. 1 in their entirety.

The proposed changes are included in Exhibits 5A and 5B and confidential Exhibits 5C, 5D, and 5E of Amendment No. 2 to File No. SR–OCC–2023–007. Material proposed to be added is underlined and material proposed to be deleted is marked in strikethrough text.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) Purpose

Executive Summary

NSCC is a clearing agency that provides clearing, settlement, risk management, and central counterparty services for trades involving equity

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Existing Accord was previously approved by the Commission. *See* Securities Exchange Act Release Nos. 81266, 81260 (July 31, 2017) (File Nos. SR–NSCC–2017–007; SR–OCC–2017–013), 82 FR 36484 (Aug. 4, 2017).

[4] OCC By-Laws are *available at https://www.theocc.com/getmedia/3309eceb-56cf-48fc-b3b3-498669a24572/occ_bylaws.pdf* and OCC Rules are *available at https://www.theocc.com/getmedia/9d3854cd-b782-450f-bcf7-33169b0576ce/occ_rules.pdf.*

[5] OCC initially filed a proposed rule change concerning the proposed Phase 1 changes on August 10, 2023. *See* Securities Exchange Act Release No. 98215 (Aug. 24, 2023), 88 FR 59976 (Aug. 30, 2023) (File No. SR–OCC–2023–007) (''Initial Filing''). OCC subsequently submitted a partial amendment to clarify the proposed implementation plan for the Initial Filing. *See* Securities Exchange Act Release No. 98932 (Nov. 14, 2023), 88 FR 80781 (Nov. 20, 2023) (File No. SR–OCC–2023–007) (''Amendment No. 1''). NSCC also has filed a proposed rule change with the Commission in connection with this proposal. *See* Securities Exchange Act Release No. 98213 (Aug. 24, 2023), 88 FR 59968 (Aug. 30, 2023) (File No. SR–NSCC–2023–007); Securities Exchange Act Release No. 98930 (Nov. 14, 2023), 88 FR 80790 (Nov. 20, 2023) (Partial Amendment No. 1 to File No. SR–NSCC–2023–007).

securities. OCC is the sole clearing agency for standardized equity options listed on national securities exchanges registered with the Commission, including options that contemplate the physical delivery of equities cleared by NSCC in exchange for cash (''physically settled'' options).[6] OCC also clears certain futures contracts that, at maturity, require the delivery of equity securities cleared by NSCC in exchange for cash. As a result, the exercise/assignment of certain options or maturation of certain futures cleared by OCC effectively results in stock settlement obligations. NSCC and OCC maintain a legal agreement, generally referred to by the parties as the ''Accord'' agreement, that governs the processing of such physically settled options and futures cleared by OCC that result in settlement obligations in underlying equity securities to be cleared by NSCC (*i.e.,* the Existing Accord). The Existing Accord establishes terms under which NSCC accepts for clearing certain securities transactions that result from the exercise and assignment of relevant options contracts and the maturity of futures contracts that are cleared and settled by OCC.[7] It also establishes the time when OCC's settlement guaranty in respect of those transactions ends and NSCC's settlement guaranty begins.

The Existing Accord allows for a scenario in which NSCC could choose not to guarantee the settlement of such securities arising out of E&A/Delivery Transactions. Specifically, NSCC is not obligated to guarantee settlement until its member has met its collateral requirements at NSCC. If NSCC chooses not to guarantee settlement, OCC would engage in an alternate method of settlement outside of NSCC. This scenario presents two primary problems. First, the cash required for OCC and its Clearing Members in certain market conditions to facilitate settlement outside of NSCC could be significantly more than the amount required if NSCC were to guarantee the relevant transactions. This is because settlement of the transactions in the underlying equity securities outside of NSCC would mean that they would no longer receive the benefit of netting through the facilities of NSCC. In such a scenario, the additional collateral required from Clearing Members to support OCC's continuing settlement guarantee would also have to be sufficiently liquid to properly manage the risks associated with those transactions being due on the second business day following the option exercise or the relevant futures contract maturity date. Based on an analysis of scenarios using historical data where it was assumed that OCC could not settle transactions through the facilities of NSCC, the worst-case outcome resulted in extreme liquidity demands of over $300 billion for OCC to effect settlement via an alternative method, *e.g.,* by way of gross broker-to-broker settlement, as discussed in more detail below. OCC Clearing Members, by way of their contributions to the OCC Clearing Fund, would bear the brunt of this demand. Furthermore, there is no guarantee that OCC Clearing Members could fund the entire amount of any similar real-life scenarios. By contrast, projected Guaranty Substitution Payments, defined below, identified during the study ranged from approximately $419 million to over $6 billion, also as discussed in more detail below.

The second primary problem relates to the significant operational complexities if settlement occurs outside of NSCC. More specifically, netting through NSCC reduces the volume and value of settlement obligations. For example, in 2022 it is estimated that netting through NSCC's continuous net settlement (''CNS'') accounting system[8] reduced the value of CNS settlement obligations by approximately 98% or $510 trillion from $519 trillion to $9 trillion. If settlement occurred outside of NSCC, on a broker-to-broker basis between OCC Clearing Members, for example, shares would not be netted and Clearing Members would have to coordinate directly with each other to settle the relevant transactions. The operational complexities and uncertainty associated with alternate means of settlement would impact every market participant involved in a settlement of OCC-related transactions.

To address these problems, the Clearing Agencies are proposing certain changes as part of Phase 1 to amend and restate the Existing Accord and make related changes to their respective rules that would allow OCC to elect to make a cash payment (the ''Guaranty Substitution Payment'' or ''GSP'') to NSCC following the default of a Common Member[9] that would cause NSCC to guarantee settlement of that Common Member's transactions and, therefore, cause those transactions to be settled through processing by NSCC. In connection with this proposal, OCC also would enhance its daily liquidity stress testing processes and procedures to account for the possibility of OCC making such a payment to NSCC in the event of a Common Member default. By making these enhancements to its stress testing, OCC could include the liquid resources necessary to make the payment in its resource planning. The Clearing Agencies believe that by NSCC accepting such a payment from OCC, the operational efficiencies and reduced costs related to the settlement of transactions through NSCC would limit market disruption following a Common Member default because settlement through NSCC following such a default would be less operationally complex and would be expected to require less liquidity and other collateral from market participants than the processes available to OCC for closing out positions. Additionally, proposed enhancements by OCC to its liquidity stress testing would add assurances that OCC could make such a payment in the event of a Common Member default. The Clearing Agencies believe that their respective clearing members and all other participants in the markets for which OCC provides clearance and settlement would benefit from OCC's ability to choose to make a cash payment to effect settlement through the facilities of NSCC. This change would provide more certainty around certain default scenarios and would blunt the financial and operational burdens market participants could experience in the case of most clearing member defaults.[10]

Finally, the Clearing Agencies are also proposing certain changes as part of Phase 2 that, if approved, would not be implemented until after the Commission shortens the standardized settlement cycle under Exchange Act Rule 15c6–

[6] The term ''physically-settled'' as used throughout the OCC Rules refers to cleared contracts that settle into their underlying interest (*i.e.,* options or futures contracts that are not cash-settled). When a contract settles into its underlying interest, shares of stock are sent, *i.e.,* delivered, to contract holders who have the right to receive the shares from contract holders who are obligated to deliver the shares at the time of exercise/assignment in the case of an option and maturity in the case of a future.

[7] Under the Existing Accord, such options and futures are defined as ''E&A/Delivery Transactions,'' which refers to ''Exercise & Assignment Delivery Transactions.''

[8] *See* Rule 11 (CNS System) and Procedure VII (CNS Accounting Operation) of the NSCC Rules. *See* NSCC's Rules, *available at https://www.dtcc.com/-/media/Files/Downloads/legal/rules/nscc_rules.pdf.*

[9] A firm that is both an OCC Clearing Member and an NSCC Member or is an OCC Clearing Member that has designated an NSCC Member to act on its behalf is referred to herein as a ''Common Member.'' The term ''Clearing Member'' as used herein has the meaning provided in OCC's By-Laws. *See* OCC's By-Laws, *supra,* note 4. The term ''Member'' as used herein has the meaning provided in NSCC's Rules. *See* NSCC's Rules, *supra* note 8.

[10] OCC provided its analysis of the financial impact of alternate means of settlement as confidential Exhibit 3A to this filing.

1(a) from two days after the traded date (''T+2'') to one day after the trade date (''T+1''), which currently is set for May 28, 2024. The Phase 2 changes would address the operational realities concerning the Accord that will result from the Commission's adoption and implementation of a new standard settlement cycle of T+1 pursuant to Rule 15c6–1(a) under the Act. The Phase 2 changes generally are designed to allow OCC to provide certain assurances with respect to OCC's ability to make a GSP in the event of a Common Member default to NSCC that would permit NSCC to begin processing Common Members' E&A/Delivery Transactions in a shortened settlement cycle prior to Guaranty Substitution occurring by introducing new or amended terms and setting out the processes associated therewith.

Background

OCC acts as a central counterparty clearing agency for U.S.-listed options and futures on a number of underlying financial assets including common stocks, currencies, and stock indices. In connection with these services, OCC provides the OCC Guaranty pursuant to its By-Laws and Rules. NSCC acts as a central counterparty clearing agency for certain equity securities, corporate and municipal debt, exchange traded funds and unit investment trusts that are eligible for its services. Eligible trading activity may be processed through NSCC's CNS system [11] or through its Balance Order Accounting system,[12] where all eligible compared and recorded transactions for a particular settlement date are netted by issue into one net long (buy), net short (sell) or flat position. As a result, for each day with activity, each Member has a single deliver or receive obligation for each issue in which it has activity at NSCC. In connection with these services, NSCC also provides the NSCC Guaranty pursuant to Addendum K of the NSCC Rules.

OCC's Rules provide that delivery of, and payment for, securities underlying certain exercised stock options and matured single stock futures that are physically settled are generally effected through the facilities of NSCC and are not settled through OCC's facilities.[13] OCC and NSCC executed the Existing Accord to facilitate, via NSCC's systems, the physical settlement of securities arising out of options and futures cleared by OCC. OCC Clearing Members that clear and settle physically settled options and futures transactions through OCC also are required under OCC's Rules [14] to be Members of NSCC or to have appointed or nominated a Member of NSCC to act on its behalf. As noted above, these firms are referred to as ''Common Members'' in the Existing Accord.

Summary of the Existing Accord

The Existing Accord governs the transfer between OCC and NSCC of responsibility for settlement obligations that involve a delivery and receipt of stock in the settlement of physically settled options and futures that are cleared and settled by OCC and for which the underlying securities are eligible for clearing through the facilities of NSCC (''E&A/Delivery Transactions''). It also establishes the time when OCC's settlement guarantee (the ''OCC Guaranty'') ends and NSCC's settlement guarantee (the ''NSCC Guaranty'') [15] begins with respect to E&A/Delivery Transactions. However, in the case of a Common Member default [16] NSCC can reject these settlement obligations, in which case the settlement guaranty would not transfer from OCC to NSCC and OCC would not have a right to settle the transactions through the facilities of NSCC. Instead, OCC would have to engage in alternative methods of settlement that have the potential to create significant liquidity and collateral requirements for both OCC and its non-defaulting Clearing Members.[17] More specifically, this could involve broker-to-broker settlement between OCC Clearing Members.[18] This settlement method is operationally complex because it requires bilateral coordination directly between numerous Clearing Members rather than relying on NSCC to facilitate multilateral netting to settle the relevant settlement obligations. As described above, it also potentially could result in significant liquidity and collateral requirements for both OCC and its non-defaulting Clearing Members because the transactions would not be netted through the facilities of NSCC. Alternatively, where NSCC accepts the E&A/Delivery Transactions from OCC, the OCC Guaranty ends and the NSCC Guaranty takes effect. The transactions are then netted through NSCC's systems, which allows settlement obligations for the same settlement date to be netted into a single deliver or receive obligation. This netting reduces the costs associated with securities transfers by reducing the number of securities movements required for settlement and further reduces operational and market risk. The benefits of such netting by NSCC may be significant with respect to the large volumes of E&A/Delivery Transactions processed during monthly options expiry periods.

Pursuant to the Existing Accord, on each trading day NSCC delivers to OCC a file that identifies the securities, including stocks, exchange-traded funds and exchange-traded notes, that are eligible (1) to settle through NSCC and (2) to be delivered in settlement of (i) exercises and assignments of stock options cleared and settled by OCC or (ii) delivery obligations from maturing stock futures cleared and settled by OCC. OCC, in turn, delivers to NSCC a file identifying securities to be delivered, or received, for physical settlement in connection with OCC transactions.[19]

After NSCC receives the list of eligible transactions from OCC and NSCC has received all required deposits to the NSCC Clearing Fund from all Common Members taking into consideration amounts required to physically settle the OCC transactions, the OCC Guaranty would end and the NSCC Guaranty

[11] *See* Rule 11 (CNS System) and Procedure VII (CNS Accounting Operation) of the NSCC Rules, *supra* note 8.

[12] *See* Rule 8 (Balance Order and Foreign Security Systems) and Procedure V (Balance Order Accounting Operation) of the NSCC Rules, *supra* note 8.

[13] *See* Chapter IX of OCC's Rules (Delivery of Underlying Securities and Payment), *supra* note 4.

[14] *See* OCC Rule 901, *supra* note 4.

[15] *See* Addendum K and Procedure III of the NSCC Rules, *supra* note 8.

[16] A Common Member that has been suspended by OCC or for which NSCC has ceased to act is referred to as a ''Mutually Suspended Member''.

[17] For example, OCC evaluated certain Clearing Member default scenarios in which OCC assumed that NSCC would not accept the settlement obligations under the Existing Accord, including the default of a large Clearing Member coinciding with a monthly options expiration. OCC has estimated that in such a Clearing Member default scenario, the aggregate liquidity burden on OCC in connection with obligations having to be settled on a gross broker-to-broker basis could reach a significantly high level. For example, in January 2022, the largest gross broker-to-broker settlement amount in the case of a larger Clearing Member default would have resulted in liquidity needs of approximately $384,635,833,942. OCC provided the data and analysis as confidential Exhibit 3A to this filing.

[18] In broker-to-broker settlement, Clearing Member parties are responsible for coordinating settlement—delivery and payment—among themselves on a transaction-by-transaction basis. Once transactions settle, the parties also have an obligation to affirmatively notify OCC so that OCC can close out the transactions. If either one of or both of the parties do not notify OCC, the transaction would remain open on OCC's books indefinitely until the time both parties have provided notice of settlement to OCC.

[19] Each day that both OCC and NSCC are open for accepting trades for clearing is referred to as an ''Activity Date'' in the Existing Accord. Securities eligible for settlement at NSCC are referred to collectively as ''Eligible Securities'' in the Existing Accord. Eligible securities are settled at NSCC through NSCC's CNS Accounting Operation or NSCC's Balance Order Accounting Operation.

would begin with respect to physical settlement of the eligible OCC-related transactions.[20] At this point, NSCC is solely responsible for settling the transactions.[21]

Each day, NSCC is required to promptly notify OCC at the time the NSCC Guaranty takes effect. If NSCC rejects OCC's transactions due to an improper submission [22] or if NSCC ''ceases to act'' for a Common Member,[23] NSCC's Guaranty would not take effect for the affected transactions pursuant to the NSCC Rules.

NSCC is required to promptly notify OCC if it ceases to act for a Common Member. Upon receiving such a notice, OCC would not continue to submit to NSCC any further unsettled transactions that involve such Common Member, unless authorized representatives of both OCC and NSCC otherwise consent. OCC would, however, deliver to NSCC a reversal file containing a list of all transactions that OCC already submitted to NSCC and that involve such Common Member. The NSCC Guaranty ordinarily would not take effect with respect to transactions for a Common Member for which NSCC has ceased to act, unless both Clearing Agencies agree otherwise. As such, NSCC does not have any existing contractual obligation to guarantee such Common Member's transactions. To the extent the NSCC Guaranty does not take effect, OCC's Guaranty would continue to apply, and, as described above, OCC would remain responsible for effecting the settlement of such Common Member's transactions pursuant to OCC's By-Laws and Rules.

As noted above, the Existing Accord does provide that the Clearing Agencies may agree to permit additional transactions for a Common Member default (''Defaulted NSCC Member Transactions'') to be processed by NSCC while subject to the NSCC Guaranty. This optional feature, however, creates uncertainty for the Clearing Agencies and market participants about how Defaulted NSCC Member Transactions may be processed following a Common Member default, and also does not provide NSCC with the ability to collect collateral from OCC that it may need to close out these additional transactions. While the optional feature would remain in the agreement as part of this proposal, the proposed changes to the Existing Accord, as described below, could significantly reduce the likelihood that it would be utilized.

Proposed Phase 1 Changes

The proposed changes to the Existing Accord would permit OCC to make a cash payment, referred to as the ''Guaranty Substitution Payment'' or ''GSP,'' to NSCC. This cash payment could occur on either or both of the day that the Common Member becomes a Mutually Suspended Member and on the next business day. Upon NSCC's receipt of the Guaranty Substitution Payment from OCC, the NSCC Guaranty would take effect for the Common Member's transactions, and they would be accepted by NSCC for clearance and settlement.[24] OCC could use all Clearing Member contributions to the OCC Clearing Fund [25] and certain Margin Assets [26] of a defaulted Clearing Member to pay the GSP, as described in more detail below.

NSCC would calculate the Guaranty Substitution Payment as the sum of the Mutually Suspended Member's unpaid required deposit to the NSCC Clearing Fund (''Required Fund Deposit'') [27] and the unpaid Supplemental Liquidity Deposit [28] obligation that is attributable to E&A/Delivery Transactions. The proposed changes to the Existing Accord define how NSCC would calculate the Guaranty Substitution Payment.

More specifically, NSCC would first determine how much of the member's unpaid Clearing Fund requirement would be included in the GSP. NSCC would look at the day-over-day change in gross market value of the Mutually Suspended Member's positions as well as day-over-day change in the member's NSCC Clearing Fund requirements. Based on such changes, NSCC would identify how much of the change in the Clearing Fund requirement was attributable to E&A/Delivery Transactions coming from OCC. If 100 percent of the day-over-day change in the NSCC Clearing Fund requirement is attributable to activity coming from OCC, then the GSP would include 100 percent of the member's NSCC Clearing Fund requirement. If less than 100 percent of the change is attributable to activity coming from OCC, then the GSP would include that percent of the member's unpaid NSCC Clearing Fund requirement attributable to activity coming from OCC. NSCC would then determine the portion of the member's unpaid SLD obligation that is attributable to E&A/Delivery Transactions. As noted above, the GSP would be the sum of these two amounts. A member's NSCC Clearing Fund requirement and SLD obligation at NSCC are designed to address the credit and liquidity risks that a member poses to NSCC. The GSP calculation is intended to assess how much of a member's obligations arise out of activity coming from OCC so that the amount paid by OCC is commensurate with the risk to NSCC of guarantying such activity.

To permit OCC to anticipate the potential resources it would need to pay the GSP for a Mutually Suspended Member, each business day, NSCC would provide OCC with (1) Required Fund Deposit and Supplemental Liquidity Deposit obligations, as calculated pursuant to the NSCC Rules, and (2) the gross market value of the E&A/Delivery Transactions and the gross market value of total Net Unsettled Positions (as such term is defined in the NSCC Rules). On options expiry days that fall on a Friday, NSCC would also provide OCC with information regarding liquidity needs and resources, and any intraday SLD requirements of Common Members. Such information would be delivered pursuant to the ongoing information sharing obligations under the Existing Accord (as proposed to be amended) and the Service Level Agreement (''SLA'') to which both NSCC and OCC are a party pursuant to

[20] The term ''NSCC Clearing Fund'' as used herein has the same meaning as the term ''Clearing Fund'' as provided in the NSCC Rules. Procedure XV of the NSCC Rules provides that all NSCC Clearing Fund requirements and other deposits must be made within one hour of demand, unless NSCC determines otherwise, *supra* note 8.

