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Presidential Documents

Title 3—

The President

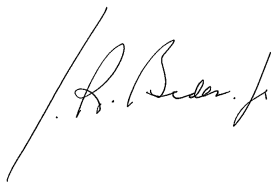
Memorandum of April 5, 2022

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

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 621 of the Foreign Assistance Act of 1961 (FAA), I hereby delegate to the Secretary of State the authority under section 506(a)(1) of the FAA to direct the drawdown of up to an aggregate value of $100 million in defense articles and services of the Department of Defense, and military education and training, to provide assistance to Ukraine and to make the determinations required under such section to direct such a drawdown.

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



THE WHITE HOUSE,
Washington, April 5, 2022

[FR Doc. 2022–07797
Filed 4–8–22; 8:45 am]
Billing code 4710–10–P

Rules and Regulations

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0451; Project Identifier AD–2022–00265–T; Amendment 39–22010; AD 2022–08–07]

RIN 2120–AA64

Airworthiness Directives; Embraer S.A. (Type Certificate Previously Held by Yaborã Indústria Aeronáutica S.A.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Embraer S.A. Model ERJ 170–100 STD, –100 LR, –100 SU, and –100 SE; ERJ 170–200 STD, –200 LR, –200 SU; ERJ 190–100 STD, –100 LR, –100 IGW, and –100 ECJ; and ERJ 190–200 STD, –200 LR, and –200 IGW airplanes. This AD was prompted by a report of the failure of the inner pane of certain passenger windows to meet maximum operating pressure and lack of fail-safe design. This AD requires determining if certain NORDAM passenger windows are installed, and performing corrective actions if any affected part is installed. This AD also prohibits the installation of affected parts. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 26, 2022.

The FAA must receive comments on this AD by May 26, 2022.

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

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

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0451; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The street address for the Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Jacob Fitch, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–4130; email *jacob.fitch@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA received a voluntary self-disclosure report indicating possible failure of the inner pane of certain passenger windows to meet fail-safe loads in the event of the complete failure of the outer pane. Manufacturer testing was performed to confirm the inadequacy of the inner window pane design. The results of the testing revealed that the inner pane of the passenger window failed to meet maximum operating pressure. The root cause was determined to be an inner window pane dimensional thickness that is inadequate to support cabin pressurization loads. As a result, the design was found to not be fail safe, meaning that the window assembly does not retain the required residual strength to maintain safe flight and landing of the aircraft after a failure or partial failure of the outer window pane. This affects any Nordam Group Inc. Transparency Division (NORDAM) passenger window having part number (P/N) NP00038–3. Failure of the window's inner pane to meet maximum operating pressure and lack of fail-safe design, if not addressed, could result in possible serious injury to a passenger near the window due to rapid decompression, and consequent reduced ability of the flightcrew to maintain the safe flight and landing of the airplane. The FAA is issuing this AD to address the unsafe condition on these products.

FAA's Determination

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

AD Requirements

This AD requires determining if any affected part, the NORDAM passenger window having P/N NP00038–3, is installed; repetitively inspecting the outer pane of affected parts for cracking; immediately replacing cracked affected parts with serviceable windows; and eventually replacing all affected parts, within 90 days, which eliminates the need for the repetitive inspections. This AD also prohibits the installation of affected parts.

Justification for Immediate Adoption and Determination of the Effective Date

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

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies forgoing notice and comment prior to adoption of this rule because due to the lack of a fail-safe design and failure of the window's inner pane to meet maximum operating pressure, a complete failure of the outer window pane could result in possible serious injury to a passenger near the window due to rapid decompression, and consequent reduced ability of the flightcrew to maintain the safe flight

and landing of the airplane. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(3)(B).

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

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include Docket No. FAA–2022–0451 and Project Identifier AD–2022–00265–T at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Jacob Fitch, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–4130; email *jacob.fitch@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act

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

Costs of Compliance

The FAA estimates that this AD affects up to 65 airplanes of U.S. registry. (A total of 65 affected parts were produced.) The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Part number inspection	Up to 1 work-hour × $85 per hour = $85.	$0	$85	Up to $5,525.

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Repetitive inspection for cracking	1 work-hour × $85 per hour = $85	$0	$85 per inspection cycle.
Replacement	2 work-hours × $85 per hour = $170	500	$670.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2022–08–07 Embraer S.A. (Type Certificate Previously Held by Yaborã Indústria Aeronáutica S.A.): Amendment 39–22010 ; Docket No. FAA–2022–0451; Project Identifier AD–2022–00265–T.

(a) Effective Date

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

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Embraer S.A. airplanes identified in paragraphs (c)(1) through (4) of this AD, certificated in any category.

(1) Model ERJ 170–100 STD, –100 LR, –100 SU, and –100 SE airplanes.

(2) Model ERJ 170–200 STD, –200 LR, and –200 SU airplanes.

(3) Model ERJ 190–100 STD, –100 LR, –100 IGW, and –100 ECJ airplanes.

(4) Model ERJ 190–200 STD, –200 LR, and –200 IGW airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 56, Windows.

(e) Unsafe Condition

This AD was prompted by a report of the failure of the inner pane of the passenger window to meet maximum operating pressure and lack of fail-safe design. The FAA is issuing this AD to address this condition, which could result in possible serious injury to a passenger near the window due to rapid decompression, and consequent reduced ability of the flightcrew to maintain the safe flight and landing of the airplane.

(f) Compliance

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

(g) Definition of Affected Parts

Affected parts are NORDAM passenger windows having part number NP00038–3.

(h) Identification of Affected Parts

Before further flight, determine whether any affected part is installed on the airplane. A review of the airplane maintenance records is acceptable, if the manufacturer and part number of the installed windows can be conclusively determined from that review.

Note 1 to paragraph (h): Guidance for the actions required by paragraph (h) of this AD can be found in NORDAM Alert Service Bulletin ERJ 56–A01, dated January 18, 2022.

(1) *If any affected part is installed:* Before further flight, do a visual inspection of the outer window pane for cracking, and do the applicable action specified in paragraph (h)(1)(i) or (ii) of this AD.

(i) If any cracking is found, before further flight, replace the affected part with a serviceable window.

(ii) If no cracking is found, repeat the inspection thereafter before each flight, until the affected part is replaced, as specified in paragraph (h)(2) of this AD.

(2) Within 90 days after the effective date of this AD: Replace all affected parts installed on the airplane with serviceable windows.

(i) Terminating Action for Repetitive Inspections

Replacement of an affected part, as specified in paragraph (h)(2) of this AD, terminates the repetitive inspection requirements specified in paragraph (h)(1)(ii) of this AD for that part.

(j) Parts Installation Prohibition

As of the effective date of this AD, no person may install a NORDAM passenger window, part number (P/N) NP00038–3, on any airplane.

(k) Alternative Methods of Compliance (AMOCs).

(1) The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (l) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

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

(l) Related Information

For more information about this AD, contact Jacob Fitch, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–4130; email *jacob.fitch@faa.gov.*

(m) Material Incorporated by Reference

None.

Issued on April 4, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–07708 Filed 4–6–22; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1146; Airspace Docket No. 21–AGL–36]

RIN 2120–AA66

Amendment of Class E Airspace; Hallock, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at Hallock, MN. This action due to an airspace review conducted as part of the decommissioning of the Humbolt very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program.

DATES: Effective 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

700 feet above the surface at Hallock Municipal Airport, Hallock, MN, to support instrument flight rule operations at this airport.

History

The FAA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (86 FR 73203; December 27, 2021) for Docket No. FAA–2021–1146 to amend the Class E airspace at Hallock, MN. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Differences From the NPRM

Subsequent to publication, the FAA discovered a typographical error in the title of the NPRM, ''Proposed Establishment of Class E Airspace; Hallock, MN'' should have been ''Proposed Amendment of Class E Airspace; Hallock, MN''. As this error was only in the title and does not impact the actual airspace being amended, it has been corrected in this action.

The Rule

This amendment to 14 CFR part 71 amends the Class E airspace extending upward from 700 feet above the surface at Hallock Municipal Airport, Hallock, MN, by removing the extension to the southeast of the airport as it is no longer needed.

This action is due to an airspace review conducted as part of the decommissioning of the Humbolt VOR, which provided navigation information for the instrument procedures at these airports, as part of the VOR MON Program.

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

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

71.1 [Amended]

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

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

* * * * *

AGL MN E5 Hallock, MN [Amended]

Hallock Municipal Airport, MN
(Lat. 48°45′10″ N, long. 96°56′35″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Hallock Municipal Airport.

Issued in Fort Worth, Texas, on April 5, 2022.

Martin A. Skinner,

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

[FR Doc. 2022–07590 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1147; Airspace Docket No. 21–AGL–37]

RIN 2120–AA66

Amendment of Class E Airspace; Pembina, ND

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at Pembina, ND. This action is due to an airspace review conducted as part of the decommissioning of the Humbolt very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program. The geographic coordinates of the airport are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation

Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

History

The FAA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (86 FR 73200; December 27, 2021) for Docket No. FAA–2021–1147 to amend the Class E airspace at Pembina, ND. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Differences From the NPRM

Subsequent to publication, the FAA discovered a typographical error in the title of the NPRM, ''Proposed Establishment of Class E Airspace; Pembina, ND'' should have been ''Proposed Amendment of Class E Airspace; Pembina, ND''. As this error was only in the title and does not impact the actual airspace being amended, it has been corrected in this action.

The Rule

This amendment to 14 CFR part 71 amends the Class E airspace extending upward from 700 feet above the surface to within a 6.4-mile (increased from a 6.2-mile) radius of Pembina Municipal Airport, Pembina, ND; removes the Humbolt VORTAC and associated extension from the airspace legal description; removes Grand Forks AFB, Devils Lake VOR/DME, and the airspace extending upward from 1,200 feet above the surface from the airspace legal description as it is covered by the Class E airspace extending upward from 1,200 feet above the surface over the State of North Dakota, is redundant, and no longer needed; adds exclusionary language north of latitude 49°00′00″ N. that prevents the airspace from extending into Canadian airspace; and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is due to an airspace review conducted as part of the decommissioning of the Humbolt VOR, which provided navigation information for the instrument procedures at this airport, as part of the VOR MON Program.

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

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

71.1 [Amended]

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

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

* * * * *

AGL ND E5 Pembina, ND [Amended]

Pembina Municipal Airport, ND
(Lat. 48°56′33″ N, long. 97°14′26″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Pembina Municipal Airport, excluding that airspace north of lat. 49°00′00″ N.

Issued in Fort Worth, Texas, on April 5, 2022.

Martin A. Skinner,

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

[FR Doc. 2022–07591 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1148; Airspace Docket No. 21–AGL–38]

RIN 2120–AA66

Amendment of Class E Airspace; Springfield, OH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at Springfield, OH. This action is due to an airspace review conducted as part of the decommissioning of the Springfield very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program.

DATES: Effective 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class E airspace extending upward from 700 feet above the surface at Springfield-Beckley Municipal Airport, Springfield, OH, to support instrument flight rule operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (86 FR 73717; December 28, 2021) for Docket No. FAA–2021–1148 to amend the Class E airspace at Springfield, OH. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received. Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 amends the Class E airspace extending upward from 700 feet above the surface at Springfield-Beckley Municipal Airport, Springfield, OH, by removing the Clark County NDB and associated extension from the airspace legal description as they are no longer needed.

This action is due to an airspace review conducted as part of the decommissioning of the Springfield VOR, which provided navigation information for the instrument procedures at this airport, as part of the VOR MON Program.

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

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

71.1 [Amended]

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

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

* * * * *

AGL OH E5 Springfield, OH [Amended]

Springfield-Beckley Municipal Airport, OH
(Lat. 39°50′25″ N, long. 83°50′25″ W)

That airspace extending upward from 700 feet above the surface within a 6.9-mile

radius of Springfield-Beckley Municipal Airport.

Issued in Fort Worth, Texas, on April 5, 2022.

Martin A. Skinner,

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

[FR Doc. 2022–07592 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1145; Airspace Docket No. 21–AGL–35]

RIN 2120–AA66

Amendment of Class E Airspace; Multiple Michigan Towns

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at Cadillac, MI; Ludington, MI; and Manistee, MI. This action due to airspace reviews conducted as part of the decommissioning of the Manistee very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program. The names and geographic coordinates of various airports are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class E airspace extending upward from 700 feet above the surface at Wexford County Airport, Cadillac, MI; Mason County Airport, Ludington, MI; and Manistee County/Blacker Airport, Manistee, MI, to support instrument flight rule operations at these airports.

History

The FAA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (86 FR 73202; December 27, 2021) for Docket No. FAA–2021–1145 to amend the Class E airspace at Cadillac, MI; Ludington, MI; and Manistee, MI. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Differences From the NPRM

Subsequent to publication, the FAA discovered a typographical error in the title of the NPRM, ''Proposed Establishment of Class E Airspace; Multiple Michigan Towns'' should have been ''Proposed Amendment of Class E Airspace; Multiple Michigan Towns''. As this error was only in the title and does not impact the actual airspace being amended, it has been corrected in this action.

The Rule

This amendment to 14 CFR part 71:

Amends the Class E airspace extending upward from 700 feet above the surface to within a 6.6-mile (decreased from a 6.7-mile) radius of Wexford County Airport, Cadillac, MI; and removes the city associated with the airport in the header to comply with changes to FAA Order JO 7400.2N, Procedures for Handling Airspace Matters;

Amends the Class E airspace extending upward from 700 feet above the surface to within a 6.6-mile (decreased from a 7-mile) radius of Mason County Airport, Ludington, MI; removes the city associated with the airport in the header to comply with changes to FAA Order JO 7400.2N; and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database;

And amends the Class E airspace extending upward from 700 feet above the surface to within a 6.6-mile (decreased from a 7-mile) radius of Manistee County/Blacker Airport, Manistee, MI; removes the Manistee VOR/DME and associated extensions from the airspace legal description; adds an extension 6.5 miles north and 5.3 miles south of the 091° bearing from the Manistee County/Blacker Airport: RWY 28–LOC extending from the 6.6-mile radius of the airport to 16.5 miles east of the Manistee County/Blacker Airport: RWY 28–LOC; adds an extension 2.2 miles each side of the 271° bearing from the airport extending from the 6.6-mile radius of the airport to 10 miles west of the airport; and updates the airport name (previously Manistee County—Blacker Airport) to coincide with the FAA's aeronautical database.

This action is due to airspace reviews conducted as part of the decommissioning of the Manistee VOR, which provided navigation information for the instrument procedures at these airports, as part of the VOR MON Program.

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

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a

''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

71.1 [Amended]

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

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

* * * * *

AGL MI E5 Cadillac, MI [Amended]

Wexford County Airport, MI
(Lat. 44°16′31″ N, long. 85°25′08″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of the Wexford County Airport.

* * * * *

AGL MI E5 Ludington, MI [Amended]

Mason County Airport, MI
(Lat. 43°57′45″ N, long. 86°24′29″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Mason County Airport.

* * * * *

AGL MI E5 Manistee, MI [Amended]

Manistee County/Blacker Airport, MI
(Lat. 44°16′21″ N, long. 86°14′49″ W)
Manistee County/Blacker Airport: RWY 28–LOC
(Lat. 44°16′22″ N, long. 86°15′31″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of the Manistee County/Blacker Airport, and within 6.5 miles north and 5.3 miles south of the 091° bearing from the Manistee County/Blacker Airport: RWY 28–LOC extending from the 6.6-mile radius of the airport to 16.5 miles east of the Manistee County/Blacker Airport: RWY 28–LOC, and within 2.2 miles each side of the 271° bearing from the airport extending from the 6.6-mile radius of the airport to 10 miles west of the airport.

Issued in Fort Worth, Texas, on April 5, 2022.

Martin A. Skinner,

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

[FR Doc. 2022–07588 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1150; Airspace Docket No. 21–ASW–28]

RIN 2120–AA66

Amendment of the Class E Airspace; Watonga, OK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at Watonga, OK. This action is due to an airspace review conducted as part of the decommissioning of the Kingfisher very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program. The name and geographic coordinates of the airport are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, July 14, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (87 FR 2566; January 18, 2022) for Docket No. FAA–2021–1150 to amend the Class E airspace at Watonga, OK. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10,

2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 amends the Class E airspace extending upward from 700 feet above the surface to within a 6.4-mile (decreased from a 6.5-mile) radius of Watonga Regional Airport, Watonga, OK; and updating the name (previously Watonga Airport) and geographic coordinates of the airport to coincide with the FAA's aeronautical database. This action is the result of an airspace review conducted as part of the decommissioning of the Kingfisher VOR, which provided navigation information for the instrument procedures at this airport, as part of the VOR MON Program.

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

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

71.1 [Amended]

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

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

* * * * *

ASW OK E5 Watonga, OK [Amended]

Watonga Regional Airport, OK
(Lat. 35°51′52″ N, long. 98°25′15″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Watonga Regional Airport.

Issued in Fort Worth, Texas, on April 5, 2022.

Martin A. Skinner,

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

[FR Doc. 2022–07593 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 220203–0039]

RIN 0694–AI70

Addition of Certain Entities to the Entity List; Correction

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Correcting amendments.

SUMMARY: The Bureau of Industry and Security (BIS) publishes these amendments to correct three errors contained in the revisions to the Entity List that were published in a final rule on February 14, 2022. That final rule amended the Export Administration Regulations (EAR) by revising the Entity List entry for ''Huawei Cloud Brazil'' (under Brazil) and by adding a new entry for ''Huawei Technologies Co., Ltd.'' (under China, People's Republic of). However, the references to the foreign direct product provisions in the EAR that apply to these two entities were incorrect. This rule amends the entries for the two entities to include the correct references to these EAR provisions and also corrects a typographical error in one of these entries.

DATES: This rule is effective April 11, 2022. This rule is applicable as of February 14, 2022.

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

SUPPLEMENTARY INFORMATION: The Entity List in supplement no. 4 to part 744 of the Export Administration Regulations (EAR) (15 CFR parts 730–774) identifies entities for which there is reasonable cause to believe, based on specific and articulable facts, that the entities have been involved, are involved, or pose a significant risk of being or becoming involved in activities contrary to the national security or foreign policy interests of the United States. The EAR impose additional license requirements on, and limit the availability of most license exceptions for, exports, reexports and transfers (in-country) to listed entities. These additional license requirements are referenced, together with other relevant EAR provisions, in the ''License requirement'' column for each entity. The license review policy for each listed entity is identified in the ''License review policy'' column for that entity on the Entity List, and the impact on the availability of license exceptions is described in the relevant **Federal Register** document adding the entities to the Entity List. BIS places entities on the Entity List pursuant to part 744 (Control Policy: End-User and End-Use Based) and part 746 (Embargoes and Other Special Controls) of the EAR.

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

decisions to remove or modify an entry by unanimous vote.

On February 14, 2022 (87 FR 8180), BIS published a final rule titled ''Addition of Certain Entities to the Entity List,'' which amended the Entity List by, *inter alia,* revising the entry for ''Huawei Cloud Brazil'' (under Brazil) and adding a new entry for ''Huawei Technologies Co., Ltd.'' (under China, People's Republic of). However, the references to certain EAR foreign direct product provisions that were identified in the ''License requirement'' column for each of these entities were incorrect. Specifically, the ''License requirement'' column for each of these entries incorrectly referenced § 736.2(b)(3)(vi) of the EAR, instead of § 734.9(e) of the EAR.

The references to § 734.9(e) of the EAR were added to a number of entities on the Entity List, replacing previous references to § 736.2(b)(3)(vi) of the EAR, by a final rule that BIS published in the **Federal Register** on February 3, 2022 (87 FR 6022). That final rule consolidated the foreign direct product (FDP) provisions in § 734.9 of the EAR. Prior to the publication of the February 3, 2022, final rule (hereinafter, the ''FDP rule''), the FDP provisions of the EAR were found in § 736.2(b)(3) (General Prohibition 3) and footnote 1 to supplement no. 4 to part 744 (the Entity List). The FDP rule relocated the license requirement, license review policy, and license exception applicability provisions for certain listed entities from the Entity List's footnote 1 to § 744.11(a) of the EAR, where the overall license requirements pertaining to listed entities are located. In addition, the FDP rule moved the description of the product scope and end-user scope of the Entity List FDP requirements from the aforementioned footnote 1 to § 734.9 of the EAR, where the FDP provisions are now consolidated. However, the scope of the global amendatory instruction that made conforming changes to the Entity List table in supplement no. 4 to part 744 did not include the entry for ''Huawei Cloud Brazil'' (under Brazil). As a result, the reference to § 736.2(b)(3), in the ''License requirement'' column for this entity was not removed and replaced with a reference to § 734.9(e) as should have been the case.

Although the February 14, 2022, Entity List rule included a revision of the entry for ''Huawei Cloud Brazil'' (under Brazil), the rule inadvertently failed to change the reference in the ''License requirement'' column for this entity from § 736.2(b)(3) to § 734.9(e). Furthermore, the addition of a new entry for ''Huawei Technologies Co., Ltd.'' (under China, People's Republic of) to the Entity List, also incorrectly referenced § 736.2(b)(3), instead of § 734.9(e), in the ''License requirement'' column for the entity.

These correcting amendments revise the ''License requirement'' column in each of the aforementioned Entity List entries to correctly reference § 734.9(e), instead of § 736.2(b)(3). These amendments also correct a typographical error, in the ''License requirement'' column for ''Huawei Technologies Co., Ltd.'' (under China, People's Republic of), by revising the phrase ''except for'' to read ''EXCEPT[2] for'', consistent with the application of Entity List footnote 2 to this entity (*i.e.,* with respect to the provision of ongoing security research critical to maintaining the integrity and reliability of an existing and currently fully operational 'third party' network and equipment providing services to the 'third party's' customers—in this instance, the term 'third party' refers to a party that is not Huawei, one of its listed non-U.S. affiliates, or the exporter, reexporter, or transferor, but rather an organization such as a telecommunications service provider).

List of Subjects in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

For the reasons stated in the preamble, part 744 of the Export Administration Regulations (15 CFR parts 730–774) is corrected by making the following correcting amendments:

PART 744—[AMENDED]

■ 1. The authority citation for 15 CFR part 744 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of September 15, 2021, 86 FR 52069 (September 17, 2021); Notice of November 10, 2021, 86 FR 62891 (November 12, 2021).

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

■ a. Under BRAZIL by revising the entry for ''Huawei Cloud Brazil''; and

■ b. Under CHINA, PEOPLE'S REPUBLIC OF by revising the entry for ''Huawei Technologies Co., Ltd.''.

The revisions read as follows:

Supplement No. 4 to Part 744—Entity List

* * * * *

Country	Entity	License requirement	License review policy	Federal Register citation
*	* * *	*	* *	*
BRAZIL	Huawei Cloud Brazil, Sao Paulo, Brazil.	For all items subject to the EAR, see §§ 734.9(e),[1] and 744.11 of the EAR, EXCEPT[2] for technology subject to the EAR that is designated as EAR99, or controlled on the Commerce Control List for anti-terrorism reasons only, when released to members of a "standards organization" (see § 772.1) for the purpose of contributing to the revision or development of a "standard" (see § 772.1).	Presumption of denial	85 FR 51603, 8/20/20. 87 FR 8182, 2/14/22. 87 FR [INSERT FR PAGE NUMBER] 4/11/22.
*	* * *	*	* *	*
*	* * *	*	* *	*
CHINA, PEOPLE'S REPUBLIC OF.	* * *	*	* *	*
	Huawei Technologies Co., Ltd., a.k.a., the following two aliases: —Shenzhen Huawei Technologies; *and* —Huawei Technology, and to include the following addresses and the following 22 affiliated entities: Addresses for Huawei Technologies Co., Ltd.: Bantian Huawei Base, Longgang District, Shenzhen, 518129, China; *and* No. 1899 Xi Yuan Road, High-Tech West District, Chengdu, 611731; *and* C1, Wuhan Future City, No. 999 Gaoxin Ave., Wuhan, Hebei Province; *and* Banxuegang Industrial Park, Buji Longgang, Shenzhen, Guangdong, 518129, China; *and* R&D Center, No. 2222, Golden Bridge Road, Pu Dong District, Shanghai, China; *and* Zone G, Huawei Base, Bantian, Longgang District, Shenzhen, China; *and* Tsim Sha Tsui, Kowloon, Hong Kong.	For all items subject to the EAR, see §§ 734.9(e),[1] and 744.11 of the EAR, EXCEPT[2] for technology subject to the EAR that is designated as EAR99, or controlled on the Commerce Control List for anti-terrorism reasons only, when released to members of a "standards organization" (see § 772.1) for the purpose of contributing to the revision or development of a "standard" (see § 772.1).	Presumption of denial	84 FR 22963, 5/21/19. 84 FR 43495, 8/21/19. 85 FR 29853, 5/19/20. 85 FR 36720, 6/18/20. 85 FR 51603, 8/20/20. 87 FR 8182, 2/14/22. 87 FR [INSERT FR PAGE NUMBER] 4/11/22.

Country	Entity	License requirement	License review policy	**Federal Register** citation
	Affiliated entities: *Beijing Huawei Longshine Information Technology Co., Ltd.,* a.k.a., the following one alias: —Beijing Huawei Longshine, to include the following subordinate. Q80–3–25R, 3rd Floor, No. 3, Shangdi Information Road, Haidian District, Beijing, China. *Hangzhou New Longshine Information Technology Co., Ltd.,* Room 605, No. 21, Xinba, Xiachang District, Hangzhou, China. *Hangzhou Huawei Communication Technology Co., Ltd.,* Building 1, No. 410, Jianghong Road, Changhe Street, Binjiang District, Hangzhou, Zhejiang, China. *Hangzhou Huawei Enterprises,* No. 410 Jianghong Road, Building 1, Hangzhou, China. *Huawei Digital Technologies (Suzhou) Co., Ltd.,* No. 328 XINHU STREET, Building A3, Suzhou (Huawei R&D Center, Building A3, Creative Industrial Park, No. 328, Xinghu Street, Suzhou), Suzhou, Jiangsu, China. *Huawei Marine Networks Co., Ltd.,* a.k.a., the following four aliases: —Huawei Marine; —HMN Technologies; —Huahai Zhihui Technology Co., Ltd.,; *and* —HMN Tech. Building R4, No. 2 City Avenue, Songshan Lake Science & Tech Industry Park, Dongguan, 523808, *and* No. 62, Second Ave., 5/F–6/F, TEDA, MSD–B2 Area, Tianjin Economic and Technological Development Zone, Tianjin, 300457, China. *Huawei Mobile Technology Ltd.,* Huawei Base, Building 2, District B, Shenzhen, China. *Huawei Tech. Investment Co.,* U1 Building, No. 1899 Xiyuan Avenue, West Gaoxin District, Chengdu City, 611731, China. *Huawei Technology Co., Ltd. Chengdu Research Institute,* No. 1899, Xiyuan Ave., Hi-Tech Western District, Chengdu, Sichuan Province, 610041, China. *Huawei Technology Co., Ltd. Hangzhou Research Institute,* No. 410, Jianghong Rd., Building 4, Changhe St., Binjiang District, Hangzhou, Zhejiang Province, 310007, China. *Huawei Technologies Co., Ltd. Beijing Research Institute,* No. 3, Xinxi Rd., Huawei Building, ShangDi Information Industrial Base, Haidian District, Beijing, 100095, China; *and* No. 18, Muhe Rd., Building 1–4, Haidian District, Beijing, China. *Huawei Technologies Co., Ltd. Material Characterization Lab,* Huawei Base, Bantian, Shenzhen 518129, China.			

Country	Entity	License requirement	License review policy	Federal Register citation
	Huawei Technologies Co., Ltd. Xi'an Research Institute, National Development Bank Building (Zhicheng Building), No. 2, Gaoxin 1st Road, Xi'an High-tech Zone, Xi'an, China. *Huawei Terminal (Shenzhen) Co., Ltd.,* Huawei Base, B1, Shenzhen, China. *Nanchang Huawei Communication Technology,* No. 188 Huoju Street, F10–11, Nanchang, China. *Ningbo Huawei Computer & Net Co., Ltd.,* No. 48 Daliang Street, Ningbo, China. *Shanghai Huawei Technologies Co., Ltd.,* R&D center, No. 2222, Golden Bridge Road, Pu Dong District, Shanghai, 286305 Shanghai, China, China. *Shenzhen Huawei Anjiexin Electricity Co., Ltd.,* a.k.a., the following one alias: -Shenzhen Huawei Agisson Electric Co., Ltd. Building 2, Area B, Putian Huawei Base, Longgang District, Shenzhen, China; *and* Huawei Base, Building 2, District B, Shenzhen, China. *Shenzhen Huawei New Technology Co., Ltd.,* Huawei Production Center, Gangtou Village, Buji Town, Longgang District, Shenzhen, China. *Shenzhen Huawei Technology Service,* Huawei Base, Building 2, District B, Shenzhen, China. *Shenzhen Huawei Technologies Software,* Huawei Base, Building 2, District B, Shenzhen, China. *Zhejiang Huawei Communications Technology Co., Ltd.,* No. 360 Jiangshu Road, Building 5, Hangzhou, Zhejiang, China.			
*	* * * * * * *			

[1] For this entity, see § 734.9(e) of the EAR for foreign-produced items that are subject to the EAR and § 744.11 of the EAR for related license requirements, license review policy, and applicable license exceptions.

[2] *Cybersecurity research and vulnerability disclosure.* The following exports, reexports, and transfers (in-country) to Huawei Technologies Co., Ltd. (Huawei) and its non-U.S. affiliates on the Entity List for cybersecurity research and vulnerability disclosure subject to other provisions of the EAR are excluded from the Entity List license requirements: when the disclosure to Huawei and/or to its listed non-U.S. affiliates is limited to information regarding security vulnerabilities in items owned, possessed, or controlled by Huawei or any of its non-U.S. affiliates when related to the process of providing ongoing security research critical to maintaining the integrity and reliability of existing and currently 'fully operational network' and equipment. A 'fully operational network' refers to a 'third party' network providing services to the 'third party's' customers. The term 'third party' refers to a party that is not Huawei, one of its listed non-U.S. affiliates, or the exporter, reexporter, or transferor, but rather an organization such as a telecommunications service provider.

* * * * *

Thea D. Rozman Kendler,

Assistant Secretary for Export Administration.

[FR Doc. 2022–07643 Filed 4–8–22; 8:45 am]

BILLING CODE 3510–33–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 211

[Release No. SAB 121]

Staff Accounting Bulletin No. 121

AGENCY: Securities and Exchange Commission.

ACTION: Publication of staff accounting bulletin.

SUMMARY: This staff accounting bulletin expresses the views of the staff regarding the accounting for obligations to safeguard crypto-assets an entity holds for platform users.

DATES: *Effective* April 11, 2022.

FOR FURTHER INFORMATION CONTACT: Karmen Ward, Professional Accounting Fellow, Office of the Chief Accountant at (202) 551–5300, or Todd E. Hardiman, Associate Chief Accountant, Division of Corporation Finance at (202) 551–3400, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SUPPLEMENTARY INFORMATION: The statements in staff accounting bulletins are not rules or interpretations of the Commission, nor are they published as bearing the Commission's official approval. They represent staff interpretations and practices followed by the staff in the Division of Corporation Finance and the Office of the Chief Accountant in administering the disclosure requirements of the federal securities laws.

Dated: March 31, 2022.

J. Matthew DeLesDernier,

Assistant Secretary.

Accordingly, Part 211 of Title 17 of the Code of Federal Regulations is amended as follows:

PART 211—INTERPRETATIONS RELATING TO FINANCIAL REPORTING MATTERS

■ 1. The authority citation for 17 CFR 211 continues to read as follows:

Authority: 15 U.S.C. 77g, 15 U.S.C. 77s(a), 15 U.S.C. 77aa(25) and (26), 15 U.S.C. 78c(b), 15 U.S.C. 78l(b), 15 U.S.C. 78m(b), 15 U.S.C. 80a–8, 15 U.S.C. 80a–29(e), 15 U.S.C. 80a–30, and 15 U.S.C. 80a–37(a).

■ 2. Amend the table in subpart B by adding an entry for Staff Accounting Bulletin No. 121 at the end of the table to read as follows:

Subpart B—Staff Accounting Bulletins

Subject	Release No.	Date	Fed. Reg. vol. and page
* * *	*	* * *	*
Publication of Staff Accounting Bulletin No. 121	SAB121	April 11, 2022	[INSERT **FEDERAL REGISTER** CITATION].

Note: The text of Staff Accounting Bulletin No. 121 will not appear in the Code of Federal Regulations.

Staff Accounting Bulletin No. 121

The staff hereby adds Section FF to Topic 5 of the Staff Accounting Bulletin Series. This staff accounting bulletin (''SAB'') adds interpretive guidance for entities to consider when they have obligations to safeguard crypto-assets held for their platform users. This SAB is applicable to entities that file reports pursuant to Sections 13(a) or 15(d) of the Securities Exchange Act of 1934 (''Exchange Act'') and entities that have submitted or filed a registration statement under the Securities Act of 1933 (''Securities Act'') or the Exchange Act that is not yet effective. The SAB is also applicable to entities submitting or filing an offering statement or post-qualification amendment thereto under Regulation A, entities subject to the periodic and the current reporting requirements of Regulation A, and private operating companies whose financial statements are included in filings with the SEC in connection with a business combination involving a shell company, including a special purpose acquisition company. Accordingly, the staff hereby amends the Staff Accounting Bulletin Series as follows:

* * * * *

Topic 5: Miscellaneous Accounting

* * * * *

The interpretations in this SAB express views of the staff regarding the accounting for entities that have obligations to safeguard crypto-assets held for their platform users.[1] In recent years, the staff has observed an increase in the number of entities that provide platform users with the ability to transact in crypto-assets. In connection with these services, these entities and/or their agents may safeguard the platform user's crypto-asset(s) and also maintain the cryptographic key information necessary to access the crypto-asset. The obligations associated with these arrangements involve unique risks and uncertainties not present in arrangements to safeguard assets that are not crypto-assets, including technological, legal, and regulatory risks and uncertainties. Specifically:

- *Technological risks*—there are risks with respect to both safeguarding of assets and rapidly-changing crypto-assets in the market that are not present with other arrangements to safeguard assets for third parties;
- *Legal risks*—due to the unique characteristics of the assets and the lack of legal precedent, there are significant legal questions surrounding how such arrangements would be treated in a court proceeding arising from an adverse event (*e.g.,* fraud, loss, theft, or bankruptcy); and
- *Regulatory risks*—as compared to many common arrangements to safeguard assets for third parties, there are significantly fewer regulatory requirements for holding crypto-assets for platform users or entities may not be complying with regulatory requirements that do apply, which results in increased risks to investors in these entities.

These risks can have a significant impact on the entity's operations and financial condition. The staff believes that the recognition, measurement, and disclosure guidance in this SAB will enhance the information received by investors and other users of financial statements about these risks, thereby assisting them in making investment and other capital allocation decisions.

FF. Accounting for Obligations To Safeguard Crypto-Assets an Entity Holds for Its Platform Users

Facts: Entity A's[2] business includes operating a platform that allows its users to transact in crypto-assets.[3] Entity A also provides a service where it will safeguard the platform users' crypto-assets,[4] including maintaining the cryptographic key information[5] necessary to access the crypto-assets. Entity A also maintains internal recordkeeping of the amount of crypto-assets held for the benefit of each platform user. Entity A secures these crypto-assets and protects them from loss or theft, and any failure to do so exposes Entity A to significant risks, including a risk of financial loss. The platform users have the right to request that Entity A transact in the crypto-asset on the user's behalf (*e.g.,* to sell the crypto-asset and provide the user with the fiat currency (cash) proceeds associated with the sale) or to transfer the crypto-asset to a digital wallet for which Entity A does not maintain the cryptographic key information.

[1] This SAB expresses no view with respect to any other questions that these activities may raise for any of the entities involved, including the applicability of the registration or other provisions of the federal securities laws or any other federal, state, or foreign laws.

[2] References throughout this SAB to ''Entity A'' are inclusive of the entity as well as any agent acting on its behalf in safeguarding the platform users' crypto-assets.

[3] For purposes of this SAB, the term ''crypto-asset'' refers to a digital asset that is issued and/or transferred using distributed ledger or blockchain technology using cryptographic techniques.

[4] The service may be provided by Entity A or by an agent acting on Entity A's behalf.

[5] The guidance in this SAB is applicable regardless of whether the cryptographic key remains in the name of the platform user or is in the name of the Entity.

However, execution and settlement of transactions involving the platform users' crypto-assets may depend on actions taken by Entity A.

Question 1: How should Entity A account for its obligations to safeguard crypto-assets held for platform users?

Interpretive Response: The ability of Entity A's platform users to obtain future benefits from crypto-assets in digital wallets where Entity A holds the cryptographic key information is dependent on the actions of Entity A to safeguard the assets. Those actions include securing the crypto-assets and the associated cryptographic key information and protecting them from loss, theft, or other misuse. The technological mechanisms supporting how crypto-assets are issued, held, or transferred, as well as legal uncertainties regarding holding crypto-assets for others, create significant increased risks to Entity A, including an increased risk of financial loss.[6] Accordingly, as long as Entity A is responsible for safeguarding the crypto-assets held for its platform users, including maintaining the cryptographic key information necessary to access the crypto-assets, the staff believes that Entity A should present a liability on its balance sheet to reflect its obligation to safeguard the crypto-assets held for its platform users.

As Entity A's loss exposure is based on the significant risks associated with safeguarding the crypto-assets held for its platform users, the staff believes it would be appropriate to measure this safeguarding liability at initial recognition and each reporting date at the fair value [7] of the crypto-assets that Entity A is responsible for holding for its platform users. The staff also believes it would be appropriate for Entity A to recognize an asset [8] at the same time that it recognizes the safeguarding liability, measured at initial recognition and each reporting date at the fair value of the crypto-assets held for its platform users.[9]

Question 2: Assume the same facts as Question 1. What disclosures would the staff expect Entity A to provide regarding its safeguarding obligations for crypto-assets held for its platform users?

Interpretive Response: In light of the significant risks and uncertainties associated with safeguarding crypto-assets, including the risks of loss associated with holding the cryptographic key information necessary to secure and transact in the crypto-asset, the staff believes the notes to the financial statements should include clear disclosure of the nature and amount of crypto-assets that Entity A is responsible for holding for its platform users, with separate disclosure for each significant crypto-asset, and the vulnerabilities Entity A has due to any concentration in such activities.[10] In addition, because the crypto-asset safeguarding liabilities and the corresponding assets are measured at the fair value of the crypto-assets held for its platform users, the entity would be required to include disclosures regarding fair value measurements.[11] The accounting for the liabilities and corresponding assets should be described in the footnotes to the financial statements.[12] In providing these disclosures, Entity A should consider disclosure about who (*e.g.,* the company, its agent, or another third party) holds the cryptographic key information, maintains the internal recordkeeping of those assets, and is obligated to secure the assets and protect them from loss or theft.

Disclosures regarding the significant risks and uncertainties associated with the entity holding crypto-assets for its platform users may also be required outside the financial statements under existing Commission rules, such as in the description of business, risk factors, or management's discussion and analysis of financial condition and results of operation.[13] For example, to the extent it is material, Entity A may need to provide disclosure describing the types of loss or additional obligations that could occur, including customer or user discontinuation or reduction of use of services, litigation, reputational harm, and regulatory enforcement actions and additional restrictions. A discussion of the analysis of the legal ownership of the crypto-assets held for platform users, including whether they would be available to satisfy general creditor claims in the event of a bankruptcy should be considered. Further, Entity A may need to provide disclosure of the potential impact that the destruction, loss, theft, or compromise or unavailability of the cryptographic key information would have to the ongoing business, financial condition, operating results, and cash flows of the entity. As part of this disclosure, Entity A should also consider including, to the extent material, information about risk-mitigation steps the entity has put in place (*e.g.,* insurance coverage directly related to the crypto-assets held for platform users).