[21] This is referred to in the Existing Accord as the ''Guaranty Substitution Time,'' and the process of the substitution of the NSCC Guaranty for the OCC Guaranty with respect to E&A/Delivery Transactions is referred to as ''Guaranty Substitution.''

[22] Guaranty Substitution by NSCC (discussed further below) does not occur with respect to an E&A/Delivery Transaction that is not submitted to NSCC in the proper format or that involves a security that is not identified as an Eligible Security on the then-current NSCC Eligibility Master File.

[23] Under NSCC's Rules, a default would generally be referred to as a ''cease to act'' and could encompass a number of circumstances, such as an NSCC Member's failure to make a Required Fund Deposit in a timely fashion. *See* NSCC Rule 46 (Restrictions on Access to Services), *supra* note 8. An NSCC Member for which it has ceased to act is referred to in the Existing Accord as a ''Defaulting NSCC Member.'' Transactions associated with a Defaulting NSCC Member are referred to as ''Defaulted NSCC Member Transactions'' in the Existing Accord.

[24] Acceptance of such transactions by NSCC would be subject to NSCC's standard validation criteria for incoming trades. *See* NSCC Rule 7, *supra* note 8.

[25] The term ''OCC Clearing Fund'' as used herein has the same meaning as the term ''Clearing Fund'' in OCC's By-Laws, *supra* note 4.

[26] The term ''Margin Assets'' as used herein has the same meaning as provided in OCC's By-Laws, *supra* note 4.

[27] The Required Fund Deposit is calculated pursuant to Rule 4 (Clearing Fund) and Procedure XV (Clearing Fund Formula and Other Matters) of the NSCC Rules, *see supra* note 8.

[28] Under the NSCC Rules, NSCC collects additional cash deposits from those Members who would generate the largest settlement debits in stressed market conditions, referred to as ''Supplemental Liquidity Deposits'' or ''SLD.'' *See* Rule 4A of the NSCC Rules, *supra* note 8.

Section 2 of the Existing Accord.[29] The SLA addresses specifics regarding the time, form, and manner of various required notifications and actions described in the Accord and also includes information applicable under the Accord.

NSCC and OCC believe the proposed calculation of the Required Fund Deposit portion of the GSP is appropriate because it is designed to provide a reasonable proxy for the impact of the Mutually Suspended Member's E&A/Delivery Transactions on its Required Fund Deposit. While impact study data did show that the proposed calculation could result in a GSP that overestimates or underestimates the Required Fund Deposit attributable to the Mutually Suspended Member's E&A/Delivery Transactions,[30] current technology constraints prohibit NSCC from performing a precise calculation of the GSP on a daily basis for every Common Member.[31]

Implementing the ability for OCC to make the GSP and cause the E&A/Delivery Transactions to be cleared and settled through NSCC would promote the ability of OCC and NSCC to be efficient and effective in meeting the requirements of the markets they serve. This is because data demonstrates that the expected size of the GSP would be smaller than the amount of cash that would otherwise be needed by OCC and its Clearing Members to facilitate settlement outside of NSCC. More specifically, based on a historical study of alternate means of settlement available to OCC from September 2021 through September 2022, in the event that NSCC did not accept E&A/Delivery Transactions, the worst-case scenario peak liquidity need OCC identified was $384,635,833,942 for settlement to occur on a gross broker-to-broker basis. OCC estimates that the corresponding GSP in this scenario would have been $863,619,056. OCC also analyzed several other large liquidity demand amounts that were identified during the study if OCC effected settlement on a gross broker-to-broker basis.[32] These liquidity demand amounts and the largest liquidity demand amount OCC observed of $384,635,833,942 substantially exceed the amount of liquid resources currently available to OCC.[33] By contrast, projected GSPs identified during the study ranged from $419,297,734 to $6,281,228,428. For each of these projected GSP amounts, OCC observed that the Margin Assets and OCC Clearing Fund contributions that would have been required of Clearing Members in these scenarios would have been sufficient to satisfy the amount of the projected GSPs.

To help address the current technology constraint that prohibits NSCC from performing a precise calculation of the GSP on a daily basis for every Common Member, proposed Section 6(b)(i) of the Existing Accord and related Section 7(d) of the SLA would provide that with respect to a Mutually Suspended Member, either NSCC or OCC may require that the Required Fund Deposit portion of the GSP be re-calculated by calculating the Required Fund Deposit for the Mutually Suspended Member both before and after the delivery of the E&A/Delivery Transactions and utilize the precise amount that is attributable to that activity in the final GSP. If such a recalculation is required, the result would replace the Required Fund Deposit component of the GSP that was initially calculated. The SLD component of the GSP would be unchanged by such recalculation.

As the above demonstrates, the GSP is intended to address the significant collateral and liquidity requirements that could be required of OCC Clearing Members in the event of a Common Member default.

Allowing OCC to make a GSP payment also is intended to allow for settlement processing to take place through the facilities of NSCC to retain operational efficiencies associated with the settlement process. Alternative settlement means such as broker-to-broker settlement add operational burdens because transactions would need to be settled individually on one-off bases. In contrast, NSCC's netting reduces the volume and value of settlement obligations that would need to be closed out in the market.[34] Because the clearance and settlement of obligations through NSCC's facilities following a Common Member default, including netting of E&A/Delivery Transactions with a Common Member's positions at NSCC, would avoid these potentially significant operational burdens for OCC and its Clearing Members, OCC and NSCC believe that the proposed changes would limit market disruption relating to a Common Member default. NSCC netting significantly reduces the total number of obligations that require the exchange of money for settlement. Allowing more activity to be processed through NSCC's netting systems would minimize risk associated with the close out of those transactions following the default of a Common Member.

Amending the Existing Accord to define the terms and conditions under which Guaranty Substitution may occur, at OCC's election, with respect to Defaulted NSCC Member Transactions *after* a Common Member becomes a Mutually Suspended Member would also provide more certainty to both the Clearing Agencies and market participants generally about how a Mutually Suspended Member's Defaulted NSCC Member Transactions may be processed.

NSCC and OCC have agreed it is appropriate to limit the availability of the proposed provision to the day of the Common Member default and the next business day because, based on historical simulations of cease to act events involving Common Members, most activity of a Mutually Suspended Member is closed out on those days.[35] Furthermore, the benefits of netting through NSCC's systems would be reduced for any activity submitted to NSCC after that time.

To implement the proposed Phase 1 changes to the Existing Accord, OCC and NSCC propose to make the following changes.

[29] OCC provided a draft of the revised SLA to the Commission as confidential Exhibit 3C to this filing.

[30] The impact study was conducted at the Commission's request to cover a three-day period and reviewed the ten Common Members with the largest Required Fund Deposits attributable to the Mutually Suspended Member's E&A/Delivery Transactions. Over the 30 instances in the study, approximately 15 instances resulted in an underestimate of the Required Fund Deposit by an average of approximately $112,900,926, four instances where the proxy calculation was the same as the Required Fund Deposit, and eleven instances of an overestimate of the Required Fund Deposit by an average of approximately $59,654,583. *See* confidential Exhibit 3D to this filing for additional detail related to the referenced study.

[31] OCC and NSCC agreed that performing the necessary technology build during Phase 1 would delay the implementation of Phase 1 of this proposal. NSCC will incorporate those technology updates in connection with Phase 2 of this proposal.

[32] *See* confidential Exhibit 3A to this filing for additional detail related to the referenced study.

[33] As of September 30, 2023, OCC held approximately $12.37 billion in qualifying liquid resources. *See OCC Quantitative Disclosure,* July–September 2023, *available at https://www.theocc.com/risk-management/pfmi-disclosures.*

[34] CNS reduces the value of obligations that require financial settlement by approximately 98%, where, for example $519 trillion in trades could be netted down to approximately $9 trillion in net settlements.

[35] OCC provided data regarding such events in confidential Exhibit 3B to this filing. The information contained therein includes the assumptions and timelines leading up to the declaration of a default for a Common Member and the anticipated timing of OCC's payment of the GSP.

Section 1—Definitions

First, new definitions would be added, and existing definitions would be amended in Section 1, which is the Definitions section.

The new defined terms would be as follows.

• The term ''Close Out Transaction'' would be defined to mean ''the liquidation, termination or acceleration of one or more exercised or matured Stock Options [36] or Stock Futures [37] contracts, securities contracts, commodity contracts, forward contracts, repurchase agreements, swap agreements, master netting agreements or similar agreements of a Mutually Suspended Member pursuant to OCC Rules 901, 1006 and 1101 through 1111 (including but not limited to Rules 1104 and 1107) and/or NSCC Rule 18.'' This proposed definition would make it clear that the payment of the Guaranty Substitution Payment and NSCC's subsequent acceptance of Defaulted NSCC Member Transactions for clearance and settlement are intended to fall within the ''safe harbors'' provided in the Bankruptcy Code,[38] the Securities Investor Protection Act,[39] and other similar laws.

• The term ''Guaranty Substitution Payment'' would be defined to mean ''an amount calculated by NSCC in accordance with the calculations set forth in Appendix A [to the Existing Accord (as proposed to be amended)], to include two components: (i) a portion of the Mutually Suspended Member's Required Fund Deposit deficit to NSCC at the time of the cease to act; and (ii) a portion of the Mutually Suspended Member's unpaid Supplemental Liquidity Deposit obligation at the time of the cease to act.''

• The term ''Mutually Suspended Member'' would mean ''any OCC Participating Member [40] that has been suspended by OCC that is also an NSCC Participating Member [41] for which NSCC has ceased to act.''

• The term ''Required Fund Deposit'' would have the meaning ''provided in Rule 4 of NSCC's Rules and Procedures (or any replacement or substitute rule), the version of which, with respect to any transaction or obligation incurred that is the subject of this Agreement, is in effect at the time of such transaction or incurrence of obligation.''

• The term ''Supplemental Liquidity Deposit'' would have the meaning ''provided in Rule 4A of NSCC's Rules and Procedures (or any replacement or substitute rule), the version of which, with respect to any transaction or obligation incurred that is the subject of this Agreement, is in effect at the time of such transaction or incurrence of obligation.''

The defined terms that would be amended in Section 1 of the Existing Accord are as follows.

• The definition for the term ''E&A/Delivery Transaction'' generally contemplates a transaction that involves a delivery and receipt of stock in the settlement of physically settled options and futures that are cleared and settled by OCC and for which the underlying securities are eligible for clearing through the facilities of NSCC. The definition would be amended to make clear that it would apply in respect of a ''Close Out Transaction'' of a ''Mutually Suspended Member'' as those terms are proposed to be defined (described above).

• The definition for the term ''Eligible Securities'' generally contemplates the securities that are eligible to be used for physical settlement under the Existing Accord. The term would be modified to clarify that this may include, for example, equities, exchange-traded funds and exchange-traded notes that are underlying securities for options issued by OCC.

Section 6—Default by an NSCC Participating Member or OCC Participating Member

Section 6 of the Existing Accord provides that NSCC is required to provide certain notice to OCC in circumstances in which NSCC has ceased to act for a Common Member. Currently, Section 6(a)(ii) of the Existing Accord also requires NSCC to notify OCC if a Common Member has failed to satisfy its Clearing Fund obligations to NSCC, but for which NSCC has not yet ceased to act. In practice, this provision would trigger a number of obligations (described below) when a Common Member fails to satisfy its NSCC Clearing Fund obligations for any reason, including those due to an operational delay. Therefore, OCC and NSCC are proposing to remove the notification requirement under Section 6(a)(ii) from the Existing Accord. Under Section 7(d) of the Existing Accord, NSCC and OCC are required to provide each other with general surveillance information regarding Common Members, which includes information regarding any Common Member that is considered by the other party to be in distress. Therefore, if a Common Member has failed to satisfy its NSCC Clearing Fund obligations and NSCC believes this failure is due to, for example, financial distress and not, for example, due to a known operational delay, and NSCC has not yet ceased to act for that Common Member, such notification to OCC would still occur but would be done pursuant to Section 7(d) of the Existing Accord (as proposed to be amended), and not Section 6(a)(ii). Notifications under Section 6 of the Existing Accord (as proposed to be amended) would be limited to instances when NSCC has actually ceased to act for a Common Member pursuant to the NSCC Rules.[42]

Following notice by NSCC that it has ceased to act for a Common Member, OCC is obligated in turn to deliver to NSCC a list of all E&A/Delivery Transactions (excluding certain transactions for which Guaranty Substitution does not occur) involving the Common Member.[43] This provision would be amended to clarify that it applies in respect of such E&A/Delivery Transactions for the Common Member for which the NSCC Guaranty has not yet attached—meaning that Guaranty Substitution has not yet occurred.

As described above in the summary of the Existing Accord, where NSCC has ceased to act for a Common Member, the Existing Accord refers to the Common Member as the Defaulting NSCC Member and also refers to the relevant E&A/Delivery Transactions in connection with that Defaulting NSCC Member for which a Guaranty Substitution has not yet occurred as Defaulted NSCC Member Transactions.

If the Defaulting NSCC Member is also suspended by OCC, it would be covered by the proposed definition that is described above for a Mutually Suspended Member. For such a Mutually Suspended Member, the proposed changes in Section 6(b) would provide that NSCC, by a time agreed upon by the parties, would provide OCC with the amount of the Guaranty Substitution Payment as calculated by NSCC and related documentation

[36] The term ''Stock Options'' is defined in the Existing Accord within the definition of ''Eligible Securities'' and refers to options issued by OCC.

[37] The term ''Stock Futures'' is defined in the Existing Accord within the definition of ''Eligible Securities'' and refers to stock futures contracts cleared by OCC.

[38] 11 U.S.C. 101 *et seq.,* including sections 362(b)(6), (7), (17), (25) and (27) (exceptions to the automatic stay), sections 546(e)–(g) and (j) (limitations on avoiding powers), and sections 555–556 and 559–562 (contractual right to liquidate, terminate or accelerate certain contracts).

[39] 15 U.S.C. 78aaa–lll, including section 78eee(b)(2)(C) (exceptions to the stay).

[40] The term ''OCC Participating Member'' is defined in the Existing Accord to mean ''(i) a Common Member; (ii) an OCC Clearing Member that is an 'Appointing Clearing Member' (as defined in Article I of OCC's By-Laws) and has appointed an Appointed Clearing Member that is an NSCC Member to effect settlement of E&A/Delivery Transactions through NSCC on the Appointing Clearing Member's behalf; (iii) an OCC Clearing Member that is an Appointed Clearing Member; or (iv) a Canadian Clearing Member.'' No changes are proposed to this definition.

[41] The term ''NSCC Participating Member'' is defined in the Existing Accord to mean ''(i) a Common Member; (ii) an NSCC Member that is an 'Appointed Clearing Member' (as defined in Article I of OCC's By-Laws); or (iii) [Canadian Depository for Securities Limited or ''CDS'']. For the avoidance of doubt, the Clearing Agencies agree that CDS is an NSCC Member for purposes of this Agreement.'' No changes are proposed to this definition.

[42] *See* Rule 46 (Restrictions on Access to Services) of the NSCC Rules, *supra* note 8.

[43] The section of the Existing Accord that addresses circumstances in which NSCC ceases to act and/or an NSCC Member defaults is currently part of Section 6(a). It would be re-designated as Section 6(b) for organizational purposes.

regarding the calculation. The Guaranty Substitution Payment would be calculated pursuant to NSCC's Rules as that portion of the unmet Required Fund Deposit [44] and Supplemental Liquidity Deposit [45] obligations of the Mutually Suspended Member attributable to the Defaulted NSCC Member Transactions. By a time agreed upon by the parties,[46] OCC would then be required to either notify NSCC of its intent to make the full amount of the Guaranty Substitution Payment to NSCC or notify NSCC that it will not make the Guaranty Substitution Payment. If OCC makes the full amount of the Guaranty Substitution Payment, NSCC's guaranty would take effect at the time of NSCC's receipt of that payment and the OCC Guaranty would end.

The proposed changes would further provide that if OCC does not suspend the Common Member (such that the Common Member would therefore not meet the proposed definition of a Mutually Suspended Member) or if OCC elects to not make the full amount of the Guaranty Substitution Payment to NSCC, then all of the Defaulted NSCC Member Transactions would be exited from NSCC's CNS Accounting Operation and/or NSCC's Balance Order Accounting Operation, as applicable, and Guaranty Substitution would not occur in respect thereof. Therefore, NSCC would continue to have no obligation to guarantee or settle the Defaulted NSCC Member Transactions, and the OCC Guaranty would continue to apply to them pursuant to OCC's By-Laws and Rules.[47]

Proposed changes to the Existing Accord would also address the application of any Guaranty Substitution Payment by NSCC. Specifically, new Section 6(d) would provide that any Guaranty Substitution Payment made by OCC may be used by NSCC to satisfy any liability or obligation of the Mutually Suspended Clearing Member to NSCC on account of transactions involving the Mutually Suspended Clearing Member for which the NSCC Guaranty applies and to the extent that any amount of assets otherwise held by NSCC for the account of the Mutually Suspended Member (including any Required Fund Deposit or Supplemental Liquidity Deposit) are insufficient to satisfy its obligations related to transactions for which the NSCC Guaranty applies. Proposed changes to Section 6(d) would further provide for the return to OCC of any unused portion of the GSP. With regard to the portion of the Guaranty Substitution Payment that corresponds to a member's Supplemental Liquidity Deposit obligation, NSCC must return any unused amount to OCC within fourteen (14) days following the conclusion of NSCC's settlement, close-out and/or liquidation. With regard to the portion of the Guaranty Substitution Payment that corresponds to a Required Fund Deposit, NSCC must return any unused amount to OCC under terms agreed to by the parties.[48]

Other Proposed Changes as Part of Phase 1

Certain other technical changes are also proposed to the Existing Accord to conform it to the proposed changes described above. For example, the preamble and the ''whereas'' clauses in the Preliminary Statement would be amended to clarify that the agreement is an amended and restated agreement and to summarize that the agreement would be modified to contemplate the Guaranty Substitution Payment structure. Section 1(c), which addresses the terms in the Existing Accord that are defined by reference to NSCC's Rules and Procedures and OCC's By-Laws and Rules would be modified to state that such terms would have the meaning then in effect at the time of any transaction or obligation that is covered by the agreement rather than stating that such terms have the meaning given to them as of the effective date of the agreement. This change is proposed to help ensure that the meaning of such terms in the agreement will not become inconsistent with the meaning in the NSCC Rules and/or OCC By-Laws and Rules, as they may be modified through proposed rule changes with the Commission.

Technical changes would be made to Sections 3(d) and (e) of the Existing Accord to provide that those provisions would not apply in the event new Section 6(b) described above, is triggered. Section 3(d) generally provides that OCC will no longer submit E&A/Delivery Transactions to NSCC involving a suspended OCC Participating Member.[49] Similarly, Section 3(e) generally provides that OCC will no longer submit E&A/Delivery Transactions to NSCC involving an NSCC Participating Member [50] for which NSCC has ceased to act. A proposed change would also be made to Section 5 of the Existing Accord to modify a reference to Section 5 of Article VI of OCC's By-Laws to instead provide that the updated cross-reference should be to Chapter IV of OCC's Rules.

Section 5 would also be amended to clarify that Guaranty Substitution occurs when NSCC has received both the Required Fund Deposit and Supplemental Liquidity Deposit, as calculated by NSCC in its sole discretion, from Common Members. The addition of the collection of the Supplemental Liquidity Deposit to the definition of the Guaranty Substitution Time in this Section 5 would reflect OCC and NSCC's agreement that both amounts are components of the Guaranty Substitution Payment (as described above) and would make this definition consistent with that agreement.

In Section 7 of the Existing Accord, proposed changes would be made to provide that NSCC would provide to OCC information regarding a Common Member's Required Fund Deposit and Supplemental Liquidity Deposit obligations, to include the Supplemental Liquidity Deposit obligation in this notice requirement, and additionally that NSCC would provide OCC with information regarding the potential Guaranty Substitution Payment for the Common Member. On an options expiration date that is a Friday, NSCC would, by close of business on that day, also provide to OCC information regarding the intra-day liquidity requirement, intra-day liquidity resources and intra-day calls for a Common Member that is subject to a Supplemental Liquidity Deposit at NSCC.