Question 3: How and when should Company A initially apply the guidance in this Topic in its financial statements?

Interpretive Response: The staff would expect an entity that files reports pursuant to Section 13(a) or Section 15(d) of the Exchange Act, or an entity required to file periodic and current reports pursuant to Rule 257(b) of Regulation A, to apply the guidance in Topic 5.FF no later than its financial statements covering the first interim or annual period ending after June 15, 2022, with retrospective application as of the beginning of the fiscal year to which the interim or annual period relates.

The staff expects all other entities, including but not limited to entities conducting an initial registration of securities under the Securities Act or Exchange Act, entities conducting an offering of securities under Regulation A, and private operating companies entering into a business combination transaction with a shell company, including a special purpose acquisition company, to apply the guidance in Topic 5.FF beginning with their next submission or filing with the SEC (*e.g.,* the initial or next amendment of the registration statement, proxy statement, or Form 1–A), with retrospective application, at a minimum, as of the beginning of the most recent annual period ending before June 15, 2022, provided the filing also includes a subsequent interim period that also reflects application of this guidance.[14] If

[6] *See generally* Report of the Attorney General's Cyber Digital Task Force: Cryptocurrency Enforcement Framework (Oct. 2020), at 15–16, available at *https://www.justice.gov/ag/page/file/1326061/download.*

[7] For U.S. generally accepted accounting principles (''U.S. GAAP''), refer to glossary definition provided in Financial Accounting Standards Board (''FASB'') Accounting Standards Codification (''ASC'') Topic 820. For International Financial Reporting Standards (''IFRS''), refer to glossary definition provided in IFRS 13.

[8] The asset recognized is similar in nature to an indemnification asset as described in FASB ASC 805 and IFRS 3. The measurement of the asset is on the same basis as the crypto-asset safeguarding liability assumed by the entity. The asset recognized by the entity is separate and distinct from the crypto-asset itself that has been transferred to and then held for the platform user.

[9] Similar to the guidance in FASB ASC 805 and IFRS 3, Entity A would need to evaluate whether any potential loss events, such as theft, impact the measurement of the asset.

[10] For U.S. GAAP, *see* FASB ASC 275–10–50. For IFRS, *see* IAS 1.

[11] For U.S. GAAP, *see* FASB ASC 820. For IFRS, *see* IFRS 13.

[12] For U.S. GAAP, *see* FASB ASC 235–10–50. For IFRS, *see* IAS 1.

[13] *See, e.g.,* Item 101 of Regulation S–K; Item 105 of Regulation S–K; Item 303 of Regulation S–K.

[14] For example, a calendar year-end company that submits a registration statement in January 2023 including financial statements as of and for the fiscal year ending December 31, 2021 and as of and

Continued

the filing does not include a subsequent interim period that also reflects application of this guidance, then the staff expects it to be applied retrospectively to the beginning of the two most recent annual periods ending before June 15, 2022.

For all entities, in the financial statements that reflect the initial application of this guidance, the effect of the initial application should be reported in the carrying amounts of assets and liabilities as of the beginning of the annual period specified above. Entities should include clear disclosure of the effects of the initial application of this guidance.[15]

[FR Doc. 2022–07196 Filed 4–8–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2011–F–0365]

Food Additives Permitted in Feed and Drinking Water of Animals; Methyl Esters of Conjugated Linoleic Acid

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 methyl esters of conjugated linoleic acid for early lactation dairy cows to reduce the energy concentration in milk. This action is in response to a food additive petition filed by BASF Corp.

DATES: This rule is effective April 11, 2022. See section V of this document for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by May 11, 2022.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before May 11, 2022. The *https://www.regulations.gov* electronic filing system will accept objections until 11:59 p.m. Eastern Time at the end of May 11, 2022. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic 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–2011–F–0365 for ''Food Additives Permitted in Feed and Drinking Water of Animals; Methyl Esters of Conjugated Linoleic Acid; Silicon Dioxide.'' 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 objections 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: Megan Hall, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV–221), Rockville, MD 20855, 301–796–3801, *Megan.Hall@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the **Federal Register** of June 6, 2011 (76 FR 32332), FDA announced that we had filed a food additive petition (animal use) (FAP 2269) submitted by BASF Corp., 100 Campus Dr., Florham Park, NJ 07932. The petition proposed that the regulations for food additives permitted in feed and drinking water of

for the nine months ended September 30, 2022 would apply the SAB to those periods.

[15] For U.S. GAAP, *see* FASB ASC 250–10–50–1 through 50–3; for IFRS, *see* IAS 8. *See also, e.g.,* Item 302 of Regulation S–K and PCAOB Auditing Standard 2820 (par. 8).

animals be amended to provide for the safe use of methyl esters of conjugated linoleic acid as a source of fatty acids in lactating dairy cow diets and for the use of silicon dioxide as a carrier for the methyl esters of conjugated linoleic acid.

In 2020, 21 CFR 573.940 was amended to provide for the safe use of silicon dioxide as an anticaking agent, grinding aid, antifoaming agent, or carrier in animal feed components (ingredients, intermediate premixes, premixes, supplements, or concentrates) across food substances under FAP 2308 (85 FR 33539, June 2, 2020).

II. Conclusion

FDA concludes that the data establish the safety and utility of methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12 octadecadienoic acids) for early lactation dairy cows to reduce the energy concentration in milk, 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

We have determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provision of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of 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 § 573.637, revise the introductory text and paragraph (b) to read as follows:

§ 573.637 Methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12-octadecadienoic acids).

The food additive, methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12-octadecadienoic acids) may be safely used in swine feed and feed for early lactation dairy cows (less than 100 days in milk) in accordance with the prescribed conditions:

* * * * *

(b) The additive is used or intended for use in the feed of:

(1) Growing and finishing swine as a source of fatty acids at levels not to exceed 0.6% in the finished feed.

(2) Early lactation dairy cows to reduce the energy concentration in milk when fed at levels not to exceed 33 grams per cow per day.

* * * * *

Dated: April 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07680 Filed 4–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301, 1309, and 1321

[Docket No. DEA–587]

RIN 1117–AB58

Requiring Online Submission of Applications for and Renewals of DEA Registration

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This rulemaking amends the Drug Enforcement Administration's (DEA) regulations to now require all applications for DEA registrations, and renewal of those registrations, to be submitted online.

DATES: This final rule is effective May 11, 2022.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (571) 776–2265.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) has the legal authority to amend its regulations to require online applications pursuant to the Controlled Substances Act (CSA). The CSA grants the Attorney General authority to promulgate rules and regulations relating to: The registration and control of the manufacture, distribution, and dispensing of controlled substances and listed chemicals; reporting changes to professional or business addresses; and the efficient execution of his statutory functions. 21 U.S.C. 821, 822(a), 827(h), 871(b), 957(a). The Attorney General is further authorized by the CSA to promulgate rules and regulations relating to the registration and control of importers and exporters of controlled substances and listed chemicals. 21 U.S.C. 958(f). The Attorney General has delegated this authority to the Administrator of DEA. 28 CFR 0.100(b).

Need for Regulatory Changes

Regulatory changes are needed to modernize DEA's approach to registration and renewal applications. The proposed changes require online submission and eliminate inefficient paper applications. Typographical errors or missing pieces of information routinely resulted in delayed or rejected applications. DEA has determined the

online application process will prove more efficient and effective for both DEA and registrants.

Purpose of the Rule

This rule mitigates issues created by paper applications by simplifying the process by which registrants submit new applications for registration, or renew current registrations. Previously, DEA regulations permitted the aforementioned DEA Registration Forms (224/224a, 225/225a, 363/363a, and 510/510a) to be submitted either through a secure online portal or via delivery to DEA Headquarters.[1] This rule amends DEA regulations by requiring all registration and renewal applications be submitted only through the secure online portal. The Administration believes this rule will mitigate some of the issues associated with paper applications by reducing inefficiencies and facilitating the application process. After careful consideration, DEA has determined that it is not necessary to amend the proposed regulations related to batch processing, because the regulations currently allow, and will continue to allow, the submission of batch applications. This rule is consistent with agency-wide efforts to reduce reliance on antiquated paper submissions and to facilitate electronic document processing.[2]

Summary of Changes

This rule amends DEA regulations by revising current sections to clarify how registrants must apply, by adding new instructions, and by removing obsolete instructions. The rule amends existing DEA regulations in seven sections.[3] Title 21 CFR 1301.13 and 1301.14 are amended to remove the option to submit paper forms and provide instructions for online application and payment instructions. This rule also amends § 1301.14 (b), which will become obsolete with the adoption of the secure application portal. Section 1309.12 is amended to specify which payment options DEA will accept now that paper applications are no longer accepted. Section 1309.32 removes the option to submit paper forms and provides instructions for online applications and payments for listed chemical handlers. Section 1309.33 clarifies the online application and payment process while removing paragraph (b), which will become obsolete with the secure application portal. Section 1309.34 is also amended to clarify the handling of defective applications. Section 1321.01 is amended to remove reference to submitting paper forms by mail to any DEA Registration Unit address.

This rule affects DEA Forms relating to applications for registration and renewal of registrations, namely DEA Forms 224, 224a, 225, 225a, 363, 363a, 510, and 510a. DEA Form 224 applies to new registration applications for practitioners, hospitals and clinics, retail pharmacies, online pharmacies, central fill pharmacies, and teaching institutions.[4] DEA Form 225 applies to new registration applications for manufacturers, distributors, researchers, canine handlers, analytical laboratories, importers, and exporters.[5] DEA Form 363 applies to new registration applications for narcotic treatment programs.[6] DEA Form 510 applies to new registration applications for all domestic handlers of List I chemicals .[7] DEA Forms 224a, 225a, 363a, and 510a address registration renewal applications.[8]

Discussion of Comments

Introduction

On January 7, 2021, DEA published a notice of proposed rulemaking (''NPRM'') that proposed requiring that all applications for DEA registrations, and renewal of those registrations, be submitted online. 86 FR 1030 (Jan. 7, 2021). DEA received four comments from the public on this NPRM, three from individuals and one from the National Association of Chain Drug Stores (NACDS). After closely analyzing each comment, DEA is promulgating this rule as proposed in the NPRM with one exception: DEA is clarifying that Automated Clearing House (ACH) fund transfers will be accepted as payment for registrations and renewals.

Comment From National Association of Chain Drug Stores

DEA received a comment from NACDS on March 8, 2021, about problems that may arise once paper applications and payments are no longer accepted. In particular, NACDS expressed concern about ambiguity surrounding whether DEA will accept ''batch'' renewals, whether the whole batch will be denied if one application is denied, and whether alternative payment options will be accepted. DEA has reviewed these comments and revised § 1309.12(b) to specify that ACH funds transfer will be accepted as a payment option, in addition to credit cards and other forms of payment that may become available.

First, NACDS observed that DEA neither proposes to modify nor to address ''batch'' submissions, a process by which companies seek to renew their registrations for multiple locations with a single packet covering a number of DEA registrations and licenses. The packet usually contains a single signed affidavit as well as a single payment. NACDS believes this process allows corporations to manage the licensing and registration process of thousands of sites efficiently. Thus, NACDS expressed its desire that DEA continue to permit registrants to submit batch applications.

NACDS argued, and DEA agrees, that this process streamlines the renewal process for both companies and DEA. Accordingly, DEA's online portal will accept online batch applications and single payments for batch renewals. After careful consideration, however, DEA has determined that it is not necessary to amend the proposed regulations on this point.

Next, NACDS asserted that, ''[c]larity is needed regarding the rejection of an application submitted in a batch submission.'' In particular, NACDS argued it is unclear whether individual applications in a batch could be rejected, or whether a single faulty application would cause its entire batch to be rejected. NACDS therefore proposes that DEA create an electronic means for registrants to correct issues with individual applications in a batch, rather than having to resubmit a batch or otherwise inhibit the application process.

Amending DEA regulations is unnecessary, as this comment displays a fundamental misunderstanding of the online application process itself. Step

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[1] *https://www.deadiversion.usdoj.gov/drugreg/index.html#regapps.*

[2] *See Reporting of Theft or Significant Loss of Controlled Substances,* 85 FR 45547 (July 29, 2020) (published notice of proposed rulemaking proposing to require all DEA Form 106's to be submitted electronically); *see Suspicious Orders of Controlled Substances,* 85 FR 69282 (Nov. 2, 2020) (published notice of proposed rulemaking proposing centralized electronic reporting for Suspicious Orders Report System (SORS) based on Congressional mandate); *see Agency Rule List—Fall 2021* (2021), *https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPub=true&agencyCode=&showStage=active&agencyCd=1100&csrf_token=F19C7C599C70B80C228EC16B60AEB150F6339AF3C80E56FE003EEB7D3A758895BC8E16A215E8A0466326EBFBA8639F799E09* (Fall 2021 Unified Agenda of Regulatory and Deregulatory Actions, Active Regulatory Actions Listed By Agency, Agency Rule list noting proposed rule stage for Electronic Submission of DEA Form 41 (Registrant Record of Controlled Substances Destroyed)—1117–AB59).

[3] 21 CFR 1301.13, 1301.14, 1309.12, 1309.32, 1309.33, 1309.34, and 1321.01.

[4] 21 CFR 1301.13(e)(1)(iv).

[5] 21 CFR 1301.13(e)(1)(i)–(iii), (v)–(vi), and (viii)–(x).

[6] 21 CFR 1301.13(e)(1)(vii).

[7] 21 CFR 1309.21.

[8] 21 CFR 1301.13(e)(1) and 1309.21.

one of this process involves inputting all necessary information and attaching all relevant documents. Step two involves an internal automated verification process through which DEA's system analyzes all information submitted and determines if an application is complete. Only completed applications actually are processed, including for payment. Since this process ensures that applicants will not be able to submit incomplete applications, NACDS' concern that entire batches could be rejected based on individual application deficiencies is moot.

Last, NACDS noted that in § 1309.12(b), the only payment option listed is ''credit card.'' NACDS thus assumed that the only form of payment DEA accepts is a credit card. NACDS noted that this would be troublesome for payments made in batch renewals (which can cost in excess of $1 million), as strict corporate policies and procedures often demand that large financial transactions be conducted via certified bank check.

DEA understands and appreciates the concerns expressed by NACDS, and has therefore amended § 1309.12(b) to provide that payment shall be made online by Automated Clearing House (ACH) funds transfer, by credit card, or by any other means made available at the time of submission using the secure application portal at *www.DEAdiversion.usdoj.gov.* DEA recognizes that some companies may be required to alter their payment methods based on this rule change, as bank checks may be the most convenient option for some registrants. DEA believes, however, that the expansion of this rule to permit ACH transfers will mitigate many of the issues typically surrounding the financial, procedural, or security concerns for applicants. On balance, DEA also believes that this regulation change will promote the policy of increasing efficiency while maintaining a convenient payment process. In keeping with its broader policy of reducing reliance on tangible forms of payment, DEA will not accept bank checks for the foreseeable future.

Other Comments

One commenter supported the proposed amendments, stating the rule would be beneficial given the utilization of modern technology to submit documents electronically, as is common among other agencies. Moreover, the commenter noted that processes that were traditionally done via mail, such as fingerprints and verification of payment, can easily be verified and submitted electronically. Last, the commenter noted that the rule would be beneficial given the ''current situation and restrictions given in-person interaction.''

Another commenter supported the rule as a ''good change for the DEA,'' noting that it will prove better for the environment, more efficient, and that ''online is the future.'' The commenter does note, however, that there is a privacy concern given the potential for this information to be accessed via hacking. DEA routinely evaluates the security mechanisms of all of its electronic processes, and expends considerable time and resources to protect the privacy of all registrants and applicants.

Last, one citizen requested information as to where to locate DEA Form 225. Given the nature of the rulemaking process, DEA considers this comment to be a mistake, but nevertheless refers the commenter to *www.deadiversion.usdoj.gov* for further information.

DEA has reviewed closely all comments, and decided to promulgate the regulations as written with the exception of permitting ACH funds transfers as a payment option. DEA appreciates the public's participation in the rulemaking process, and encourages the public to continue submitting comments in the future for all proposed rules.

Regulatory Analyses

Executive Orders 12866, 13563, Regulatory Planning and Review, and Improving Regulation and Regulatory Review

This rule was promulgated in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review established in E.O. 12866.

E.O. 12866 classifies a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O.

This final rule implements all of the changes discussed in the NPRM, and thus imposes no additional costs on registrants. OMB has determined that this final rule is not a ''significant regulatory action'' under E.O. 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by OMB.

Executive Order 12988, Civil Justice Reform

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burdens. DEA expects the instant validation of online registration applications to reduce ambiguity and reduce the number of errors in submissions and reduce burdens on both DEA and registrants.

Executive Order 13132, Federalism

This rule does not have federalism implications warranting the application of E.O. 13132. 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.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

The rule does not 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.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires an agency to analyze options for regulatory relief of small entities unless it can certify that the rule will not have a significant impact on substantial number of small entities. DEA has analyzed the economic impact of each provision of this rule and estimates that it will have minimal economic impact on affected entities, including small businesses, nonprofit

organizations, and small governmental jurisdictions.

In accordance with the RFA, DEA reviewed the economic impact of this rule on small entities and evaluated the impact in the NPRM. DEA's economic impact evaluation indicated that the rule proposed in the NPRM would not have a significant economic impact on a substantial number of small entities. This conclusion applies equally to the final rule, which implements all of the changes discussed in the NPRM.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act of 1995 (UMRA),[9] DEA has determined that this action will not result in 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 1 year.'' Therefore, neither a Small Government Agency Plan nor any other action is required under the UMRA.

Paperwork Reduction Act

This rule modifies existing collection(s) of information required under the Paperwork Reduction Act (PRA).[10] Pursuant to the PRA,[11] DEA has identified the collections of information below related to this rule. A person is not required to respond to a collection of information unless it displays a valid OMB control number.[12]

DEA is amending its regulations for all new and renewal registration applications to implement the requirement of online submission through the DEA Diversion Control Division website. This amendment will improve the submission process by aligning it with the Administration's current requirements for other online form submissions. The online submission of DEA Forms 224/224a, 225/225a, 363/363a, 510/510a are now filed with DEA through the DEA Diversion Control Division secure network (available on the DEA Diversion Control Division website). The online submission of new and renewal applications will ensure the Administration's receipt of applications in a more timely and organized manner.

DEA solicited comments from the public regarding the following:

• Whether the proposed collection of information is necessary for the proper performance of the functions of DEA, including whether the information will have practical utility.

• The accuracy of DEA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

• Recommendations to enhance the quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

DEA solicited comments on the aforementioned subjects and received no comments. As a result, DEA is finalizing the collection with no changes.

Congressional Review Act

This rulemaking is a ''rule'' pursuant to the Congressional Review Act, 5 U.S.C. 801 *et seq.*[13] This rulemaking is not a ''major rule'' as it does not have an annual effect on the economy of over 100 million dollars, constitute a major increase in cost for registrants, nor does it have significant adverse effects on the United States domestic or foreign economy.[14] DEA will submit a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, Exports, Imports, Security measures.

21 CFR Part 1321

Administrative practice and procedure.

For the reasons stated in the preamble, DEA amends 21 CFR parts 1301, 1309, and 1321 as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965 unless otherwise noted.

■ 2. Amend § 1301.13 by revising paragraphs (e)(2) and (3) to read as follows:

§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

* * * * *

(e) * * *

(2) DEA Forms 224, 225, and 363 may be obtained online at *www.DEAdiversion.usdoj.gov.* Only applications submitted online through the secure application portal on DEA's website will be accepted for processing.

(3) DEA will send renewal notifications via email to registrants approximately 60 calendar days prior to their registration expiration date. Registrants are responsible for maintaining a current email address in application portal on DEA's website. DEA Forms 224a, 225a, and 363a may be obtained online at *www.DEAdiversion.usdoj.gov.* Only renewal applications submitted online through the secure application portal on DEA's website will be accepted for processing.

* * * * *

■ 3. Amend § 1301.14 by:
■ a. Revising paragraph (a);
■ b. Removing paragraph (b);
■ c. Redesignating paragraphs (c) and (d) as paragraphs (b) and (c); and
■ d. Revising newly redesignated paragraph (b).

The revisions read as follows:

§ 1301.14 Filing of application; acceptance for filing; defective applications.

(a) All applications for registration shall be submitted for filing online using the secure application portal at *www.DEAdiversion.usdoj.gov.*

(b) Application submitted for filing are dated by the system upon receipt. If found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will be rejected by the system, with the applicate receiving error messages at the time of application.

* * * * *

PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF LIST I CHEMICALS

■ 4. The authority citation for part 1309 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 823, 824, 830, 871(b), 875, 877, 886a, 952, 953, 957, 958.

■ 5. Revise § 1309.12 to read as follows:

[9] 2 U.S.C. 1501, *et seq.*

[10] 44 U.S.C. 3501–3521.

[11] 44 U.S.C. 3507(d).

[12] Copies of existing information collections approved by OMB may be obtained at *https://www.reginfo.gov/public/do/PRAMain.*

[13] 5 U.S.C. 804(3); *see* 5 U.S.C. 551(4).

[14] 5 U.S.C. 804(2)(A)–(C).

§ 1309.12 Time and method of payment; refund.

(a) For each application for registration or reregistration to manufacture, distribute, import, or export the applicant shall pay the fee when the application for registration or reregistration is submitted for filing online using the secure application portal at *www.DEAdiversion.usdoj.gov.*

(b) Payment shall be made online by Automated Clearing House funds transfer, by credit card, or by any other means made available at the time of submission using the secure application portal at *www.DEAdiversion.usdoj.gov.*

■ 6. Amend § 1309.32 by revising paragraphs (a) through (c) to read as follows:

§ 1309.32 Application forms; contents; signature.

(a) Any person who is required to be registered pursuant to § 1309.21 and is not so registered, shall apply on DEA Form 510 using the secure application portal at *www.DEAdiversion.usdoj.gov.*

(b) Any person who is registered pursuant to § 1309.21, shall apply for reregistration on DEA Form 510a using the secure application portal at *www.DEAdiversion.usdoj.gov.*

(c) DEA Forms 510 and 510a may be obtained online at *www.DEAdiversion.usdoj.gov.* DEA will send renewal notifications via email to registrants approximately calendar 60 days prior to their registration expiration date. Registrants are responsible for keeping their email address current in the secure application portal on DEA's website throughout the duration of their registration. Only applications submitted online through the secure application portal on DEA's website will be accepted for processing.

* * * * *

■ 7. Revise § 1309.33 to read as follows:

§ 1309.33 Filing of application; joint filings.

All applications for registration shall be submitted online at *www.DEAdiversion.usdoj.gov* for filing. The appropriate registration fee and any required attachments must accompany the application.

■ 8. Amend § 1309.34 by revising paragraph (a) to read as follows:

§ 1309.34 Acceptance for filing; defective applications.

(a) Applications submitted for filing are dated upon receipt. If the application is found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will not be accepted for filing.

* * * * *

PART 1321—DEA MAILING ADDRESSES

■ 9. The authority citation for part 1321 continues to read as follows:

Authority: 21 U.S.C. 871(b).

■ 10. Amend § 1321.01 by revising the entries in the table under ''DEA Registration Section'' to read as follows:

§ 1321.01 DEA mailing addresses.

* * * * *

TABLE OF DEA MAILING ADDRESSES

Code of Federal Regulations section—topic	DEA mailing address
* * * * * * *	
DEA Registration Section	
1301.03—Procedures information request (controlled substances registration). 1301.18(c)—Research project controlled substance increase request. 1301.51—Controlled substances registration modification request. 1301.52(b)—Controlled substances registration transfer request. 1301.52(c)—Controlled substances registration discontinuance of business activities notification. 1309.03—List I chemicals registration procedures information request. 1309.61—List I chemicals registration modification request.	Drug Enforcement Administration, Attn: Registration Section/DRR P.O. Box 2639, Springfield, VA 22152.
* * * * * * *	

* * * * *

Anne Milgram,

Administrator.

[FR Doc. 2022–07570 Filed 4–8–22; 8:45 am]

BILLING CODE 4410–09–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

36 CFR Part 1213

[FDMS No. NARA–22–0008; NARA–2022–044]

RIN 3095–AC08

Agency Guidance Procedures

AGENCY: National Archives and Records Administration (NARA).

ACTION: Final rule.

SUMMARY: We are amending our regulations on general procedures applying to guidance documents NARA and its components issue. We are removing provisions added to comply with requirements in the Executive order of October 9, 2019, ''Promoting the Rule of Law through Improved Agency Guidance Documents,'' which was revoked by the Executive order of January 20, 2021, ''Revocation of Certain Executive Orders Concerning Federal Regulation.''

DATES: This rule is effective on May 11, 2022.

ADDRESSES: Regulatory and External Policy Program (MP), Suite 4100, National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001.

FOR FURTHER INFORMATION CONTACT: Kimberly Keravuori, Regulatory and External Policy Program Manager, by

email at *regulation_comments@nara.gov,* or by telephone at 301.837.3151. Contact *rmstandards@nara.gov* with any questions on electronic records management.

SUPPLEMENTARY INFORMATION:

Regulatory Analysis

Executive Order 12866, Regulatory Planning and Review, and Executive Order 13563, Improving Regulation and Regulation Review

The Office of Management and Budget (OMB) has reviewed this rulemaking and determined it is not ''significant'' under section 3(f) of Executive Order 12866. It is not significant because it involves agency internal procedures and is minor and administrative in nature and the changes are being made to align with the executive order. There is also not a public comment period on this revision, for good cause.

Regulatory Flexibility Act (5 U.S.C. 601, et seq.)

This review requires an agency to prepare an initial regulatory flexibility analysis and publish it when the agency publishes the proposed rule. This requirement does not apply if the agency certifies that the rulemaking will not, if promulgated, have a significant economic impact on a substantial number of small entities (5 U.S.C. 603). We certify, after review and analysis, that this rulemaking will not have a significant adverse economic impact on small entities.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501, *et seq.*) requires that agencies consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of PRA section 3507(d), obtain approval from OMB for each collection of information we conduct, sponsor, or require through regulations. This rulemaking does not impose additional information collection requirements on the public that are subject to the Paperwork Reduction Act.

Executive Order 13132, Federalism

Executive Order 13132 requires agencies to ensure state and local officials have the opportunity for meaningful and timely input when developing regulatory policies that may have a substantial, direct effect on the states, on the relationship between the Federal Government and the states, or on the distribution of power and responsibilities among the various levels of government. If the effects of the rule on state and local governments are sufficiently substantial, the agency must prepare a Federal assessment to assist senior policy makers. This rulemaking will not have any effects on state and local governments within the meaning of the E.O. Therefore, no federalism assessment is required.

Unfunded Mandates Reform Act (Sec. 202, Pub. L. 104–4; 2 U.S.C. 1532)

The Unfunded Mandates Reform Act requires that agencies determine whether any Federal mandate in the rulemaking may result in state, local, and tribal governments, in the aggregate, or the private sector, expending $100 million in any one year. NARA certifies that this rulemaking does not contain a Federal mandate that may result in such an expenditure.

List of Subjects in 36 CFR Part 1213

Administrative practice and procedure.

For the reasons discussed in the preamble, NARA amends 36 CFR part 1213 as follows:

PART 1213—AGENCY GUIDANCE PROCEDURES

■ 1. The authority citation for part 1213 continues to read as follows:

Authority: 44 U.S.C. 2104(a).

§ 1213.4 [Amended]

■ 2. Amend § 1213.4 by:

■ a. Removing paragraph (b)(2)(v) and redesignating paragraphs (b)(2)(vi) and (vii) as paragraphs (b)(2)(v) and (vi);

■ b. Adding the word ''and'' at the end of newly redesignated paragraph (b)(2)(vi);

■ c. In paragraph (b)(3), removing ''; and'' and adding a period in its place;

■ d. Removing paragraph (b)(4); and

■ e. In paragraph (f), removing ''§ 1213.6(a)'' and adding ''§ 1213.6'' in its place.

§ 1213.6 [Amended]

■ 3. Amend § 1213.6 by:

■ a. Removing paragraphs (b) and (c); and

■ b. Removing the paragraph designation from paragraph (a) and removing the last sentence of the paragraph.

§ 1213.8 [Amended]

■ 4. Amend § 1213.8(d) by removing '', set forth in E.O. 12866, E.O. 13563, E.O. 13609, E.O. 13771, and E.O. 13777'' from the end of the last sentence.

§ 1213.14 [Removed]

■ 5. Remove § 1213.14.

David S. Ferriero,

Archivist of the United States.

[FR Doc. 2022–07580 Filed 4–8–22; 8:45 am]

BILLING CODE 7515–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2021–0807; FRL–9680–02–R8]

Air Plan Approval; South Dakota; Revisions to South Dakota Codified Law and Administrative Rules of South Dakota

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: With this direct final rule, the Environmental Protection Agency (EPA or the ''Agency'') is promulgating approval of South Dakota's submittal requesting that EPA recognize the merger of South Dakota's Department of Agriculture (DOA) with the Department of Environment and Natural Resources (DENR) to form the new Department of Agriculture and Natural Resources (DANR) and incorporate corresponding non-substantive revisions to the South Dakota Codified Law (SDCL) and the Administrative Rules of South Dakota (ARSD) into South Dakota's Implementation Plan. Accordingly, EPA is taking this final action in accordance with Clean Air Act (CAA).

DATES: This direct final rule is effective on June 10, 2022 without further notice, unless EPA receives adverse written comments on or before May 11, 2022. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2021–0807. All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically in *www.regulations.gov.* To reduce the risk of COVID–19 transmission, for this action we do not

plan to offer hard copy review of the docket. Please email or call the person listed in the **FOR FURTHER INFORMATION CONTACT** section if you need to make alternative arrangements for access to the docket.

FOR FURTHER INFORMATION CONTACT: Kate Gregory, Air and Radiation Division, U.S. Environmental Protection Agency (EPA), Region 8, Mail Code 8P–ARD–QP, 1595 Wynkoop Street, Denver, Colorado 80202–1129, telephone number: (303) 312–6175, email address: *gregory.kate@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' and ''our'' means EPA.

I. Why is EPA using a direct final rule?

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial action and anticipates no adverse comments. However, in the Proposed Rules section of this issue of the **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve revisions to both the SDCL and the ARSD. If EPA receives adverse comments, EPA will publish a timely withdrawal in the **Federal Register** informing the public that this direct final rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

II. Background

On April 16, 2021, South Dakota's Office of Attorney General submitted a letter notifying EPA of the establishment of the South Dakota DANR. The letter stated that on January 19, 2021, South Dakota Governor, Kristi Noem, executed Executive Order 2021–03, which provided for the merger of the South Dakota DOA and the South Dakota DENR into one department—the DANR. According to the South Dakota Constitution, executive reorganization orders become effective ''within ninety days after submission'' of the executive order to the South Dakota Legislature (Legislature) unless one of the two houses of the Legislature disapproves of the executive reorganization (S.D. Constitution, Article IV, Section 8).[1] During the 2021 session, neither house of the Legislature passed a resolution of disapproval of Governor Noem's Executive Order 2021–03 and the Order became effective April 19, 2021.[2]

In the letter submitted by the South Dakota Office of Attorney General, Assistant Attorney General Steven R. Blair stated that all State programs previously authorized to carry out EPA programs would continue to function in the same manner and all current environmental protection activities conducted under existing EPA approved or delegated programs under the DOA and/or the DENR would continue intact under the newly established DANR. Further, Mr. Blair stated that the merger caused no substantive budgetary or personnel changes, that the new DANR has all the authorities, powers, and duties of the previous DOA and DENR, and that the laws in effect at the time EPA approved or delegated authority to DOA and/or DENR continue to be fully effective and enforceable. Mr. Blair explained that the merger did not require any substantive changes to state law or administrative rules; the statutes and rules were merely updated to reflect the name of the new department.[3]

III. State Submittal

On January 21, 2022, pursuant to 40 CFR part 51, South Dakota submitted a request that EPA recognize the merger of South Dakota's DOA with the DENR to form the new DANR and incorporate corresponding revisions to the SDCL and the ARSD into South Dakota's Implementation Plan at 40 CFR 52.2170. The January 21, 2022 submission included a letter from the Secretary of the DANR, Hunter Roberts, as the Governor's designee.[4] Secretary Roberts stated that the SDCL and ARSD were automatically updated with DANR's new name during the merger process. Additionally, Secretary Roberts stated that South Dakota's Board of Minerals and Environment approved the DANR's request to ask EPA to recognize the department's new name in South Dakota's State Implementation Plan (SIP) at 40 CFR 52.2170 during a public hearing on December 16, 2021. Secretary Roberts further confirmed that the merger did not cause a substantive change to state law or administrative rules and that DANR maintains the same authorities, powers, and duties covered and implemented under the previous department name.[5]

South Dakota's submittal included clean and redlined copies of the revised SDCL and ARSD, which are available in the docket for this action. The non-substantive revisions became effective on April 19, 2021.[6] The submittal also included evidence that public notice of the State's proposed submittal ran in eleven South Dakota newpapers and a public hearing was held on December 16, 2021, demonstrating compliance with 40 CFR 51.102. The State received no public comments.

The SDCL and ARSD approved into South Dakota's SIP as revised are listed in Table 1 below.[7]

TABLE 1—REVISIONS TO SOUTH DAKOTA SOUTH DAKOTA CODIFIED LAW (SDCL) AND ADMINISTRATIVE RULES OF SOUTH DAKOTA (ARSD) AIR POLLUTION CONTROL RULES

SDCL:
34A–1–2
34A–1–58.1
34A–1–60
34A–1–63
ARSD:
74:36:01:01(19)
74:36:01:01(55)

IV. Final Action

South Dakota submitted the necessary information for EPA to review the non-substantive revisions to South Dakota's statutes and administrative rules to reflect the merger of South Dakota's DOA with the DENR to form the new DANR. With the exception of 74:37:01:08, which is part of South Dakota's approved CAA title V program rather than part of South Dakota's approved SIP, EPA is now acting to approve the non-substantive revisions to the SDCL and ARSD air pollution control rules into the SIP at 40 CFR 52.2170.

V. Incorporation by Reference

In this document, EPA is finalizing regulatory text in an EPA final rule that includes incorporation by reference. In accordance with the requirements of 1 CFR 5.15, EPA is finalizing the incorporation by reference of the regulations described in section III of

[1] SD DANR Merger SIP Submittal, January 21, 2022, p. 27–28, Letter from Steven R. Blair, Assistant Attorney General, South Dakota Office of Attorney General, to Deb Thomas, Acting Regional Administrator, EPA Region 8, Re: Establishment of South Dakota Department of Agriculture and Natural Resources, April 16, 2021.

[2] SD DANR Merger SIP Submittal, p.1, Letter from Hunter Roberts, Secretary, South Dakota Department of Agriculture and Natural Resources, to KC Becker, Regional Administrator, EPA Region 8, January 20, 2022.

[3] SD DANR Merger SIP Submittal, p. 27–28.

[4] SD DANR Merger SIP Submittal, p. 9.

[5] SD DANR Merger SIP Submittal, p.1.

[6] SD DANR Merger SIP Submittal, p. 2–7.

[7] See SD DANR Merger SIP Submittal, p. 33. In addition to the listed provisions in Table 1, South Dakota also included ARSD 74:37:01:08 in the submittal. This provision is not included as part of the EPA-approved SIP. Accoridngly, we are not taking action to include the revised 74:37:01:08 in South Dakota's approved SIP. See Email dated March 4, 2022, from Kyrik Rombough, Engineer Manager III, South Dakota Department of Agriculture and Natural Resources, to Monica Morales, Acting Deputy Director, EPA Region 8 Air and Radiation Division.

this preamble and as set forth in the amendments to 40 CFR 52.2170 below. EPA has made, and will continue to make, these materials generally available through *https://www.regulations.gov* and at the EPA Region 8 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rule of EPA's approval, and will be incorporated by reference by the Director of the Federal Register in the next update to the SIP compilation.

VI. Statutory and Executive Order Reviews

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the proposed rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 10, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Greenhouse gases, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: April 2, 2022.

KC Becker,

Regional Administrator, Region 8.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart QQ—South Dakota

■ 2. In § 52.2170:

■ a. The table in paragraph (c) is amended by revising the entry ''74:36:01:01''.

■ b. The table in paragraph (e) is amended by adding the entry ''XXVII. South Dakota Codified Laws, 34A–1–2, 34A–1–58.1, 34A–1–60 and 34A–1–63'' in numerical order.

The revision and addition read as follows:

§ 52.2170 Identification of plan.

* * * * *

(c) * * *

Rule No.	Rule title	State effective date	EPA effective date	Final rule citation, date	Comments
Statewide					

Rule No.	Rule title	State effective date	EPA effective date	Final rule citation, date	Comments
*	*	*	*	*	*
74:36:01. Definitions					
74:36:01:01	Definitions	04/19/2021	5/11/2022	[insert **Federal Register** citation], 4/11/2022.	
*	*	*	*	*	*

* * * * * (e) * * *

Rule title	State effective date	EPA effective date	Final rule citation, date	Comments
*	*	*	*	*
XXVII. South Dakota Codified Laws, 34A–1–2, 34A–1–58.1, 34A–1–60 and 34A–1–63.	4/19/21	5/11/2022	[insert **Federal Register** citation], 4/11/2022.	

[FR Doc. 2022–07416 Filed 4–8–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R05–OAR–2021–0885; FRL–9523–02–R5]

Air Plan Approval; Wisconsin; Redesignation of the Wisconsin Portion of the Chicago-Naperville, Illinois-Indiana-Wisconsin Area to Attainment of the 2008 Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) finds that the Chicago-Naperville, IL-IN-WI area (Chicago area) is attaining the 2008 ozone National Ambient Air Quality Standard (NAAQS or standard) and, in response to a request from the Wisconsin Department of Natural Resources (Wisconsin or the State), is redesignating the Wisconsin portion of the area to attainment for the 2008 ozone NAAQS, because the State has met the statutory requirements for redesignation under the Clean Air Act (CAA). EPA is approving, as a revision to the Wisconsin State Implementation Plan (SIP), the State's plan for maintaining the 2008 ozone NAAQS through 2035 for the Wisconsin portion of the Chicago area. EPA finds adequate and is approving Wisconsin's 2030 and 2035 volatile organic compound (VOC) and oxides of nitrogen (NO_X) Motor Vehicle Emission Budgets (Budgets) for the Wisconsin portion. Finally, pursuant to section 110 and part D of the CAA, EPA is approving the enhanced Inspection/Maintenance (I/M) program certification included in Wisconsin's December 3, 2021 submittal, because it satisfies the serious enhanced I/M requirements for the Wisconsin portion. EPA proposed to approve this action on February 7, 2022, and received no comments.

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

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R05–OAR–2021–0885. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* 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 either through *www.regulations.gov* or at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID–19. We recommend that you telephone Michael Leslie, Environmental Engineer at (312) 353–6680 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Michael Leslie, Environmental Engineer, Control Strategies Section, Air Programs Branch (AR18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–6680, *leslie.michael@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

I. Background Information

On February 7, 2022 (87 FR 6006), EPA proposed to find that the Chicago area is attaining the 2008 ozone NAAQS, in response to a request from the Wisconsin, and is redesignating the Wisconsin portion of the area to attainment for the 2008 ozone NAAQS, because the State has met the statutory requirements for redesignation under the CAA. The Wisconsin portion of the Chicago 2008 ozone area consists of the portion of Kenosha County bounded by the I–94 corridor and the area east to Lake Michigan (Wisconsin portion). Wisconsin submitted this request on December 3, 2021. EPA proposed to approve, as a revision to the Wisconsin SIP, the State's plan for maintaining the 2008 ozone NAAQS through 2035 for the Wisconsin portion. EPA also proposed to approve and find adequate Wisconsin's 2030 and 2035 VOC and NO_X Budgets for the Wisconsin portion. Finally, pursuant to section 110 and part D of the CAA, EPA proposed to approve the enhanced I/M certification, because it satisfies the serious enhanced I/M requirements for the Wisconsin portion. The public comment period for this proposed rule ended on March 9, 2022. EPA received no comments on the proposal.