Finally, Section 14 of the Existing Accord would be modernized to provide that notices between the parties would be provided by email rather than by hand, overnight delivery service or first-class mail.

[44] The Required Fund Deposit is calculated pursuant to Rule 4 (Clearing Fund) and Procedure XV (Clearing Fund Formula and Other Matters) of the NSCC Rules, *see supra* note 8.

[45] The Supplemental Liquidity Deposit is calculated pursuant to Rule 4A (Supplemental Liquidity Deposits) of the NSCC Rules, *see supra* note 8.

[46] The time by which OCC would be required to notify NSCC of its intent would be defined in the Service Level Agreement. As of the time of this filing, the parties intend to set that time as one hour after OCC's receipt of the calculated Guaranty Substitution Payment from NSCC.

[47] Under the current and proposed terms of the Existing Accord, NSCC would be permitted to voluntarily guaranty and settle the Defaulted NSCC Member Transactions.

[48] Such amounts would be returned to OCC as appropriate and in accordance with a Netting Contract and Limited Cross-Guaranty, by and among The Depository Trust Company, Fixed Income Clearing Corporation, NSCC and OCC, dated as of January 1, 2003, as amended.

[49] *See supra* note 40 defining OCC Participating Member.

[50] *See supra* note 41 defining NSCC Participating Member.

Proposed Changes to OCC By-Laws and Rules as Part of Phase 1

General Description

OCC is also proposing certain changes to its By-Laws and Rules that are designed to complement the proposed changes described above regarding the Existing Accord. These proposed changes to the By-Laws and Rules are described below, and they generally cover the following four areas. First, the proposed changes would define Guaranty Substitution Payment. Second, the proposed changes would describe the circumstances under which OCC could make a Guaranty Substitution Payment to NSCC. Third, the proposed changes would specify what financial resources could be used by OCC to make the Guaranty Substitution Payment.[51] Fourth, the proposed changes to OCC's Comprehensive Stress Testing and Clearing Fund Methodology, and Liquidity Risk Management Description would outline enhanced stress testing incorporating the GSP and OCC's ability to call for additional resources from Clearing Members. OCC also is proposing changes to OCC's Liquidity Risk Management Framework to account for OCC's ability to make the GSP.

Article I—Definitions

OCC proposes to add ''Guaranty Substitution Payment'' as a new defined term under Article I of OCC's By-Laws, which is the Definitions section. The term ''Guaranty Substitution Payment'' would be defined to mean: ''a payment that may be made by [OCC] to [NSCC] under the terms of an agreement between them, as described in Rule 901, so that [NSCC] will not reject settlement obligations for CCC-eligible [52] securities that are directed by [OCC] for settlement through the facilities of [NSCC] on account of a Clearing Member that has been suspended, as described in Rule 1102, and for which [NSCC] has ceased to act.''

Chapter IX—Delivery of Underlying Securities and Payment

Certain changes are also proposed to Chapter IX of OCC's Rules. OCC proposes to add parenthetical language to the Introduction section of Chapter IX of OCC's Rules. It would specify that a Guaranty Substitution Payment could be made by OCC to NSCC in connection with OCC's general policy that to the extent a security to be delivered and received is CCC-eligible, OCC will direct the delivery and payment obligations to be settled through the facilities of NSCC where the obligations are physically-settled and arise out of the exercise of stock option contracts or the maturity of stock futures contracts.

Next, OCC proposes to delete certain provisions from Rule 901(b) regarding when a Guaranty Substitution occurs. Specifically, Rule 901(b) currently provides that unless otherwise agreed between OCC and NSCC, a Guaranty Substitution with respect to settlement obligations for CCC-eligible securities that settle ''regular way'' under NSCC's Rules and Procedures will occur if: (i) the applicable settlement obligations are reported to and are not rejected by NSCC; (ii) NSCC has not notified OCC that it has ceased to act for the relevant Clearing Member or Appointed Clearing Member; and (iii) the NSCC Clearing Fund requirements of the relevant Clearing Member or Appointed Clearing Member owing to NSCC, as determined in accordance with NSCC's Rules and Procedures, are received by NSCC. These considerations regarding when a Guaranty Substitution occurs are addressed under the terms of the Existing Accord, and they would continue to be relevant considerations regarding when a Guaranty Substitution occurs under the changes that OCC and NSCC are proposing to the Existing Accord. However, because additional considerations would be added to the Guaranty Substitution process in connection with the proposed ability for OCC in certain circumstances to make a Guaranty Substitution Payment to NSCC and also to eliminate the potential for a description of the Guaranty Substitution process in OCC's Rules to become inconsistent with the process that OCC and NSCC have agreed to in the Existing Accord, as it would be amended, OCC is proposing to delete the discussion of these considerations in Rule 901(b) in favor of instead simply cross referencing the terms of the agreement.[53]

In addition, OCC proposes to add a new paragraph to the end of Rule 901(b) to provide that pursuant to the proposed changes to the Existing Accord, OCC would be permitted to make a Guaranty Substitution Payment to NSCC. The proposed changes would also describe the circumstances in which OCC may make a Guaranty Substitution Payment in connection with settlement obligations of a suspended Clearing Member, and that the amount of the Guaranty Substitution Payment under the terms of the Existing Accord, as amended, would be the amount required by NSCC to satisfy its deficit(s) regarding such Clearing Member's ''Required Fund Deposit'' and ''Supplemental Liquidity Deposit'' as those terms are defined in NSCC's Rules and Procedures.[54] The changes would provide that any amount of a Guaranty Substitution Payment that NSCC does not use pursuant to its Rules and Procedures would subsequently be returned to OCC under such terms and within such times as are agreed by OCC and NSCC. OCC believes that it is useful to include this description of the proposed process for the Guaranty Substitution Payment and the circumstances in which it may be made so that a user of OCC's publicly available By-Laws and Rules would have sufficient information to understand the existence of the Guaranty Substitution Payment mechanism, the general circumstances in which it may be made and the role that a Guaranty Substitution Payment would play in causing NSCC to accept obligations for CCC-eligible securities for clearance and settlement.

Chapters X and XI—Clearing Fund Contributions and Suspension of a Clearing Member

As generally described above, the proposed changes would also provide that OCC would be permitted to borrow from the OCC Clearing Fund, and also against certain Margin Assets, of a Clearing Member that has been suspended by OCC where that Clearing Member is a Mutually Suspended Member. To implement these changes, OCC is proposing the following amendments to OCC Rule 1006 and Rule 1104.

[51] OCC would be permitted to borrow from the Clearing Fund and margin of a suspended Clearing Member, over which OCC has a general lien, where that Clearing Member is a Mutually Suspended Member. The change would merely expand the circumstances under which OCC's current By-Laws and Rules permit OCC to borrow Clearing Fund and margin. The change would not affect the treatment of such borrowing under OCC's default waterfall that determines how OCC allocates losses against available financial resources. The Mutually Suspended Member's margin and Clearing Fund collateral would remain first in line to absorb losses.

[52] The term ''CCC-Eligible'' as used herein has the meaning provided in OCC's By-Laws, *supra* note 4.

[53] For purposes of the proposed rule change process under Exchange Act Section 19(b), the agreement is treated as a rule of a clearing agency under Exchange Act Section 3(a)(27) and therefore any proposed changes to it by OCC are subject to the related rule change process and public notice and comment. OCC therefore believes that addressing the terms in the agreement and cross-referencing the agreement in OCC Rule 901 would not deprive the Commission or the public of notice regarding any future proposed changes.

[54] *See* NSCC Rules 4 (defining ''Required Fund Deposit'') and 4A (defining ''Supplemental Liquidity Deposit''), *supra* note 8.

OCC Rule 1006 addresses the purpose and permitted uses of the OCC Clearing Fund. OCC proposes to make amendments to paragraphs (a) and (f) to permit OCC to utilize assets in the Clearing Fund as a liquidity resource in connection with making a Guaranty Substitution Payment. Currently, OCC Rule 1006(a) states the conditions for use of the OCC Clearing Fund. These provide that the OCC Clearing Fund may be used for borrowings pursuant to OCC Rule 1006(f) or to make good losses or expenses suffered by OCC including: (i) as a result of the failure of any Clearing Member to discharge duly any obligation on or arising from any confirmed trade accepted by OCC, (ii) as a result of the failure of any Clearing Member (including any Appointed Clearing Member) or of CDS (Canada's national securities depository) to perform its obligations under any contract or obligation issued, undertaken, or guaranteed by OCC or in respect of which OCC is otherwise liable, (iii) as a result of the failure of any Clearing Member to perform any of its obligations to OCC in respect of the stock loan and borrow positions of such Clearing Member, (iv) in connection with any liquidation of a Clearing Member's open positions, (v) in connection with protective transactions effected for the account of OCC pursuant to Chapter XI of OCC's Rules (delivery of underlying securities and payment), (vi) as a result of the failure of any Clearing Member to make any other required payment or render any other required performance or (vii) as a result of the failure of any bank, securities or commodities clearing organization, or investment counterparty, to perform its obligations to OCC for certain specified reasons.[55]

OCC proposes to renumber clauses (iii) through (vii) in paragraph (a) as (iv) through (viii), and to insert as new clause (iii) a provision that the OCC Clearing Fund may be used ''regarding any Guaranty Substitution Payment that [OCC] may make to [NSCC] under an agreement between them, as described in [OCC] Rule 901, so that [NSCC] will not reject settlement obligations for CCC-eligible securities involving a Clearing Member for which [NSCC] has ceased to act and that [OCC] directs to [NSCC] for settlement through its facilities.'' [56] OCC also proposes to add parenthetical language to paragraphs (f)(1)(A) and (f)(2)(A)(ii) to further clarify that contributions to the OCC Clearing Fund may be borrowed by OCC for use in connection with making a Guaranty Substitution Payment to NSCC. Any borrowing from the OCC Clearing Fund by OCC to make a Guaranty Substitution Payment to NSCC would be subject to the existing terms of OCC Rule 1006(f)(3) that provide that irrespective of how any such borrowings from the OCC Clearing Fund are applied by OCC, the borrowing for a period not to exceed thirty (30) days will not be deemed to result in charges against the OCC Clearing Fund under OCC's default waterfall for allocating actual losses. For purposes of determining whether a loss resulting from a Guaranty Substitution Payment has occurred, OCC Rule 1006(f)(3) would be amended to provide that the Guaranty Substitution Payment is deemed to be repaid by OCC at such time as under the Accord that it is NSCC's obligation to return any portion of the Guaranty Substitution Payment that NSCC does not use pursuant to its rules. If, subsequent to the borrowing, OCC determines that the borrowing represents an actual loss or all or any part of the borrowing remains outstanding after thirty (30) days (or on the first Business Day thereafter if the thirtieth calendar day is not a Business Day) then the amount of OCC Clearing Fund assets used in the outstanding borrowing would be an actual loss that OCC would be required to immediately allocate under its By-Laws and Rules.[57] As noted above, losses resulting from the borrowing of Clearing Fund or Margin Assets as a liquidity resource to facilitate OCC making a Guaranty Substitution Payment would be allocated in the same sequence as any other losses charged to the default waterfall.

Consistent with these changes to permit OCC to use the OCC Clearing Fund as a borrowing resource to make a Guaranty Substitution Payment to NSCC, OCC is also proposing similar changes to OCC Rule 1104 that would permit OCC to borrow certain Margin Assets of a Clearing Member that has been suspended by OCC where that Clearing Member is a Mutually Suspended Member and OCC has a general lien [58] over the Margin Assets.

Specifically, OCC proposes to add a new paragraph (g) to OCC Rule 1104 that would provide that OCC may use specified Margin Assets of a suspended Clearing Member as a borrowing in order to use such borrowed Margin Assets to make a Guaranty Substitution Payment to NSCC. OCC would be permitted to use Margin Assets from the following accounts of a suspended Common Member: firm lien account and firm non-lien account; separate Market-Maker's account; combined Market-Maker's account; and JBO Participants' account.[59] OCC is not proposing at this time to have authority to borrow Margin Assets from other types of accounts over which OCC has a restricted lien [60] and for which the Margin Assets are security for the particular restricted lien accounts because of additional complexity that OCC believes would be associated with tracking NSCC's use of Margin Assets associated with those accounts and also due to certain regulatory requirements under Commission Rule 15c3–3 that apply to broker-dealer Clearing Members and prohibit the use of customer property of the broker-dealer to support non-customer activities.[61]

As with the terms that currently apply to any borrowing from the OCC Clearing Fund pursuant to OCC Rule 1006(f), new paragraph (g) in OCC Rule 1104 would further provide that Margin Assets borrowed by OCC to make a Guaranty Substitution Payment to NSCC

[55] The terms ''Clearing Member'' and ''Appointed Clearing Member'' as used herein have the meanings provided in OCC's By-Laws, *supra* note 4.

[56] In connection with these amendments, the reference in Rule 1006(b) to ''clauses (i) through (vi) of paragraph (a)'' would be changed to ''clauses (i) through (vii) of paragraph (a).''

[57] If the defaulting OCC Clearing Member's Margin Assets and OCC Clearing Fund contribution were insufficient to cover the associated losses, OCC would next look to certain OCC financial resources that are available for that purpose (*e.g.,* OCC's corporate contribution and Clearing Fund contributions of non-defaulting OCC Clearing Members).

[58] Article I, Section 1.G.(1) of OCC's By-Laws states that the ''term 'general lien' means a security interest of [OCC] in all or specified assets in a Clearing Member account as security for all of the Clearing Member's obligations to [OCC] regardless of the source or nature of such obligations.'' *See* OCC By-Laws, *supra* note 4.

[59] The Clearing Member accounts referenced herein are described in subparagraphs (a), (b), (c) and (h) of Article VI, Section 3 of OCC's By-Laws. *See* OCC's By-Laws, *supra* note 4.

[60] Article I, Section 1.R.(8) of OCC's By-Laws states that the ''term 'restricted lien' means a security interest of [OCC] in specified assets (including any proceeds thereof) in an account of a Clearing Member with [OCC] as security for the Clearing Member's obligations to [OCC] arising from such account or, to the extent so provided in the By-Laws or Rules, a specified group of accounts that includes such account including, without limitation, obligations in respect of all confirmed trades effected through such account or group of accounts, and exercise notices assigned to such account or group of accounts.'' *See* OCC's By-Laws, *supra* note 4.

[61] For example, under the broker-dealer customer reserve account formula to SEC Rule 15c3–3 the broker-dealer takes a debit in the formula under Item 13 for margin that is ''required and on deposit with OCC for all option contracts written or purchased in customer accounts.'' This means that such margin in turn can be used by the broker-dealer Clearing Member as Margin Assets to support the securities customers' account at OCC.

would not be deemed to be charges against the margin assets for the relevant account(s) for up to thirty (30) days; however, if all or a part of such borrowing were to be determined by OCC, in its discretion, to represent an actual loss, or if all or a part of the borrowing were to remain outstanding after such thirty (30)-day period, OCC would consider the amount of margin assets used to support OCC's obligations under the outstanding borrowing or transaction as an actual loss and immediately allocate the loss in accordance with OCC's By-Laws and Rules.

OCC anticipates that in a scenario in which it would be permitted make a Guaranty Substitution Payment to NSCC under the proposed changes to the Existing Accord and OCC's By-Laws and Rules, OCC would generally expect to borrow from the Clearing Fund as a primary liquidity resource. OCC could also borrow Margin Assets of the suspended Clearing Member that is a Common Member under the proposed terms described above. OCC is not proposing changes that would require a specific borrowing sequence because OCC believes that it is more appropriate to preserve flexibility to borrow from the available OCC Clearing Fund or Margin Assets as OCC determines appropriate under the circumstances.

In addition, OCC proposes to specify in OCC Rule 1107(a)(1) that exercised option contracts and matured, physically-settled stock futures to which the suspended Clearing Member is a party may be settled in accordance with the terms of any agreement between OCC and NSCC governing the settlement of exercised option contracts and matured, physically-settled stock futures of a suspended Clearing Member. In such an event, settlement will be governed by and subject to the agreement between OCC and NSCC and the rules of NSCC.

The purpose of the proposed changes to create the Guaranty Substitution Payment mechanism is to provide OCC and NSCC with an additional default management tool to help manage liquidity and settlement risks that OCC believes would be presented to each covered clearing agency in connection with a Mutually Suspended Member. OCC believes that having the ability to make a Guaranty Substitution Payment to NSCC in regard to any unmet Required Fund Deposit or Supplemental Liquidity Deposit obligations of a Mutually Suspended Member would promote prompt and accurate clearance and settlement in the national system for the settlement of securities transactions by causing NSCC to guarantee certain securities settlement obligations that result from exercised options and matured futures contracts that are cleared and settled by OCC. In the following ways, OCC believes that this would be beneficial to and protective of OCC, NSCC, their participants, and the markets they serve.

First, OCC's ability to make the Guaranty Substitution Payment would ensure that the relevant securities settlement obligations would be accepted by NSCC for clearance and settlement and therefore the size of the related settlement obligations could be decreased from netting through NSCC's CNS Accounting Operation and/or NSCC's Balance Order Accounting Operation. Second, this outcome would avoid a scenario in which OCC's Guaranty would continue to apply and the settlement obligations would be settled on a broker-to-broker basis between OCC Clearing Members pursuant to the applicable provisions in Chapter IX of OCC's Rules. As noted above, OCC believes that such a broker-to-broker settlement scenario could result in substantial collateral and liquidity requirements for OCC Clearing Members. OCC believes that these potential collateral and liquidity consequences would be due to the lost benefit of netting of the settlement obligations through NSCC's facilities and also due to the short time (*i.e.,* the T+2 standard settlement cycle) between a rejection by NSCC of the settlement obligations for clearing and the associated settlement date on which settlement would be otherwise required to be made bilaterally by OCC Clearing Members. This scenario also raises the potential for procyclical liquidity demands on OCC Clearing Members and participants during stressed market conditions. Third, OCC will plan to size its liquidity resource requirements to reasonable expectations with a high probability of making a Guaranty Substitution Payment in order to facilitate the settlement of a Mutually Suspended Member's obligations through NSCC. Accounting for net liquidity demands from a Mutually Suspended Member's settlement obligations at the central counterparty-level enhances liquidity in the financial system and promotes the efficient use of capital by reducing the demand for liquidity associated with gross settlement of obligations and enabling the application of resources at both clearing agencies to satisfy the Member's obligation. Fourth, OCC believes that the potential for the size of the settlement obligations to be comparatively larger than the Guaranty Substitution Payment coupled with the short time remaining to settlement could also increase the risk of default by the affected OCC Clearing Members at a time when a Common Member has already been suspended. Therefore, OCC believes that the proposed changes to implement the ability for OCC to make a Guaranty Substitution Payment to NSCC would allow OCC to avoid these risks by causing NSCC to accept the relevant obligations arising from exercised options and matured futures cleared and settled by OCC, as it ordinarily would, and guarantee their settlement, upon OCC making a Guaranty Substitution Payment to NSCC in accordance with the revised Accord.

Proposed Changes to Comprehensive Stress Testing & Clearing Fund Methodology, and Liquidity Risk Management Description and Liquidity Risk Management Framework as Part of Phase 1

Comprehensive Stress Testing & Clearing Fund Methodology, and Liquidity Risk Management Description

OCC proposes to revise the OCC Comprehensive Stress Testing & Clearing Fund Methodology, and Liquidity Risk Management Description to include the GSP in its liquidity risk management practices. Overall, the proposed changes would reflect that the GSP functions as an additional liquidity demand type at the Clearing Member Organization (''CMO'') Group level.[62]

OCC would include additional specifics to address the potential increased demand that the inclusion of the GSP may cause in its liquidity risk management practices in the Liquidity Risk Management section of the Comprehensive Stress Testing & Clearing Fund Methodology, and Liquidity Risk Management Description. Specifically, OCC proposes to amend the Liquidity Demand for Positions Rejected by NSCC subsection, which describes the Existing Accord, including the scenario in which NSCC could choose not to guaranty certain securities settlement obligations arising out of transactions cleared by OCC. This subsection would be retitled as the Liquidity Demand Associated with NSCC Performance of Physical Settlement Activities subsection to more clearly describe its content and incorporate the GSP, as further detailed below. Consistent with the changes to the Existing Accord described above, OCC proposes to clarify that the Accord allows NSCC to reject such obligations if OCC elects to not make a GSP.

[62] A Clearing Member Group is composed of a set of affiliated OCC Clearing Members.

OCC proposes a new subsection, titled the Liquidity Demand GSP, to describe the GSP, which NSCC would calculate as defined in the proposed amendments to the Existing Accord. OCC would describe a GSP as a firm specific liquidity demand (*i.e.,* the amount of cash OCC needs to pay NSCC on behalf of the defaulting Common Member). OCC would describe the components of the GSP under the Accord. OCC would explain how it accounts for the liquidity demand associated with a potential GSP. Specifically, OCC would apply an amount to account for a potential GSP obligation for every day on which option expirations occur. This amount would be based on peak GSP amounts from the prior 12 months in a given expiration category for the specific CMO Group for each forecasted liquidity demand calculation. OCC will use a one-year lookback time period to determine the appropriate GSP amount to apply. The one-year lookback allows for the best like-to-like application of a historical GSP as there is a cyclical nature to option standard expirations with quarterly (*i.e.,* March, June, September, and December) and January generally being more impactful than non-quarterly expirations. The one-year lookback also allows behavior changes of a Clearing Member to be recognized within an annual cycle. OCC proposes to utilize a historical GSP based on current system capabilities and data that will be supplied by NSCC.

OCC would use the total amount of Clearing Fund and SLD deficits at NSCC in its calculation to account for its obligation. However, in the event of a default, OCC would be responsible for a proportionate share of both NSCC Clearing Fund deficits (which are analogous to OCC margin deficits) and SLDs that are attributable to OCC E&A activity transmitted to NSCC for settlement, whereas NSCC will be responsible for the portion of the Clearing Fund and SLD deficits associated with activity that NSCC clears that is not transmitted by OCC.

The amount of notional activity sent by OCC to NSCC informs the likelihood of a GSP. Namely, the potential amount of NSCC Clearing Fund and SLD deficits that are allocable to OCC increases as the amount of activity OCC sends to NSCC increases. Since not all types of expirations are the same with respect to the notional amount of activity sent by OCC to NSCC, OCC proposes to use five separate categories of expirations with potentially different GSP amounts to apply. Each day on which expirations occur would fall into one of five categories as follows:

- Standard Monthly Expiration: typically the third Friday of each month from the previous twelve months;
- Non-Standard Monthly Expiration Fridays (''End of Week Expirations''): the last business day of every week, typically a Friday, excluding the third Friday of each month from the previous twelve months;
- End of Month Expirations: the last trading day of every month from the previous twelve months;
- Expirations falling on Bank Holidays where Markets Are Open (''Bank Holiday Expirations''): days where banks are closed but the markets are open from the previous twelve months;[63]
- Remaining Expiration Days (''Daily Expirations''): All other days with an expiration from the previous twelve months that do not fall into any of the categories above (typically most Mondays through Thursdays) from the previous twelve months.

OCC believes these five categories are appropriate after an analysis of notional activity sent to NSCC by OCC.[64] More specifically, the standard Friday monthly expiration far exceeds the needs associated with any other category.[65] The remaining categories are intended to capture like time periods that will appropriately account for the GSP.

OCC would apply the peak GSP amounts from the prior twelve months in a given expiration category for the specific CMO Group for each forecasted liquidity demand calculation by adding the GSP amounts to the CMO Group's other forecasted liquidity demands for the relevant expiration day.[66] If a Clearing Member defaults, OCC may have to pay a GSP to NSCC on two successive days to facilitate the close-out of the defaulted Clearing Member's positions. To account for this possibility in its liquidity risk management process, OCC contemplates the payment of a GSP on expirations that result in settlements on the first and second days of the default management process. As described above, this GSP amount may serve to only increase liquidity demands.[67]

Furthermore, as stated in the new Liquidity Demand GSP subsection, OCC would apply a floor to certain expirations. At a minimum, the GSPs applied to the End of Week, End of Month, and Bank Holiday Expirations will be no lower than the peak of the Daily Expirations category. If a GSP pertaining to the End of Week, End of Month, and Bank Holiday Expiration category is higher than the peak of the Daily Expirations category, then OCC will apply that higher GSP. Standard Monthly Expirations will be floored by End of Week, End of Month, and Daily Expirations. If a GSP pertaining to any of these categories is higher than the Standard Monthly Expiration category, then OCC will apply that higher GSP. OCC would set out formulas representing the floors for the Standard Monthly, End of Week, End of Month, and Bank Holiday Expirations. Finally, OCC also proposes a minor change to clarify that it would attempt to effect alternative settlement if OCC elected not to make a GSP.[68]

Liquidity Risk Management Framework

OCC proposes changes to the Liquidity Risk Management Framework to incorporate the GSP. In the Liquidity Risk Identification section, OCC would specify that, in the situation where a member defaults immediately preceding, or during the expiration, of physically-settled E&A activity, OCC may elect to make a GSP to NSCC to compel NSCC to accept and process the E&A activity. If OCC elects to not make a GSP, OCC would complete settlement of the defaulted Clearing Member's E&A transactions through its current process. Relatedly, OCC would include a minor clarification to a footnote in this section to note that NSCC is not acting on behalf of a defaulting Clearing Member ''in this situation.''

[63] The Bank Holiday category recognizes that for Veterans Day and Columbus Day, the equity and equity derivative markets are open for trading, but the banking system is closed for the day. Since the banking system is closed while the aforementioned markets are open, settlement at NSCC encompasses two days of equity trading and equity derivative E&A activity. As OCC is using NSCC deficit numbers without regard for allocation, there is a possibility of a significant outlying GSP requirement due to the settlement of two days of activity simultaneously. Prudence dictates retaining the capability to risk manage a day with such disparate characteristics differently. Additional supporting data in support of the creation of the Bank Holiday Expiration category is included as confidential Exhibit 3E to this filing.

[64] OCC provided its analysis of notional activity sent to NSCC by OCC in support of the creation of the five categories as confidential Exhibit 3E to this filing. This Exhibit 3E sets forth data related to OCC's liquidity stress testing, including Available Liquidity Resources, Minimum Cash Requirement thresholds, and/or liquidity breaches, for Sufficiency and Adequacy scenarios with and without the inclusion of the GSP.

[65] For example, the average notional transfer for Remaining Expiration Days is approximately 10% the size of Standard Expiration.

[66] As an example, if the applicable GSP is $100 and the (current) stressed liquidity demand is $150 for a Clearing Member Group, the result after the application of the GSP for that Clearing Member Group would be a combined liquidity requirement of $250 versus $150 currently.

[67] OCC provided its analysis of the impact of the GSP, including with respect to calls for collateral and liquidity demands as confidential Exhibit 3E to this filing.

[68] This clarification would maintain OCC's current process for settling transactions not processed through NSCC and does not represent the adoption of a new process or settlement method.

Proposed Phase 2 Changes

On February 15, 2023, the Commission adopted amendments to Rule 15c6–1(a) under the Act [69] to shorten the standard settlement cycle for most broker-dealer transactions in securities from T+2 to T+1. In doing so, the Commission stated that a shorter settlement cycle ''can promote investor protection, reduce risk, and increase operational and capital efficiency.'' [70] Moreover, the Commission stated that delaying the move to a shorter settlement cycle would ''allow undue risk to continue to exist in the U.S. clearance and settlement system'' [71] and that it ''believes that the May 28, 2024, compliance date will help ensure that market participants have sufficient time to implement the changes necessary to reduce risk, such as risks associated with the potential for increases in settlement fails.'' [72] The Phase 2 changes proposed herein serve those risk reduction objectives related to securities settlements by endeavoring to limit market disruption following a Common Member default. The proposed changes would allow OCC to provide certain assurances with respect to its ability to make a GSP in the event of a Common Member default to NSCC in a shortened settlement cycle, which would permit NSCC to begin processing E&A/Delivery Transactions prior to Guaranty Substitution occurring. This, in turn, would promote settlement through NSCC that is less operationally complex and would be expected to require less collateral and liquidity from market participants than if OCC engaged in the alternative settlement processes discussed above.

To address the operational realities concerning the Accord that will result from the Commission's adoption and implementation of a new standard settlement cycle of T+1 pursuant to Rule 15c6–1(a) under the Act, OCC and NSCC are proposing Phase 2 changes to further modify the Accord after the T+1 settlement cycle becomes effective. As described in greater detail below, the Phase 2 changes would allow the GSP and other changes that are part of the Phase 1 changes to continue to function appropriately and efficiently in the new T+1 settlement environment. Because of the phased approach, a separate mark-up is provided in confidential Exhibit 5C to this filing of the Phase 2 changes against the Accord as modified through the Phase 1 changes.

As described in more detail below, shortening the settlement cycle to T+1 will require NSCC to process stock settlement obligations arising from E&A Delivery Transactions one day earlier, *i.e.,* on the day after the trade date, than is currently the case. Moving processing times ahead by a full day will require processing to occur before the guaranty transfers from OCC to NSCC.[73] In this new T+1 processing environment, the Phase 2 changes would limit market disruption following a Common Member default because the Phase 2 changes would allow OCC to provide certain assurances with respect to its ability to make a GSP in the event of a Common Member default to NSCC that would permit NSCC to begin processing the defaulting Common Member's E&A/Delivery Transactions prior to Guaranty Substitution occurring. This, in turn, will promote settlement through NSCC that is less operationally complex and would be expected to require less collateral and liquidity from market participants than if OCC engaged in alternative settlement processes. The specific changes included in Phase 2 are described below. The changes would facilitate the continued ability of the GSP to function in an environment with a shorter settlement cycle. These changes are generally designed to allow OCC to provide certain assurances with respect to its ability to make a GSP in the event of a Common Member default to NSCC that would permit NSCC to begin processing E&A/Delivery Transactions prior to Guaranty Substitution occurring by introducing new or amended terms and setting out the processes associated therewith. All of the descriptions below explain the changes to the Accord as they would be made after the Accord has already been modified through prior implementation of the proposed Phase 1 changes.

Section 1—Definitions

First, new definitions would be added, and existing definitions would be amended or removed in Section 1.

The new defined terms would be as follows.

• The term ''GSP Monitoring Data'' would be defined to mean a set of margin and liquidity-related data points provided by NSCC on each Activity Date prior to the submission of E&A/Delivery Transactions by OCC to be used for informational purposes at OCC and NSCC.

• The term ''Final Guaranty Substitution Payment'' would be defined to mean an amount calculated by NSCC for each Settlement Date in accordance with Appendix A to the Accord, to include two components: (i) a portion of the NSCC Participating Member's [74] Required Fund Deposit deficit to NSCC calculated as a difference between the Required Fund Deposit deficit calculated on the NSCC Participating Member's entire portfolio and the Required Fund Deposit deficit calculated on the NSCC Participating Member's portfolio prior to submission of the E&A/Delivery Transactions; and (ii) the portion of the NSCC Participating Member's unpaid Supplemental Liquidity Deposit obligation attributable to the additional activity to be guaranteed.

• The term ''Historical Peak Guaranty Substitution Payment'' would be defined to mean the largest Final Guaranty Substitution Payment for an NSCC Participating Member and its affiliates that are also NSCC Participating Members over the 12 months immediately preceding the Activity Date, to include two components: (i) the Required Fund Deposit deficits associated with E&A/Delivery Transactions based on peak historical observations of the largest NSCC Participating Member and its affiliates that are also NSCC Participating Members; and (ii) the Supplemental Liquidity Deposit obligations associated with E&A/Delivery Transactions based on peak historical observations as calculated in accordance with applicable NSCC or OCC Rules and procedures.

• The term ''Qualifying Liquid Resources'' would be defined to have the meaning provided by Rule 17Ad–22(a)(14) of the Exchange Act, 17 CFR 240.17Ad–22(a)(14), or any successor Rule under the Exchange Act.

• The term ''Settlement Date'' would be defined to mean the date on which an E&A/Delivery Transaction is designated to be settled through payment for, and delivery of, the Eligible Securities underlying the exercised Stock Option [75] or matured Stock Future,[76] as the case may be.

• The term ''Weekday Expiration'' would be defined to mean any expiration for which the options expiration date occurs on a date other than a Friday or for which the Settlement Date is any date other than the first business date following a weekend.

• The term ''Weekend Expiration'' would be defined to mean any expiration for which the options expiration date occurs on a Friday or for which the Settlement Date is the first business date following a weekend.

The defined term that would be removed in Section 1 is as follows.

• ''Guaranty Substitution Payment,'' which would be replaced by the new defined terms ''Final Guaranty Substitution Payment'' and ''Historical Peak Guaranty Substitution Payment.''

The defined terms that would be amended in Section 1 are as follows.

[69] 17 CFR 240.15c6–1.

[70] Securities Exchange Act Release No. 96930 (Feb. 15, 2023), 88 FR 13872, 13873 (Mar. 6, 2023).

[71] *Id.* at 13881.

[72] *Id.* at 13917.

[73] Given the reduction in the settlement cycle and existing processes that must be completed for settlement, it is OCC's understanding that the NSCC would not be able to safely compress its processing times further to allow processing to occur after the guaranty transfers from OCC to NSCC. OCC provided proposed processing timelines in confidential Exhibit 3G to this filing.

[74] *See supra* note 41.

[75] *See supra* note 36.

[76] *See supra* note 37.

• The definition for the term ''Eligible Securities'' generally contemplates the securities that are eligible to be used for physical settlement under the Existing Accord. In Phase 2, the term will be modified to exclude any transactions settled through NSCC's Balance Order System and any security undergoing a voluntary corporate action that is being supported by NSCC's CNS system. This is because the processing of E&A/Delivery Transactions and potential reversals of such transactions under the Phase 2 changes would not be feasible under the anticipated operation of NSCC's CNS and Balance Order Accounting Operations under the shortened T+1 settlement cycle.

Section 3—Historical Peak Guaranty Substitution Payment

A new Section 3 would be added to describe the process by which OCC would send to NSCC evidence of sufficient funds to cover the Historical Peak Guaranty Substitution Payment. In particular, Section 3(a) would provide that on each Activity Date, at or before a time agreed upon by the Clearing Agencies (which may be modified on any given Activity Date with the consent of an authorized representative of OCC), NSCC will communicate to OCC the amount of the Historical Peak Guaranty Substitution Payment amount and the GSP Monitoring Data, which are to be used for informational purposes at OCC. The Historical Peak Guaranty Substitution Payment would reflect the largest GSP of the NSCC Participating Member and its affiliates over the prior twelve months and would be calculated based on the sum of the Required Fund Deposit deficits and Supplemental Liquidity Deposit associated with E&A/Delivery Transactions. Section 3(b) would provide that OCC would then submit to NSCC an acknowledgement of the Historical Peak Guaranty Substitution Payment amount and evidence that OCC has sufficient cash resources in the OCC Clearing Fund to cover the Historical Peak Guaranty Substitution Payment.

Section 3(c) would provide that if OCC does not provide NSCC with evidence within the designated time period that it has sufficient cash resources in the OCC Clearing Fund to cover the Historical Peak Guaranty Substitution Payment on the Activity Date, OCC will immediately contact NSCC to escalate discussions to discuss potential exposures and determine, among other things, whether OCC has other qualifying liquidity resources available to satisfy such amount.

As described above, the Historical Peak Guaranty Substitution Payment is designed to serve as a reasonable proxy for the largest potential Final Guaranty Substitution Payment. Its purpose is to allow OCC to provide evidence that it likely will be able to satisfy the Final Guaranty Substitution Payment in the event of a Common Member default, which will provide NSCC with reasonable assurances such that NSCC can begin processing E&A/Delivery Transactions upon receipt and prior to the Guaranty Substitution occurring, which will minimize the probability of reversals in a default event in light of the shortened settlement cycle. The Historical Peak Guaranty Substitution Payment amount also will provide OCC with information that will allow OCC to include the amount of a potential GSP in its liquidity resource planning.

Section 6—Final Guaranty Substitution Payment; OCC's Commitment

A new Section 6 would be added to provide the process by which NSCC would communicate the amount of, and OCC would commit to pay, the Final Guaranty Substitution Payment. In particular, Section 6(a) would provide that on each Settlement Date (or each Saturday for Weekend Expirations), by no later than the time(s) agreed upon by NSCC and OCC, NSCC will communicate to OCC the Final Guaranty Substitution Payment for each Common Member calculated by NSCC. NSCC would make such calculation according to a calculation methodology described in a new Appendix A to the Accord. This calculation would represent the sum of the Required Fund Deposit [77] and the Supplemental Liquidity Deposit [78] for the Common Member. As with the Phase 1 Accord, payment of the Final Guaranty Substitution Payment would be contingent on the mutual suspension of the Common Member and payment of the Final Guaranty Substitution Payment would continue to be the means by which Guaranty Substitution may occur.

Section 6(b) would provide that, following NSCC's communication of the Final Guaranty Substitution Payment for each Common Member to OCC, and by no later than the agreed upon time, OCC must either (i) commit to NSCC that it will pay the Final Guaranty Substitution Payment in the event of a mutual suspension of a Common Member,[79] or (ii) notify NSCC that it will not have sufficient cash resources to pay the largest Final Guaranty Substitution Payment calculated for every Common Member. Section 6(b)(i) would further provide that for Weekday Expirations, OCC's submission of E&A/Delivery Transactions to NSCC would constitute OCC's commitment to pay the Final Guaranty Substitution Payment on the Settlement Date in the event of a mutual suspension of a Common Member.

Section 6(c) would provide that if OCC notifies NSCC that it will not have sufficient cash resources to pay the Final Guaranty Substitution Payment, NSCC may, in its sole discretion (i) reject or reverse all E&A/Delivery Transactions, or (ii) voluntarily accept E&A/Delivery Transactions subject to certain terms and conditions mutually agreed upon by NSCC and OCC.[80] Section 6(c) would also provide that any necessary reversals of E&A/Delivery Transactions shall be delivered by NSCC to OCC at such time and in such form as the Clearing Agencies agree.

Section 6(d) would provide that if, at any time after OCC has acknowledged the Historical Peak Guaranty Substitution Payment in accordance with proposed Section 3(b) of the Accord or committed to pay the Final Guaranty Substitution Payment in accordance with proposed Section 6(b) of the Accord, OCC has a reasonable basis to believe it will be unable to pay the Final Guaranty Substitution Payment, OCC will immediately notify NSCC.

Section 8—Default by an NSCC Participating Member or OCC Participating Member

Section 6(b)(i), which would be renumbered as Section 8(b)(i), would be amended to reflect the modified use of the Final Guaranty Substitution Payment in the event of a mutual suspension of a Common Member. Section 8(b)(i) would also be revised to remove the ability for OCC or NSCC to require that the Guaranty Substitution Payment be re-calculated in accordance

[77] The Required Fund Deposit is the portion of the defaulted Common Member's Required Fund Deposit deficit to NSCC, calculated as a difference between the Required Fund Deposit deficit calculated on the entire portfolio and the Required Fund Deposit deficit calculated on the Common Member's portfolio prior to the submission of E&A/Delivery Transactions. The Phase 2 changes would refine the existing calculation methodology for the Required Fund Deposit in order to provide for a more accurate amount.

[78] If NSCC calculates a liquidity shortfall with respect to a defaulted Common Member, the Supplemental Liquidity Deposit is the portion of that shortfall that is attributable to the additional activity to be guaranteed.

[79] If OCC does not have sufficient cash to pay the Final GSP, then it must confirm for NSCC the availability of other qualifying liquid resources and the expected timeline for converting such resources to cash.