II. Final Action

EPA is determining that the Chicago area is attaining the 2008 ozone NAAQS, based on quality-assured and certified monitoring data for the 2019–2021 period. EPA is approving enhanced I/M revision included in Wisconsin's December 3, 2021 submittal because Wisconsin demonstrated that its current I/M program meets the applicable enhanced I/M performance standard requirements in 40 CFR part 51, subpart S, for the 2008 ozone NAAQS. EPA has determined that the Wisconsin portion of the Chicago area has met the requirements for redesignation under section 107(d)(3)(E) of the CAA. EPA is thus changing the legal designation for the Wisconsin portion of the Chicago-Naperville, IL–IN–WI area from nonattainment to attainment for the 2008 ozone NAAQS. EPA is also approving, as a revision to the Wisconsin SIP, the State's maintenance plan for the area. The maintenance plan is designed to keep the Wisconsin portion of the Chicago area in attainment of the 2008 ozone NAAQS through 2035. Finally, EPA is finding adequate and approving the newly established 2030 and 2035 Budgets for the Wisconsin portion of the Chicago area.

In accordance with 5 U.S.C. 553(d) of the Administrative Procedure Act (APA), EPA finds there is good cause for this action to become effective immediately upon publication. The immediate effective date for this action is authorized under 5 U.S.C. 553(d)(1).

Section 553(d)(1) of the APA provides that final rules shall not become effective until 30 days after publication in the **Federal Register** ''except . . . a substantive rule which grants or recognizes an exemption or relieves a restriction.'' The purpose of this provision is to ''give affected parties a reasonable time to adjust their behavior before the final rule takes effect.'' *Omnipoint Corp.* v. *Fed. Commc'n Comm'n,* 78 F.3d 620, 630 (D.C. Cir. 1996); see also *United States* v. *Gavrilovic*, 551 F.2d 1099, 1104 (8th Cir. 1977) (quoting legislative history). However, when the agency grants or recognizes an exemption or relieves a restriction, affected parties do not need a reasonable time to adjust because the effect is not adverse. EPA has determined that this rule relieves a restriction because this rule relieves sources in the area of Nonattainment New Source Review (NNSR) permitting requirements; instead, upon the effective date of this action, sources will be subject to less restrictive Prevention of Significant Deterioration (PSD) permitting requirements. For this reason, EPA finds good cause under 5 U.S.C. 553(d)(1) for this action to become effective on the date of publication of this action.

III. Statutory and Executive Order Reviews

Under the CAA, redesignation of an area to attainment and the accompanying approval of a maintenance plan under section 107(d)(3)(E) are actions that affect the status of a geographical area and do not impose any additional regulatory requirements on sources beyond those imposed by state law. A redesignation to attainment does not in and of itself create any new requirements, but rather results in the applicability of requirements contained in the CAA for areas that have been redesignated to attainment. Moreover, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 10, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: March 29, 2022.

Debra Shore,

Regional Administrator, Region 5.

For the reasons stated in the preamble, 40 CFR parts 52 and 81 are amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

■ 2. Section 52.2585 is amended by adding paragraph (ss) to read as follows:

§ 52.2585 Control strategy: Ozone.

* * * * *

(ss) *Redesignation.* Approval—On December 3, 2021, Wisconsin submitted a request to redesignate the Wisconsin portion of the Chicago-Naperville, IL-IN-WI area to attainment of the 2008 ozone National Ambient Air Quality Standards (NAAQS). As part of the redesignation request, the State submitted a maintenance plan as required by section 175A of the Clean Air Act (CAA). Elements of the section 175 maintenance plan include a contingency plan and an obligation to submit a subsequent maintenance plan revision in eight years as required by the CAA. The ozone maintenance plan also establishes 2030 and 2035 Motor Vehicle Emission Budgets (Budgets) for the area. The 2030 Budgets for the area are 0.54 tons/day for volatile organic compounds (VOC) and 0.85 tons/day for oxides of nitrogen (NO_X). The 2035 Budgets for the area are 0.47 tons/day for VOC and 0.75 tons/day for NO_X. Wisconsin also submitted a revision to its State Implementation Plan to satisfy the Enhanced Inspection/Maintenance recertification for the 2008 ozone NAAQS requirements of the CAA.

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 3. The authority citation for part 81 continues to read as follows:

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

■ 4. Section 81.350 is amended by revising the entry for ''Chicago-Naperville, IL-IN-WI'' in the table entitled ''Wisconsin-2008 8-Hour Ozone NAAQS [Primary and Secondary]'' to read as follows:

§ 81.350 Wisconsin.

* * * * *

WISCONSIN—2008 8-HOUR OZONE NAAQS

[Primary and Secondary]

Designated area	Designation		Classification	
	Date [1]	Type	Date [1]	Type
Chicago-Naperville, IL-IN-WI: [2]	4/11/2022	Attainment		Serious.
Kenosha County (part): The portion of Kenosha County bounded by the Lake Michigan shoreline on the East, the Kenosha County boundary on the North, the Kenosha County boundary on the South, and the I–94 corridor (including the entire corridor) on the West.				
* * *	*	*	*	*

[1] This date is July 20, 2012, unless otherwise noted.
[2] Excludes Indian country located in each area, unless otherwise noted.

* * * * *

[FR Doc. 2022–07538 Filed 4–8–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 22–13; RM–11914; DA 22–360; FR ID 81398]

Television Broadcasting Services Albany, New York

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: On January 11, 2022, the Media Bureau, Video Division (Bureau) issued a *Notice of Proposed Rulemaking* (*NPRM*) in response to a petition for rulemaking filed by WNYT–TV, LLC (Petitioner), the licensee of WNYT–TV (Station), channel 12, Albany, New York, requesting the substitution of channel 24 for channel 12 at Albany in the Table of Allotments. For the reasons set forth in the *Report and Order* referenced below, the Bureau amends the Federal Communications Commission (Commission or FCC) regulations to substitute channel 24 for channel 12 at Albany.

DATES: Effective April 11, 2022.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, Media Bureau, at (202) 418–1647 or *Joyce.Bernstein@fcc.gov.*

SUPPLEMENTARY INFORMATION: The proposed rule was published at 87 FR 3489 on January 24, 2022. The Petitioner filed comments in support of the petition reaffirming its commitment to apply for channel 24. No other comments were filed. In support of its channel substitution request, the Petitioner states that the Station has a long history of significant reception problems given the local terrain, specifically the proximity of the Green, Berkshire, Catskill, and Adirondack mountain ranges and that these problems were exacerbated by the station's conversion from analog to digital operations on VHF channel 12, when it received numerous complaints from viewers about the station's over-the-air signal. In response to these complaints, the Petitioner applied for and received modification authorizations to increase the Station's effective radiated power (ERP) from 9.1 kW to 30 kW. According to the Petitioner, its proposal will result in a net gain in service to 289,588 persons within the Station's predicted noise limited service contour. While the proposal will result in a loss population of 210 persons within the predicted noise limited contour, the Petitioner demonstrated that the population within the loss area is currently served by at least five over-the-air television services. In addition, the Station is an NBC affiliate, and the Petitioner submitted an analysis, using the Commission's *TVStudy* software analysis program, demonstrating that after taking into account service provided by other NBC stations, all of the population located within the Station's original DTV channel 12 noise limited contour will continue to receive NBC service, except for 130 people, a number which the Commission considers *de minimis.* Moreover, the proposed channel 21 facility will result in 30,075 persons gaining access to NBC

network programing that did not have it before.

This is a synopsis of the Commission's *Report and Order,* MB Docket No. 22–13; RM–11914; DA 22–360, adopted April 4, 2022, and released April 4, 2022. The full text of this document is available for download at *https://www.fcc.gov/edocs.* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

The Commission will send a copy of the *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Final Rule

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

■ 2. In § 73.622(j), amend the Table of Allotments, under New York, by revising the entry for Albany to read as follows:

§ 73.622 Digital television table of allotments.

* * * * *

(j) * * *

Community	Channel No.
* * * * *	
NEW YORK	
Albany	8, 21, 24
* * * * *	

[FR Doc. 2022–07637 Filed 4–8–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 22–39; RM–11917; DA 22–359; FR ID 81399]

Television Broadcasting Services Billings, Montana

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: On January 26, 2022, the Media Bureau, Video Division (Bureau) issued a *Notice of Proposed Rulemaking* (*NPRM*) in response to a petition for rulemaking filed by Scripps Broadcasting Holdings LLC (Scripps or Petitioner), the licensee of KTVQ(TV) (KTVQ or Station), channel 10, Billings, Montana, requesting the substitution of channel 20 for channel 10 at Billings in the Table of Allotments. For the reasons set forth in the *Report and Order* referenced below, the Bureau amends the Federal Communications Commission (Commission or FCC) regulations to substitute channel 20 for channel 10 at Billings.

DATES: Effective April 11, 2022.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, Media Bureau, at (202) 418–1647 or *Joyce.Bernstein@fcc.gov.*

SUPPLEMENTARY INFORMATION: The proposed rule was published at 87 FR 6473 on February 4, 2022. The Petitioner filed comments in support of the petition reaffirming its commitment to apply for channel 20. No other comments were filed. In support of its channel substitution request, the Petitioner states that the Commission has recognized that VHF channels have certain characteristics that pose challenges for their use in providing digital television service, including propagation characteristics that allow undesired signals and noise to be receivable at relatively far distances, and that the Station has received many complaints from viewers unable to receive a reliable signal on channel 10. An analysis using the Commission's *TVStudy* software tool indicates that KTVQ's move from channel 10 to channel 20 is predicted to create a small area with 3,624 persons. That loss area, however, is partially overlapped by the noise limited contours of Scripps' owned TV translator stations K15LB–D, Red Lodge, Montana, and K28ON–D, Castle Rock, Montana, both of which carry the CBS network programming aired by KTVQ, and it appears that due to VHF reception issues and terrain, most of the viewers in the loss area already receive their CBS service from these translators. Accordingly, taking into account service from the Scripps' translators, only 483 persons would lose CBS service if KTVQ moves to channel 20, a number which the Commission considers *de minimis.* In addition, the loss area is also partially overlapped by the noise limited contours of KSVI (ABC) and KULR (NBC), Billings, Montana; KHMT (FOX), Hardin, Montana; and KSGW (ABC/FOX), Sheridan, Wyoming, so viewers in the loss area will continue to have access to major network programming.

This is a synopsis of the Commission's *Report and Order,* MB Docket No. 22–39; RM–11917; DA 22–359, adopted April 4, 2022, and released April 4, 2022. The full text of this document is available for download at *https://www.fcc.gov/edocs.* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

The Commission will send a copy of the *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Final Rule

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

■ 2. In § 73.622(j), amend the Table of Allotments, under Montana, by revising the entry for Billings to read as follows:

§ 73.622 Digital television table of allotments.

* * * * *

(j) * * *

Community	Channel No.
* * * * *	
MONTANA	
Billings	11, *16, 18, 20
* * * * *	

[FR Doc. 2022–07636 Filed 4–8–22; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 22016–0049; RTID 0648–XB756]

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher Vessels Using Trawl Gear in the Western Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by catcher vessels using trawl gear in the Western Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the A season allowance of the 2022 total allowable catch of Pacific cod by catcher vessels using trawl gear in the Western Regulatory Area of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), April 6, 2022, through 1200 hours, A.l.t., June 10, 2022.

FOR FURTHER INFORMATION CONTACT: Krista Milani, 907–581–2062.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The A season allowance of the 2022 Pacific cod total allowable catch (TAC) apportioned to catcher vessels using trawl gear in the Western Regulatory Area of the GOA is 2,118 metric tons (mt) as established by the final 2022 and 2023 harvest specifications for groundfish in the GOA (87 FR 11599, March 2, 2022).

In accordance with § 679.20(d)(1)(i), the Regional Administrator has determined that the A season allowance of the 2022 Pacific cod TAC apportioned to catcher vessels using trawl gear in the Western Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 2,018 mt and is setting aside the remaining 100 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by catcher vessels using trawl gear in the Western Regulatory Area of the GOA.

While this closure is effective the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of Pacific cod by catcher vessels using trawl gear in the Western Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of April 5, 2022.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 6, 2022.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–07698 Filed 4–6–22; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 87, No. 69
Monday, April 11, 2022

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0159; Project Identifier AD–2021–01019–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all The Boeing Company Model 757 airplanes. This proposed AD was prompted by a report of cracks found in the fastener holes at a certain location on the center wing box rear spar, lower skin. This proposed AD would require repetitive inspections for cracking of certain areas of the center wing box rear spar, lower skin and lower chord; and repair. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by May 26, 2022.

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

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

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0159.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0159; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Peter Jarzomb, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5234; email: *peter.jarzomb@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0159; Project Identifier AD–2021–01019–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Peter Jarzomb, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5234; email: *peter.jarzomb@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA has received a report of cracks found in the fastener holes at the center wing box rear spar, lower skin, located at left body buttock line (LBBL) 6.50, on a Model 737–300 airplane. The lower skin cracks were hidden between the center wing box lower chord on the upper surface and the keel beam upper chord on the lower surface. An analysis by Boeing showed the same condition can occur on Model 757 airplanes. This condition, if not addressed, could result in the inability of a principal structural element to sustain limit load, which could adversely affect the structural integrity of the airplane.

FAA's Determination

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

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 757–57A0075 RB, dated August 25, 2021. This service information specifies procedures for repetitive external high-frequency eddy current (HFEC) or internal detailed inspections for cracking in the center wing box rear spar, lower skin, and lower chord between LBBL 9.5 and 39.0 and right body buttock line (RBBL) 9.5 and 39.0; repetitive internal ultrasonic inspection of the center wing box lower chord and detailed inspections of the lower skin at the rear spar between LBBL 5.5 and LBBL 9.5, and between RBBL 5.5 and RBBL 9.5 for cracking; repetitive internal detailed inspection of the center wing box lower skin and rear spar lower chord between LBBL 5.5 and RBBL 5.5 for any cracking; and repair. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in the service information already described except for any differences identified as exceptions in the regulatory text of this proposed AD. For information on the procedures and compliance times, see this service information at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0159.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 477 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
HFEC inspection or detailed inspection (between LBBL 9.5 and 39.0 and RBBL 9.5 and 39.0).	Up to 19 work-hours × $85 per hour = Up to $1,615 per inspection cycle.	$0	$1,615 per inspection cycle.	Up to $770,355 per inspection cycle.
Ultrasonic and detailed inspection	19 work-hours × $85 per hour = $1,615 per inspection cycle.	0	$1,615 per inspection cycle.	$770,355 per inspection cycle.
Detailed inspection (between LBBL 5.5 and 9.5 and RBBL 5.5 and 9.5).	18 work-hour × $85 per hour = $1,530 per inspection cycle.	0	$1,530 per inspection cycle.	$729,810 per inspection cycle.

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

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2022–0159; Project Identifier AD–2021–01019–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by May 26, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 757–200, –200PF, –200CB, and –300 series airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Unsafe Condition

This AD was prompted by a report of cracks found in the fastener holes at a certain location on the center wing box rear spar, lower skin. The FAA is issuing this AD to detect and correct cracking that, if undetected, could result in the inability of a principal structural element to sustain limit load, which could adversely affect the structural integrity of the airplane.

(f) Compliance

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

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 757–57A0075 RB, dated August 25, 2021, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 757–57A0075 RB, dated August 25, 2021.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 757–57A0075, dated August 25, 2021, which is referred to in Boeing Alert Requirements Bulletin 757–57A0075 RB, dated August 25, 2021.

(h) Exceptions to Service Information Specifications

(1) Where the Compliance Time columns of the tables in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 757–57A0075 RB, dated August 25, 2021, use the phrase ''the original issue date of Requirements Bulletin 757–57A0075 RB,'' this AD requires using ''the effective date of this AD.''

(2) Where Boeing Alert Requirements Bulletin 757–57A0075 RB, dated August 25, 2021, specifies contacting Boeing for repair instructions: This AD requires doing the repair before further flight using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

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

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

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

(j) Related Information

(1) For more information about this AD, contact Peter Jarzomb, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5234; email: *peter.jarzomb@faa.gov.*

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

Issued on March 10, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–07596 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0452; Project Identifier MCAI–2021–01356–A]

RIN 2120–AA64

Airworthiness Directives; Piaggio Aero Industries S.p.A Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Piaggio Aero Industries S.p.A (Piaggio) Model P–180 airplanes. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as accumulation of water and subsequent freezing in the pitot-tube, which results in pitot-tube blockage. This proposed AD would require modifying the total air temperature (TAT) probe heater electrical circuit and revising your existing airplane flight manual (AFM). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by May 26, 2022.

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

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

For service information identified in this NPRM, contact Piaggio Aero Industries S.p.A, P–180 Customer Support, Via Pioieri e Aviatori d'Italia snc, 16154 Genoa, Italy; phone: +39 010 099 8400; email: *technicalsupport@piaggioaviation.it;* website: *https://www.technicalsupport@piaggioaerospace.it.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0452; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the MCAI, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Mike Kiesov, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4144; email: *mike.kiesov@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0452; Project Identifier MCAI–2021–01356–A'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the

following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Mike Kiesov, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019–0144, dated June 19, 2019 (referred to after this as ''the MCAI''), to address an unsafe condition on all Piaggio Model P.180 Avanti and Avanti II airplanes. The MCAI states:

> Occurrences of pitot-tube blockage were reported, leading to in-flight air data loss. Investigation results indicated that accumulation of water and subsequent freezing was the failure cause.
>
> This condition, if not corrected, could lead to unreliable indication or loss of in-flight air data provided by systems deriving their data from measuring air pressure, possibly resulting in loss of control of the aeroplane.
>
> To address this potentially unsafe condition, Piaggio issued the applicable AFM TC [Piaggio Aviation P.180 AVANTI II/EVO Temporary Change 79, dated September 17, 2018; and Piaggio Aviation P.180 AVANTI Temporary Change No. 36 and No. 79], providing instructions to switch on pitot-tube heater before taxi if operation in heavy rain, snow or icing condition is expected. To prevent concurrent activation of TAT probe heater on ground, which could lead to temporary air data indications failure, Piaggio issued the applicable SBs [Piaggio Service Bulletin No. 80–0430 Revision 1 and Piaggio Service Bulletin No. 80–0457, original issue], providing modification instructions to inhibit on-ground power supply to TAT probe heater, when the pitot-tube heater is activated.
>
> For the reasons described above, this [EASA] AD requires amendment of the applicable AFM and, for certain aeroplanes, modification of the TAT probe heater electrical circuit.

You may examine the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0452.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Piaggio Aviation S.p.A. Service Bulletin No. 80–0430, Revision 1, dated April 30, 2019; and Piaggio Aero Industries S.p.A. Service Bulletin No. 80–0457, Revision 1, dated February 12, 2020. These service bulletins specify procedures for modifying the TAT heater circuit in order to inhibit its engagement on the ground when the pitot heater is turned on. These documents are distinct because they apply to airplanes in different configurations.

The FAA reviewed Piaggio Aviation P.180 AVANTI II/EVO Temporary Change No. 79, dated September 17, 2018. Temporary Change (TC) 79 revises the Limitations and Normal Procedures sections of the existing AFM to include updated procedures for airplane operation when the modification for inhibition of the TAT heater (on ground) has been installed.

The FAA also reviewed Piaggio Aviation P.180 AVANTI Temporary Change No. 36, dated April 11, 2019. TC 36 revises the Emergency and Normal Procedures sections of the existing AFM to include additional procedures to avoid air data computer (ADC) failure due to water trapped and frozen in pitot lines.