[80] Such terms and conditions may include, but would not be limited to, OCC's agreement to (i) pay NSCC available cash resources in partial satisfaction of the Final Guaranty Substitution Payment; (ii) collect or otherwise source additional resources that would constitute NSCC Qualifying Liquid Resources to pay the full Final Guaranty Substitution Payment amount; and/or (iii) reimburse NSCC for any losses associated with closing out such E&A/Delivery Transactions.

with an alternative methodology. This will not be necessary under the calculation methodology used in the Phase 2 changes because the proposed methodology would result in a more accurate calculation. Section 8(b)(i) would further amend the Accord by providing NSCC with discretion to voluntarily accept Defaulted NSCC Member Transactions and assume the guaranty for such transactions, subject to certain terms and conditions mutually agreed upon by NSCC and OCC. The only remaining change to the Guaranty Substitution process from its operation under the Accord would be the shortened time duration under which OCC would elect (by way of its commitment) to make the Final Guaranty Substitution Payment and the timing under which the Guaranty Substitution will be processed in order to function in a T+1 environment.

In particular, Section 8(b)(i) would provide that, with respect to a Mutually Suspended Member, if OCC has committed to make the Final Guaranty Substitution Payment, it will make such cash payment in full by no later than the agreed upon time(s). Upon NSCC's receipt of the full amount of the Final Guaranty Substitution Payment, NSCC's Guaranty would attach (and OCC's Guaranty will no longer apply) to the Defaulted NSCC Member Transactions. NSCC would have no obligation to accept a Final Guaranty Substitution Payment and attach the NSCC Guaranty to any Defaulted NSCC Member Transactions for more than the Activity Date on which it has ceased to act for that Mutually Suspended Member and one subsequent Activity Date. If NSCC does not receive the full amount of the Final Guaranty Substitution Payment in cash by the agreed upon time, the Guaranty Substitution Time would not occur with respect to the Defaulted NSCC Member Transactions and Section 8(b)(ii), described below, would apply. NSCC would, however, have discretion to voluntarily accept Defaulted NSCC Member Transactions and assume the guaranty for such transactions, subject to certain terms and conditions mutually agreed upon by NSCC and OCC.

Section 6(b)(ii), which would be renumbered as Section 8(b)(ii), would also be amended to reflect the modified use of the Final Guaranty Substitution Payment in the event OCC continues to perform or does not make the Final Guaranty Substitution Payment. In particular, Section 8(b)(ii) would add an additional criterion of OCC not satisfying any alternative agreed upon terms for Guaranty Substitution to reflect this as an additional option under the Phase 2 changes. As amended, Section 8(b)(ii) would provide that if OCC does not suspend an OCC Participating Member for which NSCC has ceased to act, OCC does not commit to make the Final Guaranty Substitution Payment, NSCC does not receive the full amount of the Final Guaranty Substitution Payment in cash by the agreed upon time, or OCC does not satisfy any alternative agreed upon terms for Guaranty Substitution, Guaranty Substitution with respect to all Defaulted NSCC Member Transactions for that Activity Date will not occur, all Defaulted NSCC Member Transactions for that Activity Date will be reversed and exited from NSCC's CNS accounting system, and NSCC will have no obligation to guaranty or settle such Defaulted NSCC Member Transactions. NSCC may, however, exercise its discretion to voluntarily accept the Defaulted NSCC Member Transactions, and assume the guaranty for such transactions, subject to certain agreed upon terms and conditions.

Section 8(b) would also be modified to provide for escalated discussion between the Clearing Agencies in the event of an intraday NSCC Cease to Act and/or NSCC Participating Member Default, particularly to confirm that OCC has sufficient qualifying liquid resources to pay the projected Final Guaranty Substitution Payment for the Defaulting NSCC Member's projected E&A/Delivery Transactions based on information provided in GSP Monitoring Data for such Defaulting NSCC Member.

Conforming changes would also be made to Section 8(d) to reflect the use of the new defined term ''Final Guaranty Substitution Payment.''

Other Proposed Changes as Part of Phase 2

Certain other technical changes are also proposed as part of the Phase 2 changes, including to conform the Accord to the proposed changes described above. For example, Section 9(c) would be revised regarding information sharing to reflect the introduction of the Historical Peak and Final Guaranty Substitution Payments and the GSP Monitoring Data; Section 4(c)(ix) would be conformed to reflect the addition of ''Settlement Date'' as a defined term in Section 1; various sections would be renumbered and internal cross-references would be adjusted to reflect the addition of new sections proposed herein; correct current references throughout the Accord to ''NSCC Rules and Procedures'' would be changed to simply read ''the NSCC Rules;'' and various non-substantive textual changes would be made to increase clarity.

Section 4(a) would also be modified to reflect that the Eligibility Master Files referenced in that paragraph, which identify Eligible Securities to OCC, are described in the SLA between OCC and NSCC. Section 9(b) would be modified to include OCC's available liquidity resources, including Clearing Fund cash balances in the information OCC provides to NSCC, and to specify that information will be provided on each Activity Date at an agreed upon time and in an agreed upon form by the Clearing Agencies. Finally, Section 16(b) would be modified to provide the correct current delivery address information for NSCC.

The Phase 2 changes would also include an Appendix A that would describe in detail the calculation methodology for the Guaranty Substitution Payment. This would provide the detailed technical calculation to determine each of the Mutually Suspended Member's Required Fund Deposit deficit and liquidity shortfall to NSCC. The full text of Appendix A is filed confidentially with the Commission as Exhibit 5 to this filing.

Phase 2 Guaranty Substitution Process Changes

As described above, the Phase 2 changes would modify the Guaranty Substitution process to reflect the shortened time duration under which the Guaranty Substitution will be processed in order to function in a T+1 environment. Below is a description of how that process would operate. The actual process would be implemented pursuant to a modified SLA between the Clearing Agencies.[81] All times provided below are in Eastern Time and represent the latest time by which the specified action must occur, unless otherwise agreed by the Clearing Agencies.

Weekend Expirations: On Friday (the Activity Date), NSCC would provide OCC with the Historical Peak GSP amount by 8:00 a.m. By 5:00 p.m. on Friday, OCC must acknowledge the Historical Peak GSP and provide evidence of OCC's Clearing Fund cash resources sufficient to cover that amount, following which NSCC would provide the Eligibility Master File by 5:45 p.m. By 1:00 a.m. on Saturday, OCC would then provide NSCC with the E&A/Delivery Transactions file and by 8:00 a.m. NSCC would provide OCC with the Final GSP, which OCC must

[81] OCC provided a draft of the SLA illustrating such changes to the Commission as confidential Exhibit 3F to this filing.

commit to pay by 9:00 a.m. in the event of a mutual suspension of a Common Member.[82] By 8:00 a.m. Monday (the Settlement Date), if a cease to act is declared over the weekend (or the later of 10:00 a.m. or one hour after the cease to act is declared if declared on Monday), OCC must pay the Final GSP if there has been a mutual suspension of a Common Member. Finally, by 1:00 p.m. on Monday, OCC must provide reversals for the defaulted member's E&A/Delivery Transactions if OCC has not satisfied (or will not satisfy) the Final GSP.

Weekday Expirations: On the Activity Date, NSCC would provide OCC with the Historical Peak GSP amount by 8:00 a.m. By 5:00 p.m. on the Activity Date, OCC must acknowledge the Historical Peak GSP and provide evidence of its cash resources in the OCC Clearing Fund sufficient to cover that amount, following which NSCC would provide the Eligibility Master File by 5:45 p.m. By 1:00 a.m. on the Settlement Date (the day after the Activity Date in the T+1 environment), OCC would then provide NSCC with the E&A/Delivery Transactions file, which also constitutes OCC's commitment to pay the Final GSP. By 8:00 a.m. NSCC would provide OCC with the Final GSP. By the later of 10:00 a.m. on the Settlement Date or one hour after a cease to act is declared, OCC must pay the Final GSP if there has been a mutual suspension of a Common Member. Finally, by 1:00 p.m. on the Settlement Date, OCC must provide reversals for the defaulted member's E&A/Delivery Transactions if OCC has not satisfied (or will not satisfy) the Final GSP.

For both Weekend Expirations and Weekday Expirations, Guaranty Substitution will take place only after the Common Members meet their start of day margin funding requirements at NSCC, if any. In a Common Member default event, the Guaranty Substitution will take place when OCC pays the Final GSP to NSCC.

The Clearing Agencies note that the Phase 2 changes described above are designed to change the process by which the GSP is implemented such that the use of the GSP as a mechanism to facilitate the acceptance of settlement obligations by NSCC can continue to operate within the condensed timing for clearance and settlement in a T+1 environment. However, the ultimate use of the GSP, its purpose, and its substantive import would remain consistent with the Phase 1 changes.

Proposed Liquidity Risk Management Framework Changes

OCC proposes changes to the Liquidity Risk Management Framework to incorporate the Phase 2 changes into its liquidity risk management practices. In the Contingency Funding Plan section, OCC would specify that it endeavors to maintain sufficient cash resources to cover its projected settlement demands. Projected settlement demands may include settlements associated with option exercise & assignment activity that create obligations for OCC under the Accord (*e.g.,* Final GSP, Historical Peak GSP). Final and Historical Peak GSP would be defined in the Definitions section. OCC proposes a footnote referencing the proposed Phase 1 changes to the Comprehensive Stress Testing & Clearing Fund Methodology, and Liquidity Risk Management Description with respect to the Final GSP. Namely, to account for the liquidity demand associated with the potential payment of a Final GSP, OCC would include the peak amount of the entire actual NSCC Required Fund Deposit deficits and SLD start-of-day obligations, without regard to allocation between NSCC and OCC, specific to each CMO Group for the relevant type of expiration on a rolling twelve-month lookback. Moreover, OCC may require the deposit of cash by a Clearing Member pursuant to its current Rules if projected settlement demands exceed OCC liquidity resources available to make settlement in the event of a Clearing Member default.

OCC also proposes related and clarifying changes in the document. For example, OCC would include a minor clarifying change to the Liquidity Risk Identification section to define GSP as a firm-specific liquidity demand. OCC would also amend the Stress Testing and Liquidity Resource Sizing section to incorporate information pertaining to GSP obligations into the annual analysis presented to the Board on projected liquidity demands that OCC may face under a variety of scenarios.

Proposed By-Law Changes

OCC proposes to update its By-Laws to conform with the revised Accord. OCC proposes to remove a reference to Balance Order Accounting Operation to align with the exclusion of transactions settled through NSCC's Balance Order System under the amended definition of Eligible Securities in the Phase 2 Accord.

Implementation Framework

The proposed Phase 1 and Phase 2 changes will be implemented as follows:

- *Phase 1:* Within 120 days after the date OCC and NSCC receive all necessary regulatory approvals for these proposed changes to the Accord, OCC will implement all Phase 1 changes. OCC would announce the implementation date by an Information Memorandum posted to its public website at least seven days prior to implementation.
- *Phase 2:* On the compliance date with respect to the final T+1 amendments to Exchange Act Rule 15c6–1(a) established by the SEC, OCC will implement all Phase 2 changes, keep in place any applicable Phase 1 changes that carry over to Phase 2, and decommission all Phase 1 changes that do not apply to Phase 2.[83]

(2) Statutory Basis

OCC believes the proposed changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. In particular, OCC believes the proposed changes are consistent with Section 17A(b)(3)(F) of the Act.[84] Section 17A(b)(3)(F) [85] of the Act requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, in general, to protect investors and the public interest. As described above in the Phase 1 changes, OCC believes that modifying its stress testing procedures to enhance its ability to call for additional liquidity resources and having the ability to make a Guaranty Substitution Payment to NSCC with respect to any unmet obligations of a Mutually Suspended Member would promote prompt and accurate clearance and settlement because it would ensure that NSCC accepts the relevant securities settlement obligations for clearance and settlement and therefore the size of the related settlement obligations for both the Mutually Suspended Member and its assigned delivery counterparties could be decreased from netting through NSCC's CNS Accounting Operation and/or NSCC's Balance Order Accounting Operation. This would also avoid a scenario in which OCC's Guaranty would continue to apply and the settlement obligations would be settled

[82] If OCC does not have sufficient cash resources to pay the Final GSP and the Clearing Agencies are unable to reach an agreement on additional terms for NSCC to accept E&A/Delivery Transactions, OCC must submit a reversal file by 12:30 a.m. on Monday so that NSCC can remove the E&A/Delivery Transactions from CNS prior to the start of NSCC's overnight processing. *See* confidential Exhibit 3H to this filing for additional details on action deadlines and processing times.

[83] If, due to the timing of regulatory approval, the implementation dates for Phase 1 and Phase 2 overlap, OCC would implement only the Phase 2 changes and Phase 1 changes that carry over to Phase 2.

[84] 15 U.S.C. 78q–1(b)(3)(F).

[85] 15 U.S.C. 78q–1(b)(3)(F).

on a broker-to-broker basis between OCC Clearing Members, which OCC believes could result in substantial collateral and liquidity requirements for OCC Clearing Members and that, in turn, could also increase a risk of default by the affected OCC Clearing Members at a time when a Common Member has already been suspended. The Phase 2 changes are also consistent with Section 17A(b)(3)(F) [86] of the Act and would promote the prompt and accurate clearance and settlement of securities transactions and protect investors and the public interest because, as described above, they would facilitate implementation of the new settlement cycle and support the Commission's stated goal of implementing necessary risk reducing changes in connection with the move to T+1 settlement, currently set for May 28, 2024. The Phase 2 changes would further enable OCC to provide certain assurances that would permit NSCC to begin processing E&A/Delivery Transactions prior to Guaranty Substitution occurring—thereby promoting the continued effectiveness of the Guaranty Substitution process in an environment with a shorter settlement cycle. For these reasons, OCC believes that the proposed changes would be beneficial to and protective of OCC, NSCC, their participants, and the markets that they serve and that the proposed changes are therefore designed, in general, to protect investors and the public interest.

OCC believes that the proposed changes are also consistent with the SEC rules that apply to OCC as a covered clearing agency.[87] In particular, SEC Rule 17Ad–22(e)(20) requires OCC to establish, implement, maintain and enforce written policies and procedures reasonably designed to identify, monitor and manage risks related to any link that OCC establishes with one or more other clearing agencies, financial market utilities, or trading markets.[88] As described in OCC's publicly available disclosure framework for financial market infrastructures,[89] the Existing Accord between OCC and NSCC is one such link. As described above, OCC believes (i) the proposed modifications to OCC's stress testing procedures that are designed to enhance its ability to call for additional liquidity resources, and (ii) that implementation of the ability for OCC to make a Guaranty Substitution Payment to NSCC in the relevant circumstances involving a Mutually Suspended Member would help manage the risks presented to OCC and its Clearing Members by the settlement link with NSCC because the Guaranty Substitution Payment would ensure that the relevant securities settlement obligations would be accepted by NSCC for clearance and settlement and therefore the size of the related settlement obligations could be decreased from netting through NSCC's CNS Accounting Operation and/or NSCC's Balance Order Accounting Operation.

For this same reason, OCC also believes that the proposed changes are consistent with the requirements of SEC Rules 17Ad–22(e)(3) and (7).[90] SEC Rule 17Ad–22(e)(3) requires OCC to establish, implement, maintain and enforce written policies and procedures reasonably designed to maintain a sound risk management framework for comprehensively managing, among other things, liquidity, credit and other risks that arise in or are borne by OCC.[91] SEC Rule 17Ad–22(e)(7) requires OCC, in relevant part, to establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively measure, monitor and manage the liquidity risk that arises in or is borne by OCC and to, among other things, address foreseeable liquidity shortfalls that would not be covered by OCC's liquid resources.[92] As noted, OCC believes the proposed stress testing enhancements and the ability to make a Guaranty Substitution Payment to NSCC would allow OCC to better manage liquidity and credit risks related to the settlement link with NSCC by ensuring that the relevant securities settlement obligations would be accepted by NSCC for clearance and settlement. It would avoid a scenario in which OCC's Guaranty would continue to apply and the settlement obligations would be settled on a broker-to-broker basis between OCC Clearing Members, which OCC believes could result in substantial collateral and liquidity requirements for OCC Clearing Members that, in turn, could also increase a risk of default by the affected OCC Clearing Members, particularly in circumstances where the prior suspension of a Mutually Suspended Member relates to broader stress in the financial system. Moreover, the incorporation of the Guaranty Substitution Payment into OCC's liquidity risk management practices would enhance OCC's ability to maintain additional liquidity resources to effect the settlement of exercise and assignment activity in the event of a Common Member default, and therefore, potentially increasing the promotion of market stability. Regarding the Phase 2 changes, OCC believes that the continued ability in a T+1 environment to make a Guaranty Substitution Payment to NSCC would allow OCC to better manage liquidity and credit risks related to the settlement link with NSCC by ensuring that the relevant securities settlement obligations would be accepted by NSCC for clearance and settlement.

(B) Clearing Agency's Statement on Burden on Competition

Section 17A(b)(3)(I) of the Act [93] requires that the rules of a clearing agency not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. OCC does not believe that the proposal would impose any burden on competition. The Phase 1 changes would implement changes that would permit OCC in certain circumstances to make a Guaranty Substitution Payment to NSCC so that the NSCC Guaranty would take effect for the Defaulted NSCC Member Transactions and the OCC Guaranty would end. The Phase 2 changes would further implement changes that would allow OCC to provide certain assurances to NSCC prior to the default of a Common Member that would enable NSCC to begin processing E&A/Delivery Transactions before the NSCC central counterparty trade guaranty attaches. The proposed changes would not inhibit access to OCC's services in any way, apply to all Clearing Members and do not disadvantage or favor any particular user in relationship to another user. Accordingly, OCC does not believe that the proposed rule change would have any impact or impose a burden on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were not and are not intended to be solicited with respect to the proposed rule change, and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of the notice in the **Federal**

[86] 15 U.S.C. 78q–1(b)(3)(F).

[87] 17 CFR 240.17Ad–22(a)(5).

[88] 17 CFR 240.17Ad–22(e)(20).

[89] *See* The Options Clearing Corporation Disclosure Framework for Financial Market Infrastructures, pg. 105, (2023), *available at https://www.theocc.com/risk-management/pfmi-disclosures.*

[90] 17 CFR 240.17Ad–22(e)(3), (7).

[91] 17 CFR 240.17Ad–22(e)(3).

[92] 17 CFR 240.17Ad–22(e)(7).

[93] 15 U.S.C. 78q–1(b)(3)(I).

Register or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–OCC–2023–007 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–OCC–2023–007. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of OCC and on OCC's website at *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.*

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–OCC–2023–007 and should be submitted on or before February 14, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[94]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–01751 Filed 1–29–24; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No.: FAA–2023–0987; Summary Notice No. 2024–06]

Petition for Exemption; Summary of Petition Received; Verge, Inc. dba Verge Aero

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

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion nor omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before February 20, 2024.

ADDRESSES: Send comments identified by docket number FAA–2023–0987 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Avi Acharya, AIR–626C, Federal Aviation Administration, at (316) 946–4192 or by email at *Avishek.Acharya@faa.gov.*

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on January 24, 2024.

Daniel J. Commins,

Manager, Integration and Performance Branch, Policy and Standards Division, Aircraft Certification Service.

Summary of Petition for Exemption

Docket No.: FAA–2023–0987.

Petitioner: Verge, Inc. dba Verge Aero.

Section(s) of 14 CFR Affected: § 89.515.

Description of Relief Sought: The petitioner seeks relief from the remote identification design and production requirements under 14 CFR 89.515 for the production of an uncrewed aircraft (UA) without design or production approval for light show events. If granted, the requested relief would allow Verge Aero to produce drones to be used exclusively for drone show operations without the UA complying with the minimum performance requirements for standard remote identification UA established in § 89.310. In lieu of complying with 14 CFR 89.515, the petitioner proposes to use a ground-based WiFi router network to broadcast identifying information for

[94] 17 CFR 200.30–3(a)(12).

the fleet of UAs operated during a light show.

[FR Doc. 2024–01726 Filed 1–29–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2013–0123; FMCSA–2014–0104; FMCSA–2014–0385;FMCSA–2016–0003; FMCSA–2017–0057; FMCSA–2017–0058; FMCSA–2017–0060; FMCSA–2018–0139; FMCSA–2019–0109; FMCSA–2019–0111; FMCSA–2019–0112]

Qualification of Drivers; Exemption Applications; Hearing

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for 18 individuals from the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these hard of hearing and deaf individuals to continue to operate CMVs in interstate commerce.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates provided below. Comments must be received on or before February 29, 2024.

ADDRESSES: You may submit comments identified by the Federal Docket Management System Docket No. FMCSA–2013–0123, Docket No. FMCSA–2014–0104, Docket No. FMCSA–2014–0385, Docket No. FMCSA–2016–0003, Docket No. FMCSA–2017–0057, Docket No. FMCSA–2017–0058, Docket No. FMCSA–2017–0060, Docket No. FMCSA–2018–0139, Docket No. FMCSA–2019–0109, Docket No. FMCSA–2019–0111, or Docket No. FMCSA–2019–0112 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov/,* insert the docket number (FMCSA–2013–0123, FMCSA–2014–0104, FMCSA–2014–0385, FMCSA–2016–0003, FMCSA–2017–0057, FMCSA–2017–0058, FMCSA–2017–0060, FMCSA–2018–0139, FMCSA–2019–0109, FMCSA–2019–0111, or FMCSA–2019–0112) in the keyword box and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click on the ''Comment'' button. Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal Holidays.
- *Fax:* (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001, (202) 366–4001, *fmcsamedical@dot.gov.* Office hours are 8:30 a.m. to 5 p.m. ET Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA–2013–0123, Docket No. FMCSA–2014–0104, Docket No. FMCSA–2014–0385, Docket No. FMCSA–2016–0003, Docket No. FMCSA–2017–0057, Docket No. FMCSA–2017–0058, Docket No. FMCSA–201–0060, Docket No. FMCSA–2018–0139, Docket No. FMCSA–2019–0109, Docket No. FMCSA–20–0111, or Docket No. FMCSA–2019–0112) indicate the specific section of this document to which each comment applies and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *www.regulations.gov/,* insert the docket number (FMCSA–2013–0123, FMCSA–2014–0104, FMCSA–2014–0385, FMCSA–2016–0003, FMCSA–2017–0057, FMCSA–2017–0058, FMCSA–2017–0060, FMCSA–2018–0139, FMCSA–2019–0109, FMCSA–2019–0111, or FMCSA–2019–0112) in the keyword box and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, click the ''Comment'' button, and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. FMCSA will consider all comments and material received during the comment period.

B. Viewing Comments

To view comments go to *www.regulations.gov.* Insert the docket number (FMCSA–2013–0123, FMCSA–2014–0104, FMCSA–2014–0385, FMCSA–2016–0003, FMCSA–2017–0057, FMCSA–2017–0058, FMCSA–2017–0060, FMCSA–2018–0139, FMCSA–2019–0109, FMCSA–2019–0111, or FMCSA–2019–0112) in the keyword box and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption requests. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov.* As described in the system of records notice DOT/ALL 14 (Federal Docket Management System), which can be reviewed at *https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices,* the comments are searchable by the name of the submitter.

II. Background

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or

greater than, the level that would be achieved absent such exemption. The statutes also allow the Agency to renew exemptions at the end of the 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The physical qualification standard for drivers regarding hearing found in 49 CFR 391.41(b)(11) states that a person is physically qualified to drive a CMV if that person first perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ASA Standard) Z24.5—1951.

This standard was adopted in 1970 and was revised in 1971 to allow drivers to be qualified under this standard while wearing a hearing aid, (35 FR 6458, 6463 (Apr. 22, 1970) and 36 FR 12857 (July 8, 1971), respectively).

The 18 individuals listed in this notice have requested renewal of their exemptions from the hearing standard in § 391.41(b)(11), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable 2-year period.

III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b), FMCSA will take immediate steps to revoke the exemption of a driver.

IV. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315(b), each of the 18 applicants has satisfied the renewal conditions for obtaining an exemption from the hearing requirement. The 18 drivers in this notice remain in good standing with the Agency. In addition, for commercial driver's license (CDL) holders, the Commercial Driver's License Information System and the Motor Carrier Management Information System are searched for crash and violation data. For non-CDL holders, the Agency reviews the driving records from the State Driver's Licensing Agency. These factors provide an adequate basis for predicting each driver's ability to continue to safely operate a CMV in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each of these drivers for a period of 2 years is likely to achieve a level of safety equal to that existing without the exemption.

In accordance with 49 U.S.C. 31136(e) and 31315(b), the following groups of drivers received renewed exemptions in the month of February and are discussed below.

As of February 14, 2024, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following eight individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Lucius Fowler (IL)
Jared Gunn (IL)
Daniel Krystosek (MN)
John Malm (IL)
Ray Norris (TX)
Abel Talamantes (WA)
Andrew Tessin (NC)
Charles Wirick (MD)

The drivers were included in docket numbers FMCSA–2013–0123, FMCSA–2014–0104, FMCSA–2017–0058, FMCSA–2018–0139, FMCSA–2019–0111, or FMCSA–2019–0112. Their exemptions are applicable as of February 14, 2024 and will expire on February 14, 2026.

As of February 19, 2024, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following 10 individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Wyatt Baldwin (NV)
Adam Hayes (CA)
Amy Ivins (NE)
Bradley Ledford (NE)
Adrian Lopez (TX)
Jeffrey Schulkers (KY)
Mark Tabangcora (CA)
Jason Thomas (TX)
Joshua Tinley (AZ)
Kerri Wright (OK)

The drivers were included in docket numbers FMCSA–2016–0003, FMCSA–2017–0057, or FMCSA–2017–0060. Their exemptions are applicable as of February 19, 2024 and will expire on February 19, 2026.

V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) each driver must report any crashes or accidents as defined in § 390.5T; and (2) report all citations and convictions for disqualifying offenses under 49 CFR parts 383 and 391 to FMCSA; and (3) each driver prohibited from operating a motorcoach or bus with passengers in interstate commerce. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. In addition, the exemption does not exempt the individual from meeting the applicable CDL testing requirements. Each exemption will be valid for 2 years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) the person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based upon its evaluation of the 18 exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the hearing requirement in § 391.41(b)(11). In accordance with 49 U.S.C. 31136(e) and 31315(b), each exemption will be valid for 2 years unless revoked earlier by FMCSA.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2024–01801 Filed 1–29–24; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA 2024–0002]

Agency Information Collection Activity Under OMB Review: Charter Service Operations

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

ACTION: Notice of request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Requirements (ICRs) abstracted below have been forwarded to the Office of Management and Budget (OMB) for review and comment. The

ICR describe the nature of the information collection and their expected burdens for the Charter Service Operations.

DATES: Comments must be submitted on or before February 29, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.* You can find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are Invited On: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this notice in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Tia Swain, Office of Administration, Management Planning Division, 1200 New Jersey Avenue., SE, Mail Stop TAD–10, Washington, DC 20590 (202) 366–0354 or *tia.swain@dot.gov.*

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act of 1995 (PRA), sec. 2, Public Law 104–13, 109 Stat. 163 (1995) (codified as revised at 44 U.S.C. 3501–3520), and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. 44 U.S.C. 3506, 3507; 5 CFR 1320.5, 1320.8(d)(1), 1320.12. On November 15, 2023, FTA published a 60-day notice (88 FR 78456) in the **Federal Register** soliciting comments on the ICR that the agency was seeking OMB approval. FTA received no comments after issuing this 60-day notice. Accordingly, DOT announces that these information collection activities have been re-evaluated and certified under 5 CFR 1320.5(a) and forwarded to OMB for review and approval pursuant to 5 CFR 1320.12(c).

Before OMB decides whether to approve these proposed collections of information, it must provide 30 days for public comment. 44 U.S.C. 3507(b); 5 CFR 1320.12(d). Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507 (b)-(c); 5 CFR 1320.12(d); *see also* 60 FR 44978, 44983. OMB believes that the 30-day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR 44983. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect. 5 CFR 1320.12(c); *see also* 60 FR 44983.

The summaries below describe the nature of the information collection requirements (ICRs) and the expected burden. The requirements are being submitted for clearance by OMB as required by the PRA.

Title: Charter Service Operations.

OMB Control Number: 2132–0543

Background: FTA's Charter Service Regulations protects private charter operators from unauthorized competition from FTA grant recipients. In essence, the charter regulations were implemented to ensure that transit agencies, subsidized with Federal money, do not unfairly compete with privately owned bus companies. Under the charter rules, with limited exceptions, local transit agencies are restricted from operating chartered services. Charter service means, but does not include demand response service to individuals:

- Transportation provided by a recipient at the request of a third party for the exclusive use of a bus or van for a negotiated price. The following features may be characteristic of charter service:
  - A third party pays the transit provider a negotiated price for the group,
  - Any fares charged to individual members of the group are collected by a third party,
  - The service is not part of the transit provider's regularly scheduled service, or is offered for a limited period of time, or
  - A third party determines the origin and destination of the trip as well as scheduling; or
- Transportation provided by a recipient to the public for events or functions that occur on an irregular basis or for a limited duration and:
  - A premium fare is charged that is greater than the usual or customary fixed route fare; or
  - The service is paid for in whole or in part by a third party.

There are limited exceptions when a grantee may provide charter service, including:

- Official government business,
- Qualified Human Service Organizations (elderly, persons with disabilities, and low- income individuals),
- When no registered charter provider responds to a notice sent by a recipient,
- Leasing (must exhaust all available vehicles first),
- By agreement with all registered charter providers,
- Petitions to the Administrator: Events of regional or national significance, or hardship.

Respondents: Transit Agencies and Private Operators.

Estimated Annual Responses: 2,000 respondents.

Estimated Total Annual Burden: 359 hours.

Frequency: Annually, bi-annually, quarterly, and as required.

Nadine Pembleton,

Deputy Associate Administrator, Office of Administration.

[FR Doc. 2024–01794 Filed 1–29–24; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2022–0058; Notice 2]

Polaris Group of America, Inc., Denial of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Denial of petition.

SUMMARY: Polaris Group of America, Inc., (Polaris), has determined that certain motorcycles manufactured by Indian Motorcycle Company do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 108, *Lamps, Reflective Devices, and Associated Equipment.* Indian Motorcycle Company, on behalf of Polaris, filed an original noncompliance report dated April 13, 2022, and later amended the report on September 9, 2022. Polaris petitioned NHTSA on May 13, 2022, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This document announces the denial of Polaris's petition.

FOR FURTHER INFORMATION CONTACT: Leroy Angeles, Safety Compliance Engineer, Office of Vehicle Safety Compliance, NHTSA, (202) 366–5304.

SUPPLEMENTARY INFORMATION:

I. Overview

Polaris determined that certain motorcycles manufactured by Indian Motorcycle Company do not fully comply with paragraph S7.3.5 and Table I-c of FMVSS No. 108, *Lamps, Reflective Devices, and Associated Equipment* (49 CFR 571.108).

Indian Motorcycle Company, on behalf of Polaris, filed an original noncompliance report dated April 13, 2022, and amended it on September 9, 2022, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* Polaris petitioned NHTSA on May 13, 2022, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance.*

Notice of receipt of Polaris's petition was published with a 30-day public comment period, on July 3, 2023, in the **Federal Register** (88 FR 42814). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) website at *https://www.regulations.gov/.* Then follow the online search instructions to locate docket number ''NHTSA–2022–0058.''

II. Motorcycles Involved

Approximately 12,619 of the following motorcycles manufactured by Indian Motorcycle Company between July 10, 2018, and April 1, 2022, were reported by the manufacturer:

- 2019–2020, 2022 Indian FTR 1200
- 2019–2020, 2022 Indian FTR 1200 S
- 2020, 2022 Indian FTR 1200 Rally
- 2022 Indian FTR R Carbon
- 2020–2022 Indian Challenger
- 2020–2022 Indian Challenger Limited
- 2020–2021 Indian Challenger Dark Horse
- 2022 Challenger Elite
- 2022 Indian Challenger Dark Horse Icon
- 2022 Indian Challenger JD Limited Edition
- 2022 Indian Pursuit Limited
- 2022 Indian Pursuit Limited Premium
- 2022 Indian Pursuit Limited Premium Icon
- 2022 Indian Pursuit Premium Dark Horse
- 2022 Indian Pursuit Dark Horse Premium
- 2022 Indian Pursuit Dark Horse Premium Icon

III. Noncompliance

Polaris explains that the subject motorcycles are equipped with a specific Antilock Braking System (ABS) module that can cause the subject motorcycle to experience stop lamp illumination without the application of the service brakes or by a device designed to retard the motion of the vehicle during certain riding conditions when a loss of wheel contact with the ground occurs.

IV. Rule Requirements

Stop lamps are lamps that give a steady light to the rear of a vehicle to indicate a vehicle is stopping or diminishing speed by braking. Paragraph S7.3.5 and Table I-c of FMVSS No. 108 include the requirements relevant to this petition. Stop lamps equipped on motorcycles must be steady burning. In addition, they must be activated upon application of the service brakes or by a device designed to retard the motion of the vehicle.

V. Summary of Polaris' Petition

The following views and arguments presented in this section, ''V. Summary of Polaris' Petition,'' are the views and arguments provided by Polaris. They do not reflect the views of the Agency. Polaris describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

Polaris explains that the subject noncompliance occurs due to an inadvertent software logic error. Specifically, Polaris says the subject noncompliance occurs because a ''loss of wheel contact may result in a front and rear wheel speed differential that exceeds the calibration threshold within the ABS module software.'' This causes the ABS module to provide a signal to the ECM, which then illuminates the brake lights, even when there is no brake application by the motorcycle user.

Polaris believes that the subject noncompliance is inconsequential to motor vehicle safety because the brake light is illuminated for 500 milliseconds and only occurs under certain conditions. Polaris says that the resulting brake light illumination is ''analogous to a rider tapping the brake lever or pedal to cancel cruise control, thereby illuminating the lights, but not meaningfully engaging the brake system to decelerate.'' Other than the subject noncompliance, Polaris states that the affected motorcycles comply with FMVSS No. 108 requirements. Furthermore, Polaris says it is not aware of any crashes or injuries related to the subject noncompliance.

Polaris references three previous petitions NHTSA has granted ''for lighting requirements where a technical noncompliance exists but does not create an adverse effect on safety.''

- In a petition submitted by Daimler Trucks North America,[1] Polaris points to the following NHTSA statement: ''when a vehicle with air brakes experiences a low-air event and notifies that driver of a brake system malfunction, NHTSA believes that the driver would likely respond by pulling over to the side of the road and taking the vehicle out of service until the brake system can be repaired.''
- Polaris cited a decision notice for a General Motor's petition for inconsequential noncompliance [2] and stated that, ''NHTSA noted that a number of factors led them to the conclusion that under the specific circumstances described in GM's Petition would have a low probability of occurrence and would neither be long lasting nor likely to occur during a period when parking lamps are generally in use.'' Polaris also points to a statement in this petition where NHTSA stated, ''when the noncompliance does occur, other lamps remain functional. The combination of all of the factors, specific to this case, abate the risk to safety.''
- In a petition submitted by General Motors Corporation,[3] Polaris points to the following NHTSA statement, ''[e]ven if a visible CHMSL illumination occurs upon hazard flasher activation, it would almost certainly have no adverse effect on safety. However, if a CHMSL illuminated due to this condition when the vehicle was on the road, a following driver would likely see a brief single flash of the CHMSL. As a practical matter, the following driver might not notice this flash at all. Even if he or she did, there would seem to be no likelihood of driver confusion or inappropriate responses.'' Polaris also points to another statement in this petition where NHTSA stated, ''[w]e can foresee no negative effects on motor vehicle safety if a vehicle's CHMSL is briefly illuminated as described upon activation of the hazard warning lamps. The intended use of a hazard warning lamp and the momentary activation of

[1] *Daimler Trucks North America, Grant of Petition for Decision of Inconsequential Noncompliance;* 87 FR 14325 (March 24, 2022).

[2] *General Motors, LLC, Grant of Petition for Decision of Inconsequential Noncompliance;* 83 FR 7847 (February 22, 2018).

[3] *General Motors Corporation; Grant of Application for Decision of Inconsequential Noncompliance;* 66 FR 32871 (June 18, 2001).

the CHMSL do not provide a conflicting message. The illumination of the CHMSL is intended to signify that the vehicles brakes are being applied and that the vehicle might be decelerating. Hazard warning lamps are intended as a more general message to nearby drivers that extra attention should be given to the vehicle. A brief illumination of the CHMSL while activating the hazard warning lamps would not confuse the intended general message, nor would the brief illumination in the absence of the other brake lamps cause confusion that the brakes were unintentionally applied.''

VI. NHTSA's Analysis

The burden of establishing the inconsequentiality of a failure to comply with a *performance requirement* in an FMVSS is substantial and difficult to meet. Accordingly, the Agency has not found many such noncompliances inconsequential.[4]

In determining inconsequentiality of a noncompliance, NHTSA focuses on the safety risk to individuals who experience the type of event against which a recall would otherwise protect.[5] In general, NHTSA does not consider the absence of complaints or injuries when determining if a noncompliance is inconsequential to safety. The absence of complaints does not mean vehicle occupants have not experienced a safety issue, nor does it mean that there will not be safety issues in the future.[6] Further, because each inconsequential noncompliance petition must be evaluated on its own facts and determinations are highly fact-dependent, NHTSA does not consider prior determinations as binding precedent. Petitioners are reminded that they have the burden of persuading NHTSA that the noncompliance is inconsequential to safety.

Polaris did not elaborate on the sensitivity of the lamp activation but did indicate that it can occur while going over a large bump like on railroad tracks and rumble strips. The Agency believes that the stop lamp illuminating for 500 milliseconds will be noticeable to other road users and going over a large bump on the road like railroad tracks or rumble strips is not an uncommon occurrence for motorists. Activation of the stop lamps for a purpose other than to indicate stopping or slowing will create confusion for the driver following the noncompliant vehicle as to the meaning of the signal, with the potential of causing the following driver to apply the brakes in his or her vehicle inappropriately. This is consistent with a decision on a petition by Daimler Trucks North America, and in response to a request for interpretation from General Motors.[7] NHTSA continues to adhere to the position that inappropriate and misleading activation of stop lamps is consequential to safety.

Polaris cited three separate Agency decisions to past petitions for inconsequential noncompliance in its petition. The Agency does not find any of these past decisions to be relevant to the subject petition. Each decision is addressed below:

First, the Daimler Trucks North America petition granted by the Agency involved the automatic illumination of the stop lamps when the low air pressure warning indicator light illuminates, which is an event that will occur once and will need to be resolved by the operator before continuing operation of the vehicle.[8] The affected vehicle is taken out of service until the brake system can be repaired, which distinguishes that decision from the subject petition.

Second, the General Motors, LLC (GM) petition concerns the activation of parking lamps which distinguishes it from the subject petition because parking lamps and stop lamps serve completely different functions.[9] Furthermore, other factors distinguish the two petitions including that the non-compliance in the GM petition only occurs during the daytime when parking lamps are generally not in use, requires a fairly high degree of unlikely user intervention for the non-compliance to occur, and the non-compliance will correct itself during operation. NHTSA believes that the noncompliance at issue here has the potential to occur more frequently because large bumps, railroad tracks, and rumble strips are obstacles found on roads throughout the United States.

The third decision notice which was cited, which is also in response to a GM petition, involved the brief activation of the center high-mounted stop lamp (''CHMSL'') when the hazard warning lamp switch was depressed to its limit of travel.[10] The Agency has previously concluded that this brief illumination of the CHMSL upon activation of the hazard warning signal did ''not provide a conflicting message'' and ''would not confuse the intended general message.'' In contrast, noticeable activation of the stop lamps in the manner described in Polaris's petition would send a conflicting or confusing message since the vehicle appears to be braking when it is not.