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

Other Related Service Information

The FAA reviewed Piaggio Aero Industries Service Bulletin No. 80–0454, Revision 0, dated March 6, 2017; Piaggio Aero Industries S.p.A. Service Bulletin No. 80–0425, Revision 0, dated May 30, 2017; and Piaggio Aero Industries S.p.A. Service Bulletin No. 80–0425, Revision 2, dated June 4, 2018. This service information specifies procedures for replacing the Messier-Dowty nose and main landing gear and steering system with a Magnaghi nose and main landing gear and Eaton steering system.

The FAA also reviewed Piaggio Aero Industries S.p.A. Service Bulletin No. 80–0430, Revision 0, dated August 10, 2017. This service information specifies procedures for modifying the TAT heater circuit in order to inhibit its engagement on the ground when the pitot heater is turned on.

FAA's Determination

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

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in the service information already described.

Differences Between This Proposed AD and the MCAI

The MCAI requires informing all flight crews of the AFM revisions and operating accordingly thereafter, and this proposed AD would not because those actions are already required by FAA operating regulations.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 101 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per airplane	Cost on U.S. operators
Modify TAT probe heater electrical circuit.	42 work-hours × $85 per hour = $3,570.	Up to $3,632	Up to $7,202	Up to $496,938 (69 airplanes).
Revise AFM	1 work-hour × $85 per hour = $85	Not Applicable	$85	$8,585 (101 airplanes).

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Piaggio Aero Industries S.p.A: Docket No. FAA–2022–0452; Project Identifier MCAI–2021–01356–A.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by May 26, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Piaggio Aero Industries S.p.A Model P–180 airplanes, all serial numbers (S/Ns), certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 3411, Pitot/Static System.

(e) Unsafe Condition

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as accumulation of water and subsequent freezing in the pitot-tube. The FAA is issuing this AD to prevent blockage of the pitot-tube. The unsafe condition, if not addressed, could result in temporary air data indications failure, which could result in loss of control of the airplane.

(f) Compliance

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

(g) Required Actions

(1) For all airplanes: Within 30 days after the effective date of this AD, revise the existing airplane flight manual (AFM) for your airplane by adding into the Emergency Procedures and Normal Procedures sections the information in Piaggio Aviation P.180 AVANTI Temporary Change No. 36, dated April 11, 2019; or by incorporating into the Limitations and Normal Procedures sections the information in Piaggio Aviation P.180 Avanti II/EVO Temporary Change No. 79, dated September 17, 2018; as applicable to your airplane S/N. Using a different document with language identical to that in Piaggio Aviation P.180 AVANTI Temporary Change No. 36, dated April 11, 2019; or Piaggio Aviation P.180 Avanti II/EVO Temporary Change No. 79, dated September 17, 2018, is acceptable for compliance with this requirement.

(2) For airplanes identified in paragraph (g)(2)(i) and (ii) of this AD: Within 660 hours time-in-service (TIS) after the effective date of this AD or 24 months after the effective date of this AD, whichever occurs first, modify the total air temperature (TAT) probe heater electrical circuit by following the Accomplishment Instructions, paragraphs (6) through (27), in Piaggio Aero Industries S.p.A. Service Bulletin No. 80–0457, Revision 1, dated February 12, 2020.

(i) S/N 1105, if Piaggio Aero Industries Service Bulletin No. 80–0454, Revision 0, dated March 6, 2017, is not incorporated; and

(ii) S/Ns 1106 through 1234 inclusive, if Piaggio Aero Industries S.p.A. Service Bulletin No. 80–0425, Revision 2, dated June 4, 2018, is not incorporated.

(3) For airplanes identified in paragraphs (g)(3)(i) through (iii) of this AD: Within 660 hours TIS after the effective date of this AD or 24 months after the effective date of this AD, whichever occurs first, modify the TAT probe heater electrical circuit by following the Accomplishment Instructions, paragraphs (6) through (21), in Piaggio Aviation S.p.A. Service Bulletin No. 80–0430, Revision 1, dated April 30, 2019.

(i) S/Ns 1002, 3001, 3003, 3004, 3006, and 3007;

(ii) S/N 1105, if Piaggio Aero Industries Service Bulletin No. 80–0454, Revision 0, dated March 6, 2017, is incorporated; and

(iii) S/Ns 1106 through 1234 inclusive, if Piaggio Aero Industries S.p.A. Service Bulletin No. 80–0425, Revision 2, dated June 4, 2018, is incorporated.

(h) Credit for Previous Actions

This paragraph provides credit for the modification required by paragraph (g)(3) of this AD, if the modification was done before the effective date of this AD using Piaggio Aviation Service Bulletin No. 80–0430, Revision 0, dated August 10, 2017.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD and email to: *9-AVS-AIR-730-AMOC@faa.gov.*

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

(j) Related Information

(1) For more information about this AD, contact Mike Kiesov, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4144; email: *mike.kiesov@faa.gov.*

(2) Refer to European Union Aviation Safety Agency (EASA) AD 2019–0144, dated June 19, 2019, for more information. You may examine the EASA AD in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0452.

(3) For service information identified in this AD, contact Piaggio Aero Industries S.p.A, P–180 Customer Support, Via Pioieri e Aviatori d'Italia snc, 16154 Genoa, Italy; phone: +39 010 099 8400; email: *technicalsupport@piaggioaviation.it;* website: *https://www.technicalsupport@piaggioaerospace.it.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

Issued on April 5, 2022.

Ross Landes,

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

[FR Doc. 2022–07621 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0398; Project Identifier MCAI–2020–00881–T]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Bombardier, Inc., Model CL–600–1A11 (600), CL–600–2A12 (601), and CL–600–2B16 (601–3A, 601–3R, and 604 Variants) airplanes. This proposed AD was prompted by reports that during certain operating modes, the flight guidance/autopilot does not account for engine failure while capturing an altitude. This proposed AD would require revising the existing airplane flight manual (AFM) to provide the flightcrew with a new limitation and procedure for operation during certain flight modes. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by May 26, 2022.

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

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

For service information identified in this NPRM, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* internet *https://www.bombardier.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0398; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the Mandatory Continuing Airworthiness Information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Steven Dzierzynski, Aerospace Engineer, Avionics and Electrical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7367; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0398; Project Identifier MCAI–2020–00881–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Steven Dzierzynski, Aerospace Engineer, Avionics and Electrical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7367; email *9-avs-nyaco-cos@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued TCCA AD CF–2020–02, dated February 13, 2020 (TCCA AD CF–2020–02) (also referred to as the MCAI), to correct an unsafe condition for certain Bombardier, Inc., Model CL–600–1A11 (600), CL–600–2A12 (601), and CL–600–2B16 (601–3A,

601–3R, and 604 Variants) airplanes. You may examine the MCAI in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0398.

This proposed AD was prompted by reports that during ALTSEL, ASEL, or ALTS CAP mode, the flight guidance/autopilot does not account for engine failure while capturing an altitude. The FAA is proposing this AD to address a possible engine failure during or before a climb while in ALTSEL, ASEL or ALTS CAP mode, which could cause the airspeed to drop significantly below the safe operating speed. Prompt crew intervention may be required to maintain a safe operating speed. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

Bombardier has issued the following service information. This service information contains a new AFM limitation and procedure for operation during certain flight modes. These documents are distinct since they apply to different airplane configurations. These configurations may include the presence or absence of winglets, incorporation of service bulletin 601–0300 which introduces an airspeed limitation placard, and the type of engine installed on the airplane.

- Automatic Flight Control System limitation in the Systems Limitations in the Limitations section and Engine Failure in Climb During ALTSEL procedure in the Airplane Handling Procedures Following Engine Failure procedures in the Normal Procedures section of the Canadair Challenger AFM, Product Publication No. 600, Revision A115, dated June 16, 2021.
- Automatic Flight Control System limitation in the Systems Limitations in the Limitations section and Engine Failure in Climb During ALTSEL procedure in the Airplane Handling Procedures Following Engine Failure procedures in the Abnormal Procedures section of the Canadair Challenger AFM, Product Support Publication (PSP) No. 600–1, Revision 107, dated June 16, 2021.
- Automatic Flight Control System limitation in the Systems Limitations in the Limitations section and Engine Failure in Climb During ALTSEL procedure in the Airplane Handling Procedures Following Engine Failure procedures in the Abnormal Procedures section of the Canadair Challenger AFM, PSP No. 601–1A, Revision 129, dated June 16, 2021.
- Automatic Flight Control System limitation in the Systems Limitations in the Limitations section and Engine Failure in Climb During ALTSEL procedure in the Airplane Handling Procedures Following Engine Failure procedures in the Abnormal Procedures section of the Canadair Challenger AFM, PSP No. 601–1A–1, Revision 83, dated June 16, 2021.
- Automatic Flight Control System limitation in the Systems Limitations in the Limitations section and Engine Failure in Climb During ALTSEL procedure in the Airplane Handling Procedures Following Engine Failure procedures in the Abnormal Procedures section of the Canadair Challenger AFM, PSP No. 601–1B, Revision 87, dated June 16, 2021.
- Automatic Flight Control System limitation in the Systems Limitations in the Limitations section and Engine Failure in Climb During ALTSEL procedure in the Airplane Handling Procedures Following Engine Failure procedures in the Abnormal Procedures section of the Bombardier Canadair Challenger AFM, PSP No. 601–1B–1, Revision 85, dated June 16, 2021.
- Automatic Flight Control System limitation in the Systems Limitations in the Limitations section and Engine Failure in Climb During ASEL procedure in the Airplane Handling Procedures Following Engine Failure procedures in the Abnormal Procedures section of the Canadair Challenger AFM, PSP No. 601A–1, Revision 107, dated June 16, 2021.
- Automatic Flight Control System limitation in the Systems Limitations in the Limitations section and Engine Failure in Climb During ASEL procedure in the Airplane Handling Procedures Following Engine Failure procedures in the Abnormal Procedures section of the Bombardier Canadair Challenger AFM, PSP No. 601A–1–1, Revision 96, dated June16, 2021.
- Automatic Flight Control Systems limitation specified in Section 02–08, Systems Limitations, of Chapter 2—Limitations; and the Engine Failure in Climb During (V) ALTS CAP or (V) ALTV CAP procedure in Section 05–03, Single Engine Procedures, of Chapter 5—Abnormal Procedures of the Bombardier Challenger 604 AFM, Publication No. PSP 604–1, Revision 124, dated November 24, 2021. (For obtaining the limitation and procedure for the Bombardier Challenger 604 AFM, Publication No. PSP 604–1, use Document Identification No. CH 604 AFM.)
- Automatic Flight Control Systems limitation specified in Section 02–08, Systems Limitations, of Chapter 2—Limitations; and the Engine Failure in Climb During (V) ALTS CAP or (V) ALTV CAP procedure in Section 05–03, Single Engine Procedures, of Chapter 5—Abnormal Procedures of the Bombardier Challenger 605 AFM, Publication No. PSP 605–1, Revision 62, dated November 24, 2021. (For obtaining the limitation and procedure for the Bombardier Challenger 605 AFM, Publication No. PSP 605–1, use Document Identification No. CH 605 AFM.)
- Automatic Flight Control Systems limitation specified in Section 02–08, Systems Limitations, of Chapter 2—Limitations; and the Engine Failure in Climb During (V) ALTS CAP or (V) ALTV CAP procedure in Section 05–03, Single Engine Procedures, of Chapter 5—Abnormal Procedures of the Bombardier Challenger 650 AFM, Publication No. PSP 650–1, Revision 27, dated November 24, 2021. (For obtaining the limitation and procedure for the Bombardier Challenger 650 AFM, Publication No. PSP 650–1, use Document Identification No. CH 650 AFM.)

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

FAA's Determination

These products have been approved by the aviation authority of another country, and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI and service information referenced above. The FAA is proposing this AD because the FAA evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop on other products of these same type designs.

Proposed Requirements of This NPRM

This proposed AD would require revising the existing AFM to provide the flightcrew with a new limitation and procedure for operation during flight in certain flight modes.

Differences Between This Proposed AD and the MCAI

This NPRM updates certain AFM revision levels identified in TCCA AD CF–2020–02, and therefore identifies the complete, most recent service information that will be incorporated by reference in the final rule. Operators should note that Bombardier revised the ALTS CAP mode to (V) ALTS CAP or

(V) ALTV CAP mode in a revision prior to the latest revisions of the Bombardier Challenger 604/605/650 AFMs referenced in this AD.

Costs of Compliance

The FAA estimates that this proposed AD affects 133 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hour × $85 per hour = $85	$0	$85	$11,305

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Bombardier, Inc.: Docket No. FAA–2022–0398; Project Identifier MCAI–2020–00881–T.

(a) Comments Due Date

The FAA must receive comments by May 26, 2022.

(b) Affected Airworthiness Directives (ADs)

None.

(c) Applicability

This AD applies to the Bombardier, Inc., airplanes, certificated in any category, identified in paragraphs (c)(1) through (6) of this AD.

(1) Model CL–600–1A11 (600), serial numbers 1001 through 1085 inclusive.

(2) Model CL–600–2A12 (601), serial numbers 3001 through 3066 inclusive.

(3) Model CL–600–2B16 (601–3A and 601–3R Variants), serial numbers 5001 through 5194 inclusive.

(4) Model CL–600–2B16 (604 Variant), serial numbers 5301 through 5665 inclusive.

(5) Model CL–600–2B16 (604 Variant), serial numbers 5701 through 5988 inclusive.

(6) Model CL–600–2B16 (604 Variant), serial numbers 6050 through 6999 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 22, Auto flight.

(e) Reason

This AD was prompted by reports that during certain operating modes, the flight guidance/autopilot does not account for engine failure while capturing an altitude. The FAA is issuing this AD to address a possible engine failure during or before a climb while in ALTSEL, ASEL or ALTS CAP mode, which could cause the airspeed to drop significantly below the safe operating speed. Prompt crew intervention may be required to maintain a safe operating speed.

(f) Compliance

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

(g) Revision of the Existing Airplane Flight Manual (AFM)

Within 30 days after the effective date of this AD: Revise the existing AFM to incorporate the information specified in the limitation and procedure specified in the applicable AFM specified in figure 1 to paragraph (g) of this AD.

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Figure 1 to paragraph (g) – *AFM Revisions*

Airplane Serial Numbers	New Limitation and Procedure	AFM	Revision
Model CL-600-1A11 (600 variant), serial numbers 1001 through 1085 for non-winglets	Automatic Flight Control System limitation in the Systems Limitations in the Limitations section and Engine Failure in Climb During ALTSEL procedure in the Airplane Handling Procedures Following Engine Failure procedures in the Normal Procedures section	Canadair Challenger AFM, Product Publication No. 600	Revision A115, dated June 16, 2021
Model CL-600-1A11 (600 variant), serial numbers 1001 through 1085 for winglets	Automatic Flight Control System limitation in the Systems Limitations in the Limitations section and Engine Failure in Climb During ALTSEL procedure in the Airplane Handling Procedures Following Engine Failure	Canadair Challenger AFM, Product Support Publication (PSP) No. 600-1	Revision 107, dated June 16, 2021

Airplane Serial Numbers	New Limitation and Procedure	AFM	Revision
	procedures in the Abnormal Procedures section		
Model CL-600-2A12 (601 variant), serial numbers 3001 through 3066	Automatic Flight Control System limitation in the Systems Limitations in the Limitations section and Engine Failure in Climb During ALTSEL procedure in the Airplane Handling Procedures Following Engine Failure procedures in the Abnormal Procedures section	Canadair Challenger AFM, PSP No. 601-1A	Revision 129, dated June 16, 2021
Model CL-600-2A12 (601 variant), serial numbers 3001 through 3066 with Service Bulletin (SB) 601-0360 incorporated	Automatic Flight Control System limitation in the Systems Limitations in the Limitations section and Engine Failure in Climb During ALTSEL procedure in the Airplane Handling Procedures Following Engine Failure procedures in the Abnormal Procedures section	Bombardier Canadair Challenger AFM, PSP No. 601-1A-1	Revision 83, dated June 16, 2021
Model CL-600-2A12 (601 variant), serial numbers 3001 through 3066 with -3A engine	Automatic Flight Control System limitation in the Systems Limitations in the Limitations section and Engine Failure in Climb During ALTSEL procedure in the Airplane Handling Procedures Following Engine Failure procedures in the Abnormal Procedures section	Canadair Challenger AFM, PSP No. 601-1B	Revision 87, dated June 16, 2021

Airplane Serial Numbers	New Limitation and Procedure	AFM	Revision
Model CL-600-2A12, serial numbers 3001 through 3066 with -3A engine and SB 601-0360 incorporated	Automatic Flight Control System limitation in the Systems Limitations in the Limitations section and Engine Failure in Climb During ALTSEL procedure in the Airplane Handling Procedures Following Engine Failure procedures in the Abnormal Procedures section	Bombardier Canadair Challenger AFM, PSP No. 601-1B-1	Revision 85, dated June 16, 2021
Model CL-600-2B16 (601-3A/3R variant), serial numbers 5001 through 5194	Automatic Flight Control System limitation in the Systems Limitations in the Limitations section and Engine Failure in Climb During ASEL procedure in the Airplane Handling Procedures Following Engine Failure procedures in the Abnormal Procedures section	Canadair Challenger AFM, PSP No. 601A-1	Revision 107, dated June 16, 2021
Model CL-600-2B16 (601-3A/3R variant), serial numbers 5001 through 5194 with SB 601-0360 incorporated	Automatic Flight Control System limitation in the Systems Limitations in the Limitations section and Engine Failure in Climb During ASEL procedure in the Airplane Handling Procedures Following Engine Failure procedures in the Abnormal Procedures section	Bombardier Canadair Challenger AFM, PSP No. 601A-1-1	Revision 96, dated June 16, 2021
Model CL-600-2B16 (604 variant), serial numbers 5301 through 5665	Automatic Flight Control Systems limitation specified in Section 02-08, Systems Limitations, of Chapter 2 – Limitations; and the Engine Failure in Climb During (V) ALTS CAP	Bombardier Challenger 604 AFM, Publication No. PSP 604-1[1]	Revision 124, dated November 24, 2021

Airplane Serial Numbers	New Limitation and Procedure	AFM	Revision
	or (V) ALTV CAP procedure in Section 05-03, Single Engine Procedures, of Chapter 5 – Abnormal Procedures		
Model CL-600-2B16 (604 variant), serial numbers 5701 through 5988	Automatic Flight Control Systems limitation specified in Section 02-08, Systems Limitations, of Chapter 2 – Limitations; and the Engine Failure in Climb During (V) ALTS CAP or (V) ALTV CAP procedure in Section 05-03, Single Engine Procedures, of Chapter 5 – Abnormal Procedures	Bombardier Challenger 605 AFM, Publication No. PSP 605-1[2]	Revision 62, dated November 24, 2021
Model CL-600-2B16 (604 variant), serial numbers 6050 through 6999	Automatic Flight Control Systems limitation specified in Section 02-08, Systems Limitations, of Chapter 2 – Limitations; and the Engine Failure in Climb During (V) ALTS CAP or (V) ALTV CAP procedure in Section 05-03, Single Engine Procedures, of Chapter 5 – Abnormal Procedures	Bombardier Challenger 650 AFM, Publication No. PSP 650-1[3]	Revision 27, dated November 24, 2021

[1] For obtaining the limitation and procedure for the Bombardier Challenger 604 AFM, Publication No. PSP 604-1, use Document Identification No. CH 604 AFM.

[2] For obtaining the limitation and procedure for the Bombardier Challenger 605 AFM, Publication No. PSP 605-1, use Document Identification No. CH 605 AFM.

[3] For obtaining the limitation and procedure for the Bombardier Challenger 650 AFM, Publication No. PSP 650-1, use Document Identification No. CH 650 AFM.

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

the DAO, the approval must include the DAO-authorized signature.

(i) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) TCCA AD CF–2020–02, dated February 13, 2020, for related information. This MCAI may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0398.