VII. NHTSA's Decision

In consideration of the foregoing, NHTSA has decided that Polaris has not met its burden of persuasion that the subject FMVSS No. 108 noncompliance is inconsequential to motor vehicle safety. Accordingly, Polaris's petition is hereby denied and Polaris is consequently obligated to provide notification of and free remedy for that noncompliance under 49 U.S.C. 30118 and 30120.

(Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8)

Eileen Sullivan,

Associate Administrator for Enforcement.

[FR Doc. 2024–01736 Filed 1–29–24; 8:45 am]

BILLING CODE 4910–59–P

[4] *Cf. Gen. Motors Corporation; Ruling on Petition for Determination of Inconsequential Noncompliance,* 69 FR 19897, 19899 (Apr. 14, 2004) (citing prior cases where noncompliance was expected to be imperceptible, or nearly so, to vehicle occupants or approaching drivers).

[5] *See Gen. Motors, LLC; Grant of Petition for Decision of Inconsequential Noncompliance,* 78 FR 35355 (June 12, 2013) (finding noncompliance had no effect on occupant safety because it had no effect on the proper operation of the occupant classification system and the correct deployment of an air bag); *Osram Sylvania Prods. Inc.; Grant of Petition for Decision of Inconsequential Noncompliance,* 78 FR 46000 (July 30, 2013) (finding occupant using noncompliant light source would not be exposed to significantly greater risk than occupant using similar compliant light source).

[6] *See Morgan 3 Wheeler Limited; Denial of Petition for Decision of Inconsequential Noncompliance,* 81 FR 21663, 21666 (Apr. 12, 2016); *see also United States* v. *Gen. Motors Corp.,* 565 F.2d 754, 759 (D.C. Cir. 1977) (finding defect poses an unreasonable risk when it ''results in hazards as potentially dangerous as sudden engine fire, and where there is no dispute that at least some such hazards, in this case fires, can definitely be expected to occur in the future'').

[7] *See Daimler Trucks North America, Denial of Petition for Decision of Inconsequential Noncompliance,* 85 FR 67812 (Oct. 26, 2020); Letter from F. Seales, Jr., NHTSA, to C. Terry, GM (May 26, 2000), *https://isearch.nhtsa.gov/files/21281.ztv.html.*

[8] *See Daimler Trucks North America, Grant of Petition for Decision of Inconsequential Noncompliance,* 87 FR 14325 (March 24, 2022),

[9] 83 FR 7847 (February 22, 2018).

[10] *See General Motors Corporation; Grant of Application for Decision of Inconsequential Noncompliance,* 66 FR 32871 (June 18, 2001).

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

Agency Information Collection Activities; Proposed Collection; Comment Request; Beneficial Ownership Information Requests

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

ACTION: Notice and request for comments.

SUMMARY: FinCEN invites all interested parties to comment on the proposed information collection associated with requests made to FinCEN, by certain persons, for beneficial ownership information, consistent with the requirements of the Beneficial Ownership Information Access and Safeguards final rule. The details included in the information collection are listed below. This request for comment is made pursuant to the Paperwork Reduction Act of 1995.

DATES: Written comments must be received on or before April 1, 2024.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal E-rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Refer to Docket Number FINCEN–2024–0002 and the specific Office of Management and Budget (OMB) control number 1506–0077.
- *Mail:* Policy Division, Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183. Refer to Docket Number FINCEN–2024–0002 and OMB control number 1506–0077.

Please submit comments by one method only. Comments will be reviewed consistent with the Paperwork Reduction Act of 1995 (PRA) and applicable OMB regulations and guidance. Comments submitted in response to this notice will become a matter of public record. Therefore, you should submit only information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: The FinCEN Resource Center at 1–800–767–2825 or electronically at *https://www.fincen.gov/contact.*

SUPPLEMENTARY INFORMATION:

I. Statutory and Regulatory Provisions

FinCEN issued the Beneficial Ownership Information Access and Safeguards final rule (the ''BOI Access Rule'') on December 22, 2023,[1] regarding access by authorized recipients to beneficial ownership information (BOI) that will be reported to FinCEN pursuant to Section 6403 of the Corporate Transparency Act (CTA), enacted into law as part of National Defense Authorization Act for Fiscal Year 2021 (NDAA).[2] The BOI Access Rule implements the strict protocols required by the CTA to protect sensitive personally identifiable information (PII) reported to FinCEN and establish the circumstances in which specified recipients have access to BOI, along with the data protection protocols and oversight mechanisms applicable to each recipient category. The disclosure of BOI to authorized recipients in accordance with appropriate protocols and oversight will help law enforcement and national security agencies prevent and combat money laundering, terrorist financing, tax fraud, and other illicit activity, as well as protect national security.

II. Paperwork Reduction Act of 1995[3]

Title: Beneficial Ownership Information (BOI) Requests.

OMB Control Number: 1506–0077.

Type of Review: Regular.

Description: As explained in the regulatory impact analysis (RIA) of the BOI Access Rule, the rule requires State, local, and Tribal agencies and financial institutions that access BOI to satisfy certain security and confidentiality requirements, including establishing certain standards and procedures, and developing and implementing safeguards. As a prerequisite for access to BOI, the rule also requires State, local, and Tribal agencies and financial institutions to provide a certification for each BOI request. Along with the certification, State, local, and Tribal agencies and financial institutions will also provide information by filling out data fields for each BOI request; these data fields are set out in the Appendix. While some data fields will be optional, others will be required.

As previewed in the BOI Access Rule, FinCEN is issuing this notice with regard to the information collection associated with such BOI requests. Thus, this notice seeks comment only on the burden for the information collection associated with such BOI requests, which corresponds to the burden associated with ''submit[ting] written certification for each request that it meets certain requirements.'' Further details about those burdens are set forth in the BOI Access Rule RIA (see Action G within Tables 1 and 2) and below. Also, as previously noted in the BOI Access Rule, FinCEN intends to provide additional detail regarding the form and manner of BOI requests for all categories of authorized recipients through specific instructions and guidance.

The following analysis represents the entirety of the burden under OMB control number 1506–0077, which is associated with the BOI Access Rule. FinCEN previously solicited public comment on the full burden of the Access Rule, including the certification requirement for the information collection associated with BOI requests, as part of that rulemaking.

Form: None.

Affected Public: State, local and Tribal agencies, self-regulatory organizations (SROs), and financial institutions with customer due diligence requirements under applicable law, as defined in the final BOI access rule. While Federal and foreign requesters are able to access BOI after meeting specific requirements, FinCEN does not include them in the PRA analysis because the regulations implementing the PRA define ''person'' as an individual, partnership, association, corporation (including operations of government-owned contractor-operated facilities), business trust, or legal representative, an organized group of individuals, a State, territorial, tribal, or local government or branch thereof, or a political subdivision of a State, territory, Tribal, or local government or a branch of a political subdivision.[4] For foreign requesters in particular, FinCEN assumes that such requests will be made at the national level.

Estimated Number of Respondents: 15,934 entities. This total is composed of an estimated 215 State, local, and Tribal agencies, of which 158 are State, local, and Tribal law enforcement agencies and 57 are State regulatory agencies, 3 SROs, and 15,716 financial institutions.[5] While the requirements in the rule are only imposed on those that optionally access BOI, for purposes of PRA burden analysis, FinCEN assumes maximum participation from State, local, and Tribal agencies, SROs, and financial institutions.

Frequency of Response: As required; varies depending on the requirement.

Estimated Time per Respondent: See ''Hours per Entity'' column in Table 1 below for estimated time for each requirement per respondent.

Estimated Total Annual Reporting and Recordkeeping Burden: FinCEN estimates that during year 1 the annual

[1] FinCEN, *Beneficial Ownership Information Access and Safeguards,* 88 FR 88732 (Dec. 22, 2023), available at *https://www.federalregister.gov/documents/2023/12/22/2023-27973/beneficial-ownership-information-access-and-safeguards.*

[2] Specifically, the CTA is Title LXIV of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Public Law 116–283 (Jan. 1, 2021). Division F of the NDAA is the Anti-Money Laundering Act of 2020, which includes the CTA. Section 6403 of the CTA, among other things, amends the Bank Secrecy Act (BSA) by adding a new section 5336, Beneficial Ownership Information Reporting Requirements, to subchapter II of chapter 53 of title 31, United States Code.

[3] Public Law 104–13, 44 U.S.C. 3506(c)(2)(A).

[4] *See* 5 CFR 1320.3(k).

[5] *See* Table 1 in the RIA of the BOI Access Rule for the types of financial institutions covered by this notice. 88 FR 88789 (Dec. 22, 2023).

hourly burden will be 8,743,781 hours. In year 2 and onward, FinCEN estimates that the annual hourly burden will be 3,616,964 hours. The annual estimated burden hours for State, local, and Tribal entities and SROs is 2,268,789 hours in the first year, and 1,699,612 hours in year 2 and onward. As shown in Table 1 below, the hourly burden in year 1 for State, local, and Tribal agencies and SROs includes the hourly burden associated with the following requirements in the rule: enter into an agreement with FinCEN and establish standards and procedures (Action B); establish a secure system to store BOI (Action D); establish and maintain an auditable system of standardized records for requests (Action E); submit written certification for each request that it meets certain requirements (Action G); restrict access to appropriate persons within the entity (Action H); conduct an annual audit and cooperate with FinCEN's annual audit (Action I); obtain certification of standards and procedures, initially and then semi-annually, by the head of the entity (Action J); and provide annual reports on procedures (Action K). The hourly burden in year 2 and onward for State, local, and Tribal agencies and SROs is associated with the same requirements as year 1, with the exception of Action B because FinCEN expects this action will result in costs for these entities in year 1 only.

The annual estimated hourly burden for financial institutions is 6,474,992 hours in the first year and 1,917,352 hours in year 2 and onward. The hourly burden for financial institutions in year 1 is associated with the following: develop and implement administrative and physical safeguards (Action A); develop and implement technical safeguards (Action C); obtain and document customer consent (Action F); submit certification for each request that it meets certain requirements (Action G); undergo training (Action H); comply with certain geographic restrictions (Action L); and notify FinCEN if they receive an information demand from a foreign government (Action M). The hourly burden in year 2 and onward for financial institutions is associated only with the requirements for Actions F, G, and H because FinCEN expects the other actions will result in costs for these entities in year 1 only.

Annual estimated burden declines in year 2 and onward because State, local, and Tribal agencies, SROs, and financial institutions no longer need to complete Actions A and B, and have a lower hourly burden for Actions E and F. State, local, and Tribal law enforcement agencies have a lower hourly burden for Action G. Table 1 lists the type of entity, the number of entities, the hours per entity, and the total hourly burden by action. For Actions A, B, C, D, E, F, I, J, K, L, and M the hours per entity are the maximum of the range estimated in the cost analysis of the RIA. For Action G and H, the hours per entity calculations are specified in footnotes to Table 1. Total annual hourly burden is calculated by multiplying the number of entities by the hours per entity for each action. In each subsequent year after initial implementation, FinCEN estimates that the total hourly annual burden is 3,616,964. This results in a 5-year average burden estimate of approximately 4,642,327 hours.[6]

This notice seeks comment on the estimated total annual reporting and recordkeeping burden for the information collection associated with BOI requests, specifically the requirement to submit written certification for each request that it meets certain requirements (Action G in Table 1 below). FinCEN previously provided notice and an opportunity for public comment on all actions that constitute the reporting and recordkeeping burden associated with the BOI Access Rule, including the certification requirement, as well as the estimated total annual burden, through the BOI Access rulemaking. As explained above, FinCEN is issuing this notice with regard to the information collection associated with BOI requests; therefore, this notice seeks comment only on the certification requirement.

TABLE 1—ANNUAL HOURLY BURDEN ASSOCIATED WITH RULE REQUIREMENTS

Action	Type of entity	Number of entities	Hours per entity	Total annual hourly burden
A. Develop and implement administrative and physical safeguards.	Financial institutions	15,716	240 in Year 1; 0 in Years 2+	3,771,840 in Year 1; 0 in Years 2+.
B. Enter into an agreement with FinCEN and establish standards and procedures.	State, local, and Tribal agencies and SROs.	218	300 in Year 1; 0 in Years 2+	65,400 in Year 1; 0 in Years 2+.
C. Develop and implement technical safeguards.	Financial institutions	15,716	0 in Year 1; 0 in Years 2+	0 in Year 1; 0 in Years 2+.
D. Establish a secure system to store BOI.	State, local, and Tribal agencies and SROs.	218	300 in Year 1; 4 in Years 2+	65,400 in Year 1; 872 in Years 2+.
E. Establish and maintain an auditable system of standardized records for requests.	State, local, and Tribal agencies and SROs.	218	200 in Year 1; 20 in Years 2+	43,600 in Year 1; 4,360 in Years 2+.
F. Obtain and document customer consent.	Financial institutions	15,716	70 in Year 1; 20 in Years 2+	1,100,120 in Year 1; 314,320 in Years 2+.
G. Submit certification for each request that it meets certain requirements [1].	Financial institutions	15,716	94 in Year 1; 94 in Years 2+	1,474,161 in Year 1; 1,474,161 in Years 2+.
G. Submit written certification for each request that it meets certain requirements, including court authorization.	State, local, and Tribal law enforcement.	158	12,975 in Year 1; 10,443 in Years 2+.	2,050,003 in Year 1; 1,649,994 in Years 2+.
G. Submit written certification for each request that it meets certain requirements.	State regulatory agencies and SROs.	60	125 in Year 1; 125 in Years 2+.	7,500 in Year 1; 7,500 in Years 2+.

[6] The 5-year average equals the sum of (Year 1 burden hours of 8,743,781 + Year 2 burden hours of 3,616,964 + Year 3 burden hours of 3,616,964 + Year 4 burden hours of 3,616,964 + Year 5 burden hours of 3,616,964) divided by 5.

TABLE 1—ANNUAL HOURLY BURDEN ASSOCIATED WITH RULE REQUIREMENTS—Continued

Action	Type of entity	Number of entities	Hours per entity	Total annual hourly burden
H. Undergo training[2]	Financial institutions	15,716	8 in Year 1; 8 in Years 2+	128,871 in Year 1; 128,871 in Years 2+.
H. Restrict access to appropriate persons within the entity, which specifies that appropriate persons will undergo training[3].	State, local, and Tribal agencies and SROs.	218	9 in Year 1, 9 in Years 2+	2,006 in Year 1; 2,006 in Years 2+.
I. Conduct an annual audit and cooperate with FinCEN's annual audit.	State, local, and Tribal agencies and SROs.	218	160 in Year 1; 160 in Years 2+.	34,880 in Year 1; 34,880 in Years 2+.
J. Obtain certification of standards and procedures initially and then semi-annually, by the head of the entity.	State, local, and Tribal agencies and SROs.	218	Included in I.	Included in I.
K. Provide initial and then an annual report on procedures.	State, local, and Tribal agencies and SROs.	218	Included in I.	Included in I.
L. Comply with certain geographic restrictions.	Financial institutions	15,716	0 in Year 1; 0 in Years 2+	0 in Year 1; 0 in Years 2+.
M. Notify FinCEN of information demand from foreign government.	Financial institutions	15,716	0 in Year 1; 0 in Years 2+	0 in Year 1; 0 in Years 2+.
Total Annual Hourly Burden.				8,743,781 in Year 1; 3,616,964 in Years 2+.

[1] For all types of entities, the hours per entity for Action G is the per entity share of the aggregate burden estimated in the RIA.
[2] For financial institutions, the hours per entity for Action H equals the weighted average of the large and small financial institutions' maximum burden estimated in the RIA.
[3] For State, local, and Tribal agencies and SROs, the hours per entity for Action H equals the per entity share of the aggregate burden.

Estimated Total Annual Reporting and Recordkeeping Cost: As described in Table 3 of the BOI Access Rule RIA, FinCEN calculated the fully loaded hourly wage for each type of affected entity type.[7] Using these estimated wages, the total cost of the annual burden in year 1 is $868,200,270. In year 2 and onward, FinCEN estimates that the total cost of the annual burden is $339,309,502, owing to Actions A and B only imposing burdens in year 1, Actions D and E having lower annual per entity burdens, and Action G having lower burden per request for State, local, and Tribal law enforcement agencies. The annual estimated cost for State, local, and Tribal agencies and SROs is $181,851,118 in the first year and $136,070,190 in year 2 and onward. The annual estimated cost for financial institutions is $686,349,152 in the first year and $203,239,312 in year 2 and onward. The 5-year average annual cost estimate is $445,087,656.[8]

This notice seeks comment on the estimated total annual reporting and recordkeeping cost for the information collection associated with BOI requests, specifically the requirement to ''submit written certification for each request that it meets certain requirements'' (Action G in Table 2 below). FinCEN previously provided notice and an opportunity for public comment on all actions that constitute the reporting and recordkeeping cost associated with the BOI Access Rule, including the certification requirement, as well as the estimated total annual reporting and recordkeeping cost, through the BOI Access rulemaking. As FinCEN is issuing this notice with regard to the information collection associated with BOI requests, this notice seeks comment only on the certification requirement.

TABLE 2—ANNUAL COST ASSOCIATED WITH RULE REQUIREMENTS

Action	Type of entity	Hourly wage	Total annual hourly burden	Total annual cost
A. Develop and implement administrative and physical safeguards.	Financial institutions	$106	3,771,840 in Year 1; 0 in Years 2+.	$399,815,040 in Year 1; $0 in Years 2+.
B. Enter into an agreement with FinCEN and establish standards and procedures.	State, local, and Tribal agencies.	80	65,400 in Year 1; 0 in Years 2+.	$5,232,000 in Year 1; $0 in Years 2+.
C. Develop and implement technical safeguards.	Financial institutions	106	0 in Year 1; 0 in Years 2+	$0 in Year 1; $0 in Years 2+.
D. Establish a secure system to store BOI.	State, local, and Tribal agencies.	80	65,400 in Year 1; 872 in Years 2+.	$5,232,000 in Year 1; $69,760 in Years 2+.

[7] 88 FR 88791 (Dec. 22, 2023).

[8] The 5-year average equals the sum of (Year 1 costs of $868,200,270 + Year 2 costs of $339,309,502 + Year 3 costs of $339,309,502 + Year 4 costs of $339,309,502 + Year 5 costs of $339,309,502) divided by 5.

TABLE 2—ANNUAL COST ASSOCIATED WITH RULE REQUIREMENTS—Continued

Action	Type of entity	Hourly wage	Total annual hourly burden	Total annual cost
E. Establish and maintain an auditable system of standardized records for requests.	State, local, and Tribal agencies.	80	43,600 in Year 1; 4,360 in Years 2+.	$3,488,000 in Year 1; $348,800 in Years 2+.
F. Obtain and document customer consent.	Financial institutions	106	1,100,120 in Year 1; 314,320 in Years 2+.	$116,612,720 in Year 1; $33,317,920 in Years 2+.
G. Submit certification for each request that it meets certain requirements.	Financial institutions	106	1,474,161 in Year 1; 1,474,161 in Years 2+.	$156,261,066 in Year 1; $156,261,066 in Years 2+.
G. Submit written certification for each request that it meets certain requirements, including court authorization.	State, local, and Tribal law enforcement.	80	2,050,003 in Year 1; 1,649,994 in Years 2+.	$164,000,240 in Year 1; $131,999,520 in Years 2+.
G. Submit written certification for each request that it meets certain requirements.	State regulatory agencies	80	7,500 in Year 1; 7,500 in Years 2+.	$600,000 in Year 1; $600,000 in Years 2+.
H. Undergo training	Financial institutions	106	128,871 in Year 1; 128,871 in Years 2+.	$13,660,326 in Year 1; $13,660,326 in Years 2+.
H. Restrict access to appropriate persons within the agency, which specifies that appropriate persons will undergo training.	State, local, and Tribal agencies.	80	2,006 in Year 1; 2,006 in Years 2+.	$160,480 in Year 1; $160,480 in Years 2+.
I. Conduct an annual audit and cooperate with FinCEN's annual audit.	State, local, and Tribal agencies.	80	34,880 in Year 1; 34,880 in Years 2+.	$2,790,400 in Year 1; $2,790,400 in Years 2+.
J. Obtain certification of standards and procedures initially and then semi-annually, by the head of the entity.	State, local, and Tribal agencies.	80	Included in I.	Included in I.
K. Provide initial and then an annual report on procedures.	State, local, and Tribal agencies.	80	Included in I.	Included in I.
L. Comply with certain geographic restrictions.	Financial institutions	106	0 in Year 1; 0 in Years 2+	$0 in Year 1; $0 in Years 2+.
M. Notify FinCEN of information demand from foreign government.	Financial institutions	106	0 in Year 1; 0 in Years 2+	$0 in Year 1; $0 in Years 2+.
Actions B, D, E, G, H, I–K	SRO	106	3,283 in Year 1; 955 in Years 2+.	$347,998 in Year 1; $101,230 in Years 2+.
Total Annual Cost		.....		$868,200,270 in Year 1; $339,309,502 in Years 2+.