(2) For more information about this AD, contact Steven Dzierzynski, Aerospace Engineer, Avionics and Electrical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7367; email *9-avs-nyaco-cos@faa.gov.*

(3) For service information identified in this AD, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com*; internet *https://www.bombardier.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued on April 5, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–07633 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–C

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0454; Project Identifier MCAI–2021–01124–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2019–03–25, which applies to certain Airbus SAS Model A318 series airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. AD 2019–03–25 requires repetitive inspections of the center and outer wing box lower stiffeners and panels at a certain junction on the left- and right-hand sides for any cracking, and repair if necessary. AD 2019–03–25 also provides an optional modification, which would terminate the repetitive inspections. Since the FAA issued AD 2019–03–25, it has been determined that, for certain airplanes, the compliance time for the initial inspection is inadequate and must be revised. This proposed AD continues to require the actions specified in AD 2019–03–25 with revised compliance times for certain airplanes and additional actions for certain airplanes, and expands the applicability, as specified in a European Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by May 26, 2022.

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

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

For material that will be incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0454.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0454; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223; email *Vladimir.Ulyanov@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0454; Project Identifier MCAI–2021–01124–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Vladimir Ulyanov, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax

206–231–3223; email *Vladimir.Ulyanov@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2019–03–25, Amendment 39–19577 (84 FR 8805, March 12, 2019) (AD 2019–03–25), which applies to certain Airbus SAS Model A318 series airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. AD 2019–03–25 requires repetitive special detailed inspections (SDIs) of the center and outer wing box lower stiffeners and panels at a certain junction on the left- and right-hand sides for any cracking, and repair if necessary. AD 2019–03–25 also provides an optional modification, which would terminate the repetitive inspections. The FAA issued AD 2019–03–25 to address the loss of pre-tension in the fasteners, which could affect the structural integrity of the airplane.

Actions Since AD 2019–03–25 Was Issued

Since the FAA issued AD 2019–03–25, it has been determined that, for certain airplanes, the compliance time for the initial inspection is inadequate and must be revised and additional actions are required. Additionally, the applicability is expanded.

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2021–0228, dated October 12, 2021 (EASA AD 2021–0228) (also referred to as the MCAI), to correct an unsafe condition for certain Airbus SAS Model A318 series airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –215, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. Model A320–215 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this AD therefore does not include those airplanes in the applicability.

EASA AD 2021–0228 superseded EASA AD 2018–0218, dated October 11, 2018; corrected October 26, 2018 (which corresponds to FAA AD 2019–03–25).

This proposed AD was prompted by a report that taperloks used in the wing-to-fuselage junction at rib 1 were found to be noncompliant with the applicable specification, resulting in a loss of pre-tension in the fasteners; and a determination that, for certain airplanes, the compliance time for the initial inspection is inadequate and must be revised. The FAA is proposing this AD to address the loss of pre-tension in the fasteners, which could affect the structural integrity of the airplane. See the MCAI for additional background information.

Explanation of Retained Requirements

Although this proposed AD does not explicitly restate the requirements of AD 2019–03–25, this proposed AD would retain the requirements of AD 2019–03–25. Those requirements are referenced in EASA AD 2021–0228, which, in turn, is referenced in paragraph (g) of this proposed AD.

Related Service Information Under 1 CFR Part 51

EASA AD 2021–0228 specifies procedures for repetitive internal and external SDIs (ultrasonic inspections) of the center and outer wing box lower stiffeners and panels at the level of rib 1 junction on the left- and right-hand sides for any cracking, and repair if necessary; and additional actions (re-protection of the inspected area at the lower panel at rib1 junction at the left- and right-hand sides) for airplanes on which certain service information was used. EASA AD 2021–0228 also specifies procedures for an optional modification, which would terminate the repetitive inspections. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of these same type designs.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2021–0228 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2021–0228 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2021–0228 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2021–0228 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2021–0228. Service information required by EASA AD 2021–0228 for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0454 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this proposed AD affects 765 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from 2019–03–25	51 work-hours × $85 per hour = $4,335.	$0	$4,335	$25,860 (516 airplanes).

ESTIMATED COSTS FOR REQUIRED ACTIONS—Continued

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
New additional proposed actions ...	13 work-hours × $85 per hour = $1,105.	0	1,105	Up to $845,325 (Up to 765 airplanes).

The FAA has received no definitive data that would enable the agency to provide cost estimates for the repair specified in this proposed AD.

Paperwork Reduction Act

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

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2019–03–25, Amendment 39–19577 (84 FR 8805, March 12, 2019); and

■ b. Adding the following new AD:

Airbus SAS: Docket No. FAA–2022–0454; Project Identifier MCAI–2021–01124–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by May 26, 2022.

(b) Affected ADs

This AD replaces AD 2019–03–25, Amendment 39–19577 (84 FR 8805, March 12, 2019) (AD 2019–03–25).

(c) Applicability

This AD applies to Airbus SAS Model A318–111, –112, –121, and –122 airplanes; Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes; certificated in any category; as identified in European Aviation Safety Agency (EASA) AD 2021–0228, dated October 12, 2021 (EASA AD 2021–0228).

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Unsafe Condition

This AD was prompted by a report that taperloks used in the wing-to-fuselage junction at rib 1 were found to be non-compliant with the applicable specification, resulting in a loss of pre-tension in the fasteners; and a determination that, for certain airplanes, the compliance time for the initial inspection is inadequate and must be revised and additional actions are required. The FAA is issuing this AD to address the loss of pre-tension in the fasteners, which could affect the structural integrity of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2021–0228.

(h) Exceptions to EASA AD 2021–0228

(1) Where EASA AD 2021–0228 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraph (3) of EASA AD 2021–0228 specifies to ''contact Airbus for approved repair instructions'' if any damage (cracking) is found, for this AD, if any cracking is found, the cracking must be repaired before further flight using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) The ''Remarks'' section of EASA AD 2021–0228 does not apply to this AD.

(i) Additional FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft

Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (j)(2). Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(3) *Required for Compliance (RC):* For any service information referenced in EASA AD 2021–0228 that contains paragraphs that are labeled as RC, the instructions in RC paragraphs, including subparagraphs under an RC paragraph, must be done to comply with this AD; any paragraphs, including subparagraphs under those paragraphs, that are not identified as RC are recommended. The instructions in paragraphs, including subparagraphs under those paragraphs, not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the instructions identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to instructions identified as RC require approval of an AMOC.

(j) Related Information

(1) For EASA AD 2021–0228 contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0454.

(2) For more information about this AD, contact Vladimir Ulyanov, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223; email *Vladimir.Ulyanov@faa.gov.*

Issued on April 5, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–07618 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0453; Project Identifier MCAI–2020–01557–T]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes. This proposed AD was prompted by reports of the loss of all air data system information provided to the flightcrew during flight; the air data system information was recovered as the airplane descended to lower altitudes. This proposed AD would require revising the existing airplane flight manual (AFM) to update the Unreliable Airspeed and Landing Distance Factor emergency procedures, which provide instructions for the flightcrew to stabilize the airspeed and altitude. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by May 26, 2022.

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

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

For service information identified in this NPRM, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 1–514–855–2999; email *ac.yul@aero.bombardier.com;* internet *https://www.bombardier.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0453; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

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

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0453; Project Identifier MCAI–2020–01557–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be

placed in the public docket of this NPRM. Submissions containing CBI should be sent to Chirayu Gupta, Aerospace Engineer, Mechanical Systems and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued TCCA AD CF–2020–50, dated November 20, 2020 (TCCA AD CF–2020–50) (also referred to after this as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for certain Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes. You may examine the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0453.

This proposed AD was prompted by reports of the loss of all air data system information provided to the flightcrew during flight; the air data system information was recovered as the airplane descended to lower altitude. An investigation determined that the root cause was usually high altitude icing (ice crystal contamination). The FAA is proposing this AD to address loss of all air data system information, which could lead to loss of continued safe flight and landing of the airplane. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

Bombardier, Inc., has issued the following service information. This service information describes procedures for stabilizing the airspeed and altitude of the airplane. These documents are distinct since they apply to different airplane models.

- Unreliable Airspeed procedure, Section 03–12, Primary Flight Displays, Chapter 3—Emergency Procedures; and Instruments procedure, Landing Distance Factors section, of the Emergency Procedures section of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, Chapter 7—Supplements; of the Bombardier Global Express AFM, Publication No. CSP 700–1, Revision 107, dated February 22, 2021. (For obtaining the procedures for Bombardier Global Express AFM, Publication No. CSP 700–1, use Document Identification No. GL 700 AFM–1.)
- Unreliable Airspeed procedure, Section 03–12, Primary Flight Displays, Chapter 3—Emergency Procedures; and Instruments procedure, Landing Distance Factors section, of the Emergency Procedures section of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, Chapter 7—Supplements; of the Bombardier Global Express AFM, Publication No. CSP 700–1A, Revision 107, dated February 22, 2021. (For obtaining the procedures for Bombardier Global Express AFM, Publication No. CSP 700–1A, use Document Identification No. GL 700 AFM–1A.)
- Unreliable Airspeed procedure, Section 03–12, Primary Flight Displays, Chapter 3—Emergency Procedures; and Instruments procedure, Landing Distance Factors section, of the Emergency Procedures section of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, Chapter 7—Supplements; of the Bombardier Global 5000 AFM, Publication No. CSP 700–5000–1, Revision 68, dated February 22, 2021. (For obtaining the procedures for Bombardier Global 5000 AFM, Publication No. CSP 700–5000–1, use Document Identification No. GL 5000 AFM.)
- Unreliable Airspeed procedure, Section 03–12, Primary Flight Displays, Chapter 3—Emergency Procedures; and Instruments procedure, Landing Distance Factors section, of the Emergency Procedures section of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, Chapter 7—Supplements; of the Bombardier Global 5000 Featuring Global Vision Flight Deck AFM, Publication No. CSP 700–5000–1V, Revision 37, dated February 22, 2021. (For obtaining the procedures for Bombardier Global 5000 Featuring Global Vision Flight Deck AFM, Publication No. CSP 700–5000–1V, use Document Identification No. GL 5000 GVFD AFM.)
- Unreliable Airspeed procedure, Section 03–12, Primary Flight Displays, Chapter 3—Emergency Procedures, of the Bombardier Global 5500 AFM, Publication No. CSP 700–5500–1, Revision 8, dated November 11, 2020. (For obtaining the procedures for Bombardier Global 5500 AFM, Publication No. CSP 700–5500–1, use Document Identification No. GL 5500 AFM.)
- Unreliable Airspeed procedure, Section 03–12, Primary Flight Displays, Chapter 3—Emergency Procedures; and Instruments procedure, Landing Distance Factors section, of the Emergency Procedures section of Supplement 20—Operations at Airport Elevations Above 10,000 Feet, Chapter 7—Supplements; of the Bombardier Global 6000 AFM, Publication No. CSP 700–1V, Revision 37, dated February 22, 2021. (For obtaining the procedures for Bombardier Global 6000 AFM, Publication No. CSP 700–1V, use Document Identification No. GL 6000 AFM.)
- Unreliable Airspeed procedure, Section 03–12, Primary Flight Displays, Chapter 3—Emergency Procedures of the Bombardier Global 6500 AFM, Publication No. CSP 700–6500–1, Revision 8, dated November 11, 2020. (For obtaining the procedures for Bombardier Global 6500 AFM, Publication No. CSP 700–6500–1, use Document Identification No. GL 6500 AFM.)

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

FAA's Determination

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

Proposed AD Requirements in This NPRM

This proposed AD would require revising the existing AFM to update the Unreliable Airspeed and Landing Distance Factor emergency procedures, which provide instructions for the flightcrew to stabilize the airspeed and altitude.

TCCA AD CF–2020–50 requires operators to ''inform all flight crews'' of revisions to the AFM, and thereafter to ''operate the aeroplane accordingly.'' However, this proposed AD would not specifically require those actions as those actions are already required by FAA regulations. FAA regulations require operators furnish to pilots any changes to the AFM (for example, 14 CFR 121.137), and to ensure the pilots are familiar with the AFM (for example, 14 CFR 91.505). As with any other flightcrew training requirement, training on the updated AFM content is tracked by the operators and recorded in each

pilot's training record, which is available for the FAA to review. FAA regulations also require pilots to follow the procedures in the existing AFM including all updates. 14 CFR 91.9 requires that any person operating a civil aircraft must comply with the operating limitations specified in the AFM. Therefore, including a requirement in this proposed AD to operate the airplane according to the revised AFM would be redundant and unnecessary.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 395 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hour × $85 per hour = $85	$0	$85	$33,575

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Bombardier, Inc.: Docket No. FAA–2022–0453; Project Identifier MCAI–2020–01557–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by May 26, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes, certificated in any category, serial numbers (S/Ns) 9002 through 9998 inclusive, and S/Ns 60001 through 60027 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Unsafe Condition

This AD was prompted by reports of the loss of all air data system information provided to the flightcrew during flight; the air data system information was recovered as the airplanes descended to lower altitudes. The FAA is issuing this AD to address loss of all air data system information, which could lead to loss of continued safe flight and landing of the airplane.

(f) Compliance

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

(g) Revision of the Existing Airplane Flight Manual (AFM)

Within 30 days after the effective date of this AD: Revise the existing AFM to incorporate the information specified in the AFM sections and supplements, as applicable, of the AFM revisions specified in figure 1 to paragraph (g) of this AD.

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Figure 1 to paragraph (g) – *AFM References*

Bombardier Airplane Model (Marketing Designation)	AFM	AFM Section	AFM Supplement, If Applicable	AFM Revision and Issue Date
BD-700-1A10 (Global Express)	Bombardier Global Express AFM, Publication No. CSP 700-1[1]	Unreliable Airspeed procedure, Section 03-12, Primary Flight Displays, Chapter 3 – Emergency Procedures	Instruments procedure, Landing Distance Factors section, of the Emergency Procedures section of Supplement 20 – Operations at Airport Elevations Above 10,000 Feet, Chapter 7 – Supplements	Revision 107, dated February 22, 2021
BD-700-1A10 (Global Express XRS)	Bombardier Global Express AFM, Publication No. CSP 700-1A[2]	Unreliable Airspeed procedure, Section 03-12, Primary Flight Displays, Chapter 3 – Emergency Procedures	Instruments procedure, Landing Distance Factors section, of the Emergency Procedures section of Supplement 20 – Operations at Airport Elevations Above 10,000 Feet, Chapter 7 – Supplements	Revision 107, dated February 22, 2021
BD-700-1A11 (Global 5000)	Bombardier Global 5000 AFM, Publication No. CSP 700-5000-1[3]	Unreliable Airspeed procedure, Section 03-12, Primary Flight Displays, Chapter 3 – Emergency Procedures	Instruments procedure, Landing Distance Factors section, of the Emergency Procedures section of Supplement 20 – Operations at Airport Elevations Above 10,000 Feet, Chapter 7 – Supplements	Revision 68, dated February 22, 2021

Bombardier Airplane Model (Marketing Designation)	AFM	AFM Section	AFM Supplement, If Applicable	AFM Revision and Issue Date
BD-700-1A11 (Global 5000 ft. GVFD)	Bombardier Global 5000 Featuring Global Vision Flight Deck AFM, Publication No. CSP 700-5000-1V[4]	Unreliable Airspeed procedure, Section 03-12, Primary Flight Displays, Chapter 3 – Emergency Procedures	Instruments procedure, Landing Distance Factors section, of the Emergency Procedures section of Supplement 20 – Operations at Airport Elevations Above 10,000 Feet, Chapter 7 – Supplements	Revision 37, dated February 22, 2021
BD-700-1A11 (Global 5500)	Bombardier Global 5500 AFM, Publication No. CSP 700-5500-1[5]	Unreliable Airspeed procedure, Section 03-12, Primary Flight Displays, Chapter 3 – Emergency Procedures	Not applicable	Revision 8, dated November 11, 2020
BD-700-1A10 (Global 6000)	Bombardier Global 6000 AFM, Publication No. CSP 700-1V[6]	Unreliable Airspeed procedure, Section 03-12, Primary Flight Displays, Chapter 3 – Emergency Procedures	Instruments procedure, Landing Distance Factors section, of the Emergency Procedures section of Supplement 20 – Operations at Airport Elevations Above 10,000 Feet, Chapter 7 – Supplements	Revision 37, dated February 22, 2021
BD-700-1A10 (Global 6500)	Bombardier Global 6500 AFM, Publication No. CSP 700-6500-1[7]	Unreliable Airspeed procedure, Section 03-12, Primary Flight Displays, Chapter 3 – Emergency Procedures	Not applicable	Revision 8, dated November 11, 2020

Bombardier Airplane Model (Marketing Designation)	AFM	AFM Section	AFM Supplement, If Applicable	AFM Revision and Issue Date
[1] For obtaining the procedures for Bombardier Global Express AFM, Publication No. CSP 700-1, use Document Identification No. GL 700 AFM-1.				
[2] For obtaining the procedures for Bombardier Global Express AFM, Publication No. CSP 700-1A, use Document Identification No. GL 700 AFM-1A.				
[3] For obtaining the procedures for Bombardier Global 5000 AFM, Publication No. CSP 700-5000-1, use Document Identification No. GL 5000 AFM.				
[4] For obtaining the procedures for Bombardier Global 5000 Featuring Global Vision Flight Deck AFM, Publication No. CSP 700-5000-1V, use Document Identification No. GL 5000 GVFD AFM.				
[5] For obtaining the procedures for Bombardier Global 5500 AFM, Publication No. CSP 700-5500-1, use Document Identification No. GL 5500 AFM.				
[6] For obtaining the procedures for Bombardier Global 6000 AFM, Publication No. CSP 700-1V, use Document Identification No. GL 6000 AFM.				
[7] For obtaining the procedures for Bombardier Global 6500 AFM, Publication No. CSP 700-6500-1, use Document Identification No. GL 6500 AFM.				

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

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

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

(i) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) TCCA AD CF–2020–50, dated November 20, 2020, for related information. This MCAI may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0453.

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

(3) For service information identified in this AD, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 1–514–855–2999; email *ac.yul@aero.bombardier.com;* internet *https://www.bombardier.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued on April 5, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–07619 Filed 4–8–22; 8:45 a.m.]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0295; Project Identifier MCAI–2021–00840–R]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Airbus Helicopters Model AS–365N2, AS 365 N3, EC 155B, EC155B1, and SA–365N1 helicopters. This proposed AD was prompted by a large amount of critical scale particles found on the tail rotor gearbox (TGB) chip detector magnetic plug during an unscheduled check of the TGB. The particles belonged to the double bearing (pitch control rod bearing) installed inside the TGB. This proposed AD would require repetitive inspections of the TGB chip detector for particles, analyzing any particles collected, performing a double bearing washing, repetitive replacements of certain part-numbered

double bearings, and corrective actions if necessary, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by May 26, 2022.

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

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

For EASA material that is proposed for IBR in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find the EASA material on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. The EASA material is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0295.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0295; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the EASA AD, any comments received, and other information. The street address for Docket Operations is listed above.

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

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0295; Project Identifier MCAI–2021–00840–R'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Andrea Jimenez, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7330; email *andrea.jimenez@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

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

This proposed AD was prompted by a large amount of critical scale particles found on the TGB chip detector magnetic plug during an unscheduled check of a Model AS 365 N2 helicopter. EASA advises the particles belonged to the double bearing (pitch control rod bearing) installed inside the TGB and further advises the reported event showed a speed of degradation faster than expected. The FAA is proposing this AD to prevent bearing degradation and subsequent failure, which could result in loss of yaw control. See EASA AD 2021–0170 for additional background information.

Related Service Information Under 1 CFR Part 51

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

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

This material is reasonably available because the interested parties have access to it through their normal course

of business or by the means identified in the **ADDRESSES** section.

Other Related Service Information

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

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

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA is proposing this AD after evaluating all known relevant information and determining that the unsafe condition described previously is likely to exist or develop on other helicopters of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2021–0170, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this proposed AD and except as discussed under ''Differences Between this Proposed AD and EASA AD 2021–0170.''