Request for Comments:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. Comments submitted in response to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services required to provide information.

(Authority: 44 U.S.C. 3501 *et seq.*)

Andrea M. Gacki,

Director, Financial Crimes Enforcement Network.

Appendix—Beneficial Ownership Information (BOI) Request: Summary of Data Fields by Authorized Recipient

I. Financial Institutions

Proposed data fields and certification:

Company name (*reporting company legal name*)

Identifier type (*reporting company tax identification number type; select one from list of options*)

- EIN (Employer Identification Number)
- SSN/ITIN (Social Security Number/Individual Taxpayer Identification Number)
- Foreign

Company identifier (*reporting company tax identification number*)

[*Select* ''I agree''] I certify on behalf of the financial institution making this request that: The financial institution is subject to customer due diligence requirements under applicable law and is requesting beneficial ownership information from FinCEN to facilitate the financial institution's compliance with those requirements; the financial institution has obtained and documented the consent of the above identified company to request its beneficial ownership information from FinCEN; and the financial institution has fulfilled all other requirements of 31 CFR 1010.955(d)(2).

II. State, Local, and Tribal Law Enforcement Agencies

Proposed data fields and certification:

Agency Reference (*agency's internal reference name for BOI Request*)

Name of court of competent jurisdiction
Date of court authorization
Court authorization description (*description of the information the court has authorized the agency to seek*)
Checkbox Request on behalf of another person in the same agency (*select this checkbox if the BOI Request is made on behalf of another person in the same agency; provide the following information for this person, as applicable: first name; middle name; last name; title; city; country/jurisdiction; state; ZIP/foreign postal code*)

[*Select* ''I agree''] I certify that a court of competent jurisdiction has authorized my agency to seek this information in a criminal or civil investigation and that the requested information is relevant to the criminal or civil investigation.

III. State Regulatory Agencies

Proposed data fields and certification:

Financial Institution(s)
Financial Institution Employer Identification Number
Reporting Company Legal Name
Reporting Company Tax Identification Number
Start Date
End Date

[*Select* ''I agree''] I certify that my agency is authorized by law to assess, supervise, enforce, or otherwise determine the compliance of a relevant financial institution with customer due diligence requirements under applicable law and that my agency will use the requested information solely for the purpose of conducting such activities.

[FR Doc. 2024–01828 Filed 1–29–24; 8:45 am]

BILLING CODE 4810–02–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 effective 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 January 25, 2024, 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.

Individuals

1. AL-ATIFI, Mohamed (a.k.a. AL-ATIFI, Mohammad; a.k.a. AL-ATIFI, Mohammed; a.k.a. AL-ATIFI, Muhammad Nasser), Yemen; DOB 1969; POB Bani Atef Village, Sanaa Governorate, Yemen; nationality Yemen; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (individual) [SDGT].

Designated pursuant to section 1(a)(iii)(C) 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 materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, an act of terrorism, as defined in section 3(d) of E.O. 13224, as amended.

2. AL-QADIRI, Muhammad Ali (a.k.a. AL-QADIRI, Muhammad; a.k.a. AL-QADRI, Muhammad), Yemen; DOB 1970; POB Hudaydah Governorate, Yemen; nationality Yemen; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (individual) [SDGT].

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 service to or in support of, an act of terrorism, as defined in section 3(d) of E.O. 13224, as amended.

3. AL-TALIBI, Muhammad Ahmad (a.k.a. ''AL-TALIBI, Abi Ja'far''), Yemen; DOB 01 Jan 1983; POB Dhahyan, Sa'dah, Yemen; nationality Yemen; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Passport 01197425 (Yemen) (individual) [SDGT].

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 service to or in support of, an act of terrorism, as defined in section 3(d) of E.O. 13224, as amended.

4. AL-NABI, Muhammad Fadl Abd (a.k.a. NABI, Mohammed Fadl Abdul), Yemen; DOB 01 Jan 1952; nationality Yemen; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (individual) [SDGT].

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 service to or in support of, an act of terrorism, as defined in section 3(d) of E.O. 13224, as amended.

Dated: January 25, 2024.

Bradley T. Smith,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2024–01775 Filed 1–29–24; 8:45 am]

BILLING CODE 4810–AL–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 January 22, 2024, 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.

Individuals

BILLING CODE 4810–AL–P

Individuals

1. HIRZALLAH, Na'im Kamil Raghib (Arabic: نعام كمال راغب حرزالله) (a.k.a. HERZALLAH, Naem Kamel; a.k.a. HIRZ-ALLAH, Na'im Kamil Raghib), Gaza; DOB 16 Sep 1966; nationality Palestinian; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; National ID No. 911395275 (Palestinian) (individual) [SDGT] (Linked To: HAMAS).

   Designated pursuant to section 1(a)(iii)(C) 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 materially assisted, sponsored, or provided financial, material, or technological support for, or goods or service to or in support of, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

2. HIRZALLAH, Thair Abd Al Raziq Shukri (Arabic: ثائر عبدالرازق شكري حرزالله) (a.k.a. HIRZALLAH, Thafir; a.k.a. HIRZALLAH, Thair Abd Al Razzaq Shukri; a.k.a. HIRZALLAH, Tha'ir 'Abd-al-Raziq Shukri), Gaza; DOB 14 Oct 1973; POB Israel; nationality Israel; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; National ID No. 2001052383 (Israel); Electoral Registry No. 7602061 (Israel); Identification Number 700154933 (Palestinian) (individual) [SDGT] (Linked To: HAMAS).

   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 service to or in support of, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

3. HIRZALLAH, Salah Kamil Raghib (Arabic: صالح كمال راغب حرزالله) (a.k.a. HARAZALLAH, Salah Kamil; a.k.a. HERZALLAH, Salah Kamel; a.k.a. HERZALLAH, Salah Kamel Raghib; a.k.a. HIRZALLAH, Salah Kamil), Gaza; DOB 08 Jan 1960; POB Gaza Strip; nationality Palestinian; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; National ID No. 911395259 (Israel); Electoral Registry No. 8105411 (Israel) (individual) [SDGT] (Linked To: HAMAS).

   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 service to or in support of, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

4. HIRZALLAH, Samir 'Abd Al-Mu'in 'Abd (Arabic: سمير عبدالمين عبد حرزالله) (a.k.a. HERZALLAH, Sameer Abdel Mueen Abed; a.k.a. HERZALLAH, Sameer Abdulmooti; a.k.a. HERZALLAH, Samer Abdulmoaien Abed; a.k.a. HERZALLAH, Samir; a.k.a. HIRZALLAH, Abd al-Mu'in 'Abd Ismail (Arabic: عبدالمعين عبد إسماعيل حرزالله)), Gaza; DOB 11 Jan 1978; POB Gaza Strip; nationality Palestinian; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; National ID No. 900511445 (Palestinian) (individual) [SDGT] (Linked To: HAMAS).

   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 service to or in support of, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

5. HIRZALLAH, Muhammad Fallah Kamil (Arabic: محمد فلاح كمال حرزالله) (a.k.a. HARZALLAH, Mohamed; a.k.a. HERZAL ALLAH, Mohamed; a.k.a. HERZALLAH, Mohamed; a.k.a. HERZALLAH, Mohamed Falah; a.k.a. HERZALLAH, Mohammed Falah; a.k.a. HERZALLAH, Mohammed Falah Kamel; a.k.a. HERZALLAH, Muhammad; a.k.a. HIRZALLAH, Muhammad Fallah), Gaza; DOB 09 Sep 1989; POB Gaza Strip; nationality Palestinian; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; National ID No. 802413112 (Palestinian) (individual) [SDGT] (Linked To: HAMAS).

   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 service to or in support of, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

6. SHAMLAKH, Alaa (a.k.a. SHAMALLAKH, Ala' Yunis Hamid; a.k.a. SHAMALLAKH, Alla Y. H.), Istanbul, Turkey; DOB 07 Apr 1974; nationality Palestinian; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Passport 3596875 (Palestinian) issued 23 Nov 2014 expires 22 Nov 2019; National ID No. 900222415 (Palestinian) (individual) [SDGT] (Linked To: HAMAS).

   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 service to or in support of, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

7. SHAMLAKH, Ahmed (a.k.a. SHAMALLAKH, Ahmad; a.k.a. SHAMLAKH, Ahmad Shabbir; a.k.a. SHAMLAKH, Ahmed Abd al-Rahman Ahmed), Gaza; DOB 09 Feb 1986; nationality Palestinian; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; National ID No. 80148715 (Palestinian) (individual) [SDGT] (Linked To: HAMAS).

   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 service to or in support of, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

8. SHAMLAKH, Imad Younes (Arabic: عماد يونس شملخ) (a.k.a. SHAMALLAKH, Imad Y. H.), Gaza; DOB 19 May 1972; POB Gaza Strip; nationality Palestinian; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Passport 5173596 (Palestinian) issued 22 Apr 2021 expires 21 Apr 2026; National ID No. 919264366 (Palestinian) (individual) [SDGT] (Linked To: HAMAS).

   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 service to or in support of, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

9. SHAMLAKH, Zuhair (Hebrew: זהיר יונס שמלח) (a.k.a. SHAMALCH, Zuhir Yunes Hammed (Arabic: زهير يونس حامد شملخ); a.k.a. SHAMLAKH, Zuheir; a.k.a. SHMALACH, Zahir Younes), Gaza; DOB 15 Nov 1980; nationality Palestinian; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; National ID No. 905396560 (Palestinian) (individual) [SDGT] (Linked To: HAMAS).

   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 service to or in support of, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

Entities

1. HERZALLAH EXCHANGE AND GENERAL TRADING COMPANY LLC (Arabic: شركة حرزالله للصرافة والتجارة العامة المساهمة الخصوصية المحدودة) (a.k.a. HARAZULLAH EXCHANGE AND GENERAL TRADING COMPANY LLC; a.k.a. HERZALLA EXCHANGE CO.; a.k.a. HERZALLAH COMPANY FOR MONEY; a.k.a. HERZALLAH COMPANY FOR MONEY - EXCHANGE; a.k.a. HERZALLAH EXCHANGE AND GENERAL TRADING; a.k.a. HERZALLAH EXCHANGE AND GENERAL TRADING COMPANY (Arabic: شركة حرزالله للصرافة والتجارة العامة); a.k.a. HERZALLAH EXCHANGE COMPANY; a.k.a. HERZALLAH EXCHANGE COMPANY AND TRANSFER), Gaza; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 24 Apr 2006; Organization Type: Other monetary intermediation; Identification Number 563141746 (Palestinian) [SDGT] (Linked To: HAMAS).

   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 service to or in support of, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

2. SAMIR HERZALLAH AND BROTHERS FOR MONEY EXCHANGE AND REMITTANCES (Arabic: شركة سمير حرزالله وإخوانه للصرافة والحوالات المالية) (a.k.a. SAMEER ABED ALMOEEN HERZALLAH AND HIS BROTHERS COMPANY FOR MONEY - EXCHANGE AND TRANSFERS; a.k.a. SAMEER ABED AL-MOEEN HERZALLAH AND HIS BROTHERS COMPANY FOR MONEY - EXCHANGE AND TRANSFERS; a.k.a. SAMEER HERZALLAH AND BROTHERS CO FOR MONEY EXCHANGE

AND TRANSFER; a.k.a. SAMEER HERZALLAH AND BROTHERS CO.; a.k.a. SAMEER HERZALLAH BROTHERS CO; a.k.a. SAMEER HERZALLAH COMPANY; a.k.a. SAMEER HERZALLAH FOR MONEY EXCHANGE & REMMITTANCES; a.k.a. SAMEER HERZALLAH FOR MONEY EXCHANGE AND REMMITTANCES; a.k.a. SAMIR HERZALLAH COMPANY), Gaza; Website https://www.herzallah.ps/; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Type: Other monetary intermediation; Identification Number 563478999 (Palestinian) [SDGT] (Linked To: HAMAS).

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 service to or in support of, HAMAS, a person whose property and interests in property are blocked pursuant to E.O. 13224.

3. AL-MARKAZIYA LI-SIARAFA (Arabic: شركة المركزية للصرافة) (a.k.a. AL MUTAHADUN COMPANY; a.k.a. AL MUTAHADUN FOR EXCHANGE), Gaza; Aksaray Mah. Cerrahpasa Cad. MURATPASA, Apt. No:3/12, Fatih, Istanbul, Turkey; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Commercial Registry Number 563157932 (Palestinian); Istanbul Chamber of Comm. No. 142520-5 (Turkey); Business Registration Number 267113103200001 (Turkey) [SDGT] (Linked To: SHAMLAKH, Zuhair).

   Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, directly or indirectly, Zuhair SHAMLAKH, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

4. ARAB CHINA TRADING COMPANY (a.k.a. "ARAB COMPANY TO STATE TRADING"; a.k.a. "ARAB TRADING COMPANY CHINA"), Gaza; Aksaray MAH. Cerrahpasa CAD. Muratpasa Apt. No 3/12 Fatih, Istanbul, Turkey; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Commercial Registry Number 563157932 (Palestinian) [SDGT] (Linked To: SHAMLAKH, Zuhair).

   Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, directly or indirectly, Zuhair SHAMLAKH, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

Dated: January 22, 2024.

Bradley T. Smith,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2024–01787 Filed 1–29–24; 8:45 am]

BILLING CODE 4810–AL–C

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act Meetings

TIME AND DATE: February 1, 2024, 12:00 p.m. to 1:30 p.m., Eastern Time.

PLACE: This meeting will be accessible via conference call and via Zoom Meeting and Screenshare. Any interested person may call (i) 1–929–205–6099 (US Toll) or 1–669–900–6833 (US Toll), Meeting ID: 937 1981 0934, to listen and participate in this meeting. The website to participate via Zoom Meeting and Screenshare is *https://kellen.zoom.us/meeting/register/tJcqduCgrzsjGdA0qxGd_B_Gu7JOUbF6t_ol.*

STATUS: Portions of this meeting will be open to the public. A portion of this meeting will be closed to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Board of Directors (the ''Board'') will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

Proposed Agenda

Portions Open to the Public

I. Welcome and Call to Order—UCR Board Chair

The UCR Board Chair will welcome attendees, call the meeting to order, call roll for the Board, confirm the presence

of a quorum, and facilitate self-introductions.

II. Verification of Meeting Notice—UCR Executive Director

The UCR Executive Director will verify publication of the meeting notice on the UCR website and distribution to the UCR contact list via email followed by subsequent publication of the notice in the **Federal Register**.

III. Review and Approval of Board Agenda—UCR Board Chair

For Discussion and Possible Action

Agenda will be reviewed and the Board will consider adoption.

Ground Rules

➢ Board actions taken only in designated areas on agenda

Portion Closed to the Public

Pursuant to the Government in the Sunshine Act at 5 U.S.C. 552b(d)(1), the Board must now vote to approve closing the portion of the meeting dealing with item IV on the agenda.

The Chief Legal Officer has advised that the Board may close this portion of this meeting pursuant to Government in the Sunshine Act exemptions (9)(B) and (10). By approving this action, the Board determines that public participation would likely disclose information for which premature disclosure would likely frustrate implementation of a proposed agency action and/or specifically concern the discussion of information, the premature disclosure of which would likely negatively impact the agency's participation in an ongoing civil action or proceeding. Therefore, by approving this action, the Board is invoking Exemptions (9)(B) and (10) to close this portion of the meeting (5 U.S.C. 552b(c)(9)(B) and (10)).

A copy of the vote on the closure of this portion of this meeting shall be made publicly available on the Unified Carrier Registration Plan website within one day of the vote taken herein (*https://plan.ucr.gov*).

IV. Discussion and Possible UCR Board Action Concerning the ICANN Domain Name Dispute With Uliana Bogash/ Excelsior Enterprises International, Inc.

—UCR Chief Legal Officer

For Discussion and Possible Action

The UCR Chief Legal Officer will discuss the recent adverse decision of the 3-person panel against the UCR in the ICANN domain name dispute initiated by the UCR against Uliana Bogash/Excelsior Enterprises International, Inc. The UCR Chief Legal Officer will also discuss the legal and financial options available to the UCR in responding to the letter received on January 17, 2024 from legal counsel to Ms. Bogash/EEI demanding reimbursement by the UCR of the legal and ICANN proceeding expenses incurred by Ms.Bogash/EEI in responding to the ICANN domain name dispute initiated by the UCR. The Board may vote to authorize legal and/or financial responses to the January 17, 2024 demand letter.

Portions Open to the Public

V. Other Business—UCR Board Chair

The UCR Board Chair will call for any business, old or new, from the floor.

VI. Adjournment—UCR Board Chair

The UCR Board Chair will adjourn the meeting.

The agenda will be available no later than 5:00 p.m. Eastern time, January 25, 2024, at: *https://plan.ucr.gov.*

CONTACT PERSON FOR MORE INFORMATION: Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305–3783, *eleaman@board.ucr.gov.*

Alex B. Leath,

Chief Legal Officer, Unified Carrier Registration Plan.

[FR Doc. 2024–01927 Filed 1–26–24; 4:15 pm]

BILLING CODE 4910–YL–P

DEPARTMENT OF VETERANS AFFAIRS

Research Advisory Committee on Gulf War Veterans' Illnesses, Amended, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. Ch. 10., that the Research Advisory Committee on Gulf War Veterans' Illnesses (hereinafter the Committee) will meet by teleconference on February 12, 2024. The meeting will begin at 11 a.m. Eastern Standard Time (EST) and adjourn at 3 p.m. ET.

The open session will be available to the public by connecting to Webex URL: *https://veteransaffairs.webex.com/veteransaffairs/j.php?MTID=mce20c7eb47a3f2e1ad620c4ffe8575de.* Or, join by phone: 1–833–558–0712 Toll-free; meeting number (access code): 2760 876 6175. Meeting password: GWVets1991!

The purpose of the Committee is to provide advice and make recommendations to the Secretary of Veterans Affairs on proposed research studies, research plans, and research strategies relating to the health consequences of military service in the Southwest Asia theater of operations during the Gulf War in 1990–91.

The Committee will review VA program activities related to Gulf War Veterans' illnesses and updates on relevant scientific research published since the last Committee meeting. This meeting will focus on Federal Advisory Committee annual training, the Committee Charter and deliberation of Committee recommendations.

Time will be allocated for receiving public comments on February 12, 2024 at 2:30 p.m. EST. Individuals wishing to make public comments should contact Marsha Turner at *VARACGWVI@va.gov.* Public comment speakers are requested to submit a 1–2-page summary of their comments for inclusion in the official meeting record. Written comments will also be accepted for the record. Members of the public who have confirmed public speaker registrations will be allowed to provide public comment first followed by non-registered speakers time permitting. Each public comment speaker will be held to a 5-minute time limit. Individuals wishing to seek additional information should contact Dr. Karen Block, Designated Federal Officer, at *Karen.Block@va.gov.*

Dated: January 25, 2024.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2024–01826 Filed 1–29–24; 8:45 am]

BILLING CODE 8320–01–P

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S. 3250/P.L. 118–37
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