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2021–0170 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2021–0170 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2021–0170 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2021–0170. Service information referenced in EASA AD 2021–0170 for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0295 after the FAA final rule is published.

Differences Between This Proposed AD and EASA AD 2021–0170

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

Interim Action

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

Costs of Compliance

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

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

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

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

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

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

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

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

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

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

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

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

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus Helicopters: Docket No. FAA–2022–0295; Project Identifier MCAI–2021–00840–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by May 26, 2022.

(b) Affected ADs

None.

(c) Applicability

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

(d) Subject

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

(e) Unsafe Condition

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

(f) Compliance

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

(g) Requirements

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

(h) Exceptions to EASA AD 2021–0170

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) Comply with paragraph 2.D.

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

(iv) Inform EST using chip detection tracking sheet.

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

(13) Where a work card referenced in the service information referenced in EASA AD

2021–0170 specifies ''send all oversized particles for analysis and wait for results before continuing flight,'' this AD does not require sending particles for analysis, however this AD does require before further flight, analyzing the particles using a method in accordance with FAA-approved procedures.

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

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

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

(i) No Reporting Requirement

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

(j) Special Flight Permit

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

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (l)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

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

(l) Related Information

(1) For EASA AD 2021–0170, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. This material may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0295.

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

Issued on March 22, 2022.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–07576 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0243; Airspace Docket No. 20–AWP–10]

RIN 2120–AA66

Proposed Modification of Class D Airspace, Proposed Removal and Establishment of Class E Airspace; Oxnard Airport, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to remove the Class E airspace, designated as an extension to a Class D or Class E surface area. Additionally, this action proposes to establish Class E airspace extending upward from 700 feet above the surface. Lastly, this action proposes administrative updates to the Class D airspace legal description. These actions will ensure the safety and management of instrument flight rules (IFR) at the airport.

DATES: Comments must be received on or before May 26, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1–800–647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2021–0243; Airspace Docket No. 20–AWP–10, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

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

FOR FURTHER INFORMATION CONTACT: Nathan A. Chaffman, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–3460.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would modify Class D and Class E airspace, and establish Class E airspace at Oxnard Airport, to support IFR operations at the airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2021–0243; Airspace Docket No. 20–AWP–10''. The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by removing the Class E airspace, designated as an extension to a Class D or Class E surface area. This airspace is west of the airport and is no longer required to contain IFR arrivals descending below 1,000 feet above the surface.

This action also proposes to establish Class E airspace extending upward from 700 feet above the surface. This airspace is designated to contain arriving IFR aircraft descending below 1,500 feet above the surface, and departing IFR aircraft until they reach 1,200 feet above the surface.

Finally, the FAA proposes several administrative updates to the Class D legal description. The current description requires modification to replace the use of the phrases ''Notice to Airmen'' and ''Airport/Facility Directive.'' These phrases should read ''Notice to Air Missions'' and ''Chart Supplement,'' respectively, in the Oxnard Class D airspace legal description. Additionally, the Oxnard Airport's Class D airspace abuts the Class D areas of Point Mugu Naval Air Station Airport and Camarillo Airport. The geographic coordinates in the Oxnard Airport Class D legal description should be updated to more accurately define the common borders of the three Class D surface areas, which would not represent a change to the current boundaries.

Class D, Class E4 and Class E5 airspace designations are published in paragraphs 5000, 6004, and 6005, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

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

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

§ 71.1 [Amended]

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

Paragraph 5000 Class D Airspace.

* * * * *

AWP CA D Oxnard, CA [Amended]

Oxnard Airport, CA
(Lat. 34°12′03″ N, long. 119°12′26″ W)

That airspace extending upward from the surface to and including 2,000 feet MSL within a 4.3-mile radius of the airport, excluding that portion east and southeast of a line beginning at lat. 34°15′38.75″ N, long. 119°09′34.88″ W, to lat. 34°10′22″ N, long. 119°09′27″ W, to lat. 34°07′44.53″ N, long. 119°12′18.39″ W. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

AWP CA E4 Oxnard, CA [Removed]

Oxnard Airport, CA
(Lat. 34°12′03″ N, long. 119°12′26″ W)

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

* * * * *

AWP CA E5 Oxnard, CA [New]

Oxnard Airport, CA
(Lat. 34°12′03″ N, long. 119°12′26″ W)

That airspace extending upward from 700 feet above the surface within a 4.8-mile radius of the airport, and within 2 miles each side of the 091° bearing from the airport, extending from the 4.8-mile radius to 12.4 miles east of the airport, and within 1.8 miles each side of the 265° bearing from the airport, extending from the 4.8-mile radius to 6.5 miles west of Oxnard Airport.

Issued in Des Moines, Washington, on April 4, 2022.

B.G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2022–07569 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0307; Airspace Docket No. 22–AGL–17]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Milbank and South Dakota, SD

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Milbank, SD, and the State of South Dakota. The FAA is proposing this action due to an airspace review conducted as part of the decommissioning of the Watertown very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program. The geographic coordinates of the airport would also be updated to coincide with the FAA's aeronautical database.

DATES: Comments must be received on or before May 26, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2022–0307/Airspace Docket No. 22–AGL–17 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Milbank Municipal Airport, Milbank, SD, to support instrument flight rule operations at this airport, and amend the Class E airspace extending upward from 700 feet above the surface over the State of South Dakota to clarify, simplify, standardize the airspace over the state, and close any gaps in the Class E airspace to support instrument flight rule operation over the state.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–0307/Airspace Docket No. 22–AGL–17.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by:

Amending the Class E airspace extending upward from 700 feet above the surface at Milbank Municipal Airport, Milbank, SD, by removing the Watertown VOR from the airspace legal description; updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database; and removing the airspace extending upward from 1,200 feet above the surface as it will become redundant with the amendment of the Class E airspace over the State of South Dakota;

And amending the Class E airspace extending upward from 1,200 feet above the surface at South Dakota, SD, from ''. . . an area bounded on the north by lat. 43°40′00″ N, on the east by long. 100°05′00″ W, on the south by the South Dakota, Nebraska border, and on the west by long. 102°00′02″ W'' to ''. . . the boundary of the State of South Dakota'' to clarify, simply, standardize the airspace over the state, and close any gaps in the Class E airspace.

This action is due to an airspace review conducted as part of the decommissioning of the Watertown VOR, which provided navigation information for the instrument procedures at this airport, as part of the VOR MON Program.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

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

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

71.1 [Amended]

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

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

* * * * *

AGL SD E5 Milbank, SD [Amended]

Milbank Municipal Airport, SD,
(Lat. 45°13′50″ N, long. 96°33′58″ W)

That airspace extending upward from 700 feet or more above the surface within a 6.4-mile radius of the Milbank Municipal Airport.

* * * * *

AGL SD E5 South Dakota, SD [Amended]

That airspace extending upward from 1,200 feet above the surface within the boundary of the State of South Dakota.

Issued in Fort Worth, Texas, on April 5, 2022.

Martin A. Skinner,

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

[FR Doc. 2022–07583 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0352; Airspace Docket No. 22–AGL–15]

RIN 2120–AA66

Proposed Establishment of Class E Airspace; Fertile, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace at Fertile, MN. The FAA is proposing this action to support the establishment of public instrument procedures at Fertile Municipal Airport, Fertile, MN.

DATES: Comments must be received on or before May 26, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2022–0352/Airspace Docket No. 22–AGL–15 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would establish Class E airspace extending upward form 700 feet above the surface at Fertile Municipal Airport, Fertile, MN, to support instrument flight rule operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis

supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–0352/Airspace Docket No. 22–AGL–15.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov*. Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/*.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by establishing Class E airspace extending upward form 700 feet above the surface within a 6.3-mile radius of Fertile Municipal Airport, Fertile, MN.

This action supports the establishment of public instrument procedures at Fertile Municipal Airport.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

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

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

71.1 [Amended]

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

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

* * * * *

AGL MN E5 Fertile, MN [Establish]

Fertile Municipal Airport, MN
(lat. 47°33′07″ N, long. 96°17′32″ W)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Fertile Municipal Airport.

Issued in Fort Worth, Texas, on April 5, 2022.

Martin A. Skinner,

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

[FR Doc. 2022–07581 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0310; Airspace Docket No. 22–ASW–6]

RIN 2120–AA66

Proposed Amendment of the Class E Airspace; Oakwood, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Oakwood, TX. The FAA is proposing this action due to an airspace review conducted as part of the decommissioning of the Leona very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program.

DATES: Comments must be received on or before May 26, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2022–0310/Airspace Docket No. 22–ASW–6, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Carter Ranch Airport, Oakwood, TX, to support instrument flight rule operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–0310/Airspace Docket No. 22–ASW–6.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov*. Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by amending the Class E airspace extending upward from 700 feet above the surface at Carter Ranch Airport, Oakwood, TX, by removing the Leona VORTAC and associated extension from the airspace legal description; removing the exclusionary language from the airspace legal description as it is not required; and removing the city associated with the airport to comply with changes to FAA Order JO 7400.2N, Procedures for Handling Airspace Matters.

This action is the result of an airspace review conducted as part of the decommissioning of the Leona VOR, which provided navigation information for the instrument procedures at this airport, as part of the VOR MON Program.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

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

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

71.1 [Amended]

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

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

* * * * *

ASW TX E5 Oakwood, TX [Amended]

Carter Ranch Airport, TX
(Lat. 31°34′01″ N, long. 95°46′00″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Carter Ranch Airport.

Issued in Fort Worth, Texas, on April 5, 2022.

Martin A. Skinner,

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

[FR Doc. 2022–07586 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0306; Airspace Docket No. 22–AGL–16]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Baldwin, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Baldwin, MI. The FAA is proposing this action due to an airspace review conducted as part of the decommissioning of the White Cloud very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program. The geographic coordinates of the airport would also be updated to coincide with the FAA's aeronautical database.

DATES: Comments must be received on or before May 26, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2022–0306/Airspace Docket No. 22–AGL–16 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Baldwin Municipal Airport, Baldwin, MI, to support instrument flight rule operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–0306/Airspace Docket No. 22–AGL–16.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by amending the Class E airspace extending upward from 700 feet above the surface at Baldwin Municipal Airport, Baldwin, MI, by removing the White Cloud VOR and associated extension from the airspace legal description; and updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is due to an airspace review conducted as part of the decommissioning of the White Cloud VOR, which provided navigation information for the instrument procedures at this airport, as part of the VOR MON Program.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

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

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

71.1 [Amended]

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

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

* * * * *

AGL MI E5 Baldwin, MI [Amended]

Baldwin Municipal Airport, MI
(Lat. 43°52′32″ N, long. 85°50′31″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Baldwin Municipal Airport.

Issued in Fort Worth, Texas, on April 5, 2022.

Martin A. Skinner,

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

[FR Doc. 2022–07582 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0309; Airspace Docket No. 22–AEA–3]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Connellsville, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Connellsville, PA. The FAA is proposing this action as the result of an airspace review caused by the decommissioning of the Indian Head VHF omnidirectional range (VOR) navigation aids as part of the VOR Minimum Operational Network (MON) Program. The name and geographic coordinates of the airport would also be updated to coincide with the FAA's aeronautical database.

DATES: Comments must be received on or before May 26, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2022–0309/Airspace Docket No. 22–AEA–3, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Joseph A. Hardy Connellsville Airport, Connellsville, PA, to support instrument flight rule operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–0309/Airspace Docket No. 22–AEA–3.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov*. Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/*.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by amending the Class E airspace extending upward from 700 feet above the surface within a 6.4-mile (decreased from a 6.5-mile) radius of Joseph A. Hardy Connellsville Airport, Connellsville, PA; removing the CAMOR LOM/NDB and associated extension from the airspace legal description as it is no longer needed; removing the Indian Head VORTAC and associated extension from the airspace legal description; and updating the name (previously Connellsville Airport) and geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is the result of an airspace review caused by the decommissioning of the Indian Head VOR, which provided navigation information for the instrument procedures at this airport, as part of the VOR MON Program.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

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

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR 71 as follows:

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

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

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

71.1 [Amended]

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

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

* * * * *

AEA PA E5 Connellsville, PA [Amended]

Joseph A. Hardy Connellsville Airport, PA
(Lat. 39°57′33″ N, long. 79°39′27″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Joseph A. Hardy Connellsville Airport.

Issued in Fort Worth, Texas, on April 5, 2022.

Martin A. Skinner,

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

[FR Doc. 2022–07585 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0346; Airspace Docket No. 22–ASW–8]

RIN 2120–AA66

Proposed Amendment of the Class E Airspace; Mexia, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Mexia, TX. The FAA is proposing this action due to an airspace review conducted as part of the decommissioning of the Mexia non-directional beacon (NDB). The geographic coordinates of the airport would also be updated to coincide with the FAA's aeronautical database.

DATES: Comments must be received on or before May 26, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2022–0346/Airspace Docket No. 22–ASW–8, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Mexia-Limestone County Airport, Mexia, TX, to support instrument flight rule operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–0346/Airspace Docket No. 22–ASW–8.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by amending the Class E airspace extending upward from 700 feet above the surface to within a 6.5-mile (increased from a 6.4-mile) radius at Mexia-Limestone County Airport, Mexia, TX; removing the Mexia RBN and the associated extension from the airspace legal description; and updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is the result of an airspace review conducted as part of the decommissioning of the Mexia NDB

which provided navigation information for the instrument procedures at this airport.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

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

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

71.1 [Amended]

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

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

* * * * *

ASW TX E5 Mexia, TX [Amended]

Mexia-Limestone Country Airport, TX
(Lat. 31°38′28″ N, long. 96°30′52″ W)

That airspace extending from 700 feet above the surface within a 6.5-mile radius of Mexia-Limestone County Airport.

Issued in Fort Worth, Texas, on April 5, 2022.

Martin A. Skinner,

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

[FR Doc. 2022–07589 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0311; Airspace Docket No. 22–ASW–7]

RIN 2120–AA66

Proposed Amendment of the Class E Airspace; Graham, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Graham, TX. The FAA is proposing this action due to an airspace review conducted as part of the decommissioning of the Graham non-directional beacon (NDB). The geographic coordinates of the airport would also be updated to coincide with the FAA's aeronautical database.

DATES: Comments must be received on or before May 26, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2022–0311/Airspace Docket No. 22–ASW–7, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Graham Municipal Airport, Graham, TX, to support instrument flight rule operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in

triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–0311/Airspace Docket No. 22–ASW–7.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by amending the Class E airspace extending upward from 700 feet above the surface to within a 6.5-mile (increased from a 6.4-mile) radius of Graham Municipal Airport, Graham, TX; removing the Graham RBN and the associated extension from the airspace legal description; and updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is the result of an airspace review conducted as part of the decommissioning of the Graham NDB which provided navigation information for the instrument procedures at this airport.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

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

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

71.1 [Amended]

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

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

* * * * *

ASW TX E5 Graham, TX [Amended]

Graham Municipal Airport, TX
(Lat. 33°06′39″ N, long. 98°33′17″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Graham Municipal Airport.

Issued in Fort Worth, Texas, on April 5, 2022.

Martin A. Skinner,

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

[FR Doc. 2022–07587 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0308; Airspace Docket No. 22–AGL–18]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Mosinee, WI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Mosinee, WI. The FAA is proposing this action due to an airspace review conducted as part of the decommissioning of the Wausau very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program.

DATES: Comments must be received on or before May 26, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of

Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2022–0308/Airspace Docket No. 22–AGL–18 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Central Wisconsin Airport, Mosinee, WI, to support instrument flight rule operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–0308/Airspace Docket No. 22–AGL–18.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by amending the Class E airspace extending upward from 700 feet above the surface at Central Wisconsin Airport, Mosinee, WI, by removing the Wausau VORTAC from the airspace legal description; adding an extension 1 mile each side of the 170° bearing from the Central Wisconsin: RWY 35–LOC extending from the 7-mile radius from the airport to 11.2 miles south of the airport; adding an extension 1 mile each side of the 257° bearing from the airport extending from the 7-mile radius of the airport to 11.5 miles west of the airport; and removing the extension north of the airport as the amended extension would be contained within the Wausau, WI, Class E airspace so would be redundant.

This action is due to an airspace review conducted as part of the decommissioning of the Wausau VOR, which provided navigation information for the instrument procedures at this airport, as part of the VOR MON Program.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

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

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

71.1 [Amended]

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

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

* * * * *

AGL WI E5 Mosinee, WI [Amended]

Central Wisconsin Airport, WI
(Lat. 44°46′39″ N, long. 89°40′00″ W)
Central Wisconsin: RWY 35–LOC
(Lat. 44°47′02″ N, long. 89°40′34″ W)
Central Wisconsin: RWY 08–LOC
(Lat. 44°47′07″ N, long. 89°28′30″ W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of the Central Wisconsin Airport, and within 1 mile each side of the 170° bearing from the Central Wisconsin: RWY 35–LOC extending from the 7-mile radius of the airport to 11.2 miles south of the airport, and within 1 mile each side of the 257° bearing from the Central Wisconsin: RWY 08–LOC extending from the 7-mile radius of the airport to 11.5 miles west of the airport.

Issued in Fort Worth, Texas, on April 5, 2022.

Martin A. Skinner,

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

[FR Doc. 2022–07584 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2022–F–0342]

Anitox Corporation; Filing of Food Additive Petition (Animal Use)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Anitox Corporation, proposing that the food additive regulations be amended to provide for the safe use of trans-2-hexenal as a preservative in food for poultry and swine.

DATES: The food additive petition was filed on March 8, 2022.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this 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.

FOR FURTHER INFORMATION CONTACT: Carissa Adams, Center for Veterinary Medicine (HFV–221), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6283, *Carissa.Adams@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 2315), submitted by Anitox Corporation, 1055 Progress Circle, Lawrenceville, GA 30043–4646. The petition proposes to amend 21 CFR part 573—Food Additives Permitted in Feed and Drinking Water of Animals to provide for the safe use of trans-2-hexenal as a preservative in food for poultry and swine.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(r) because it is of a type that does not individually or cumulatively have a significant effect on the human environment. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist that may significantly affect the quality of the human environment. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: April 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07683 Filed 4–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA824]

Schedules of Controlled Substances: Placement of 2,5-dimethoxy-4-iodoamphetamine (DOI) and 2,5-dimethoxy-4-chloroamphetamine (DOC) in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing two phenethylamine hallucinogens, as identified in this proposed rule, in schedule I of the Controlled Substances Act. This action is being taken, in part, to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances for one of these substances. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle these two specific controlled substances.

DATES: Comments must be submitted electronically or postmarked on or before June 10, 2022.

Interested persons may file a request for hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and/or 1316.47, as applicable. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing, together with a written statement of position on the matters of fact and law asserted in the hearing, must be received on or before May 11, 2022.

ADDRESSES: Interested persons may file written comments on this proposal in

accordance with 21 CFR 1308.43(g). The electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period. To ensure proper handling of comments, please reference ''Docket No. DEA–824'' on all electronic and written correspondence, including any attachments.

• *Electronic comments:* DEA encourages commenters to submit all comments electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the on-line instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number. Submitted comments are not instantaneously available for public view on *regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

• *Paper comments:* Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA FR Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

• *Hearing requests:* All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law asserted in the hearing, must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA FR Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION: In this proposed rule, the Drug Enforcement Administration (DEA) proposes to schedule the following two controlled substances in schedule I of the Controlled Substances Act (CSA), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- 2,5-dimethoxy-4-iodoamphetamine (DOI) and
- 2,5-dimethoxy-4-chloroamphetamine (DOC)

Posting of Public Comments

All comments received in response to this docket are considered part of the public record. DEA will make comments available, unless reasonable cause is given, for public inspection online at *https://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want DEA to make it publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

DEA will generally make available in publicly redacted form comments containing personal identifying information and confidential business information identified, as directed above. If a comment has so much confidential business information that DEA cannot effectively redact it, DEA may not make available publicly all or part of that comment. Comments posted to *https://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as confidential as directed above.

An electronic copy of this document and supplemental information to this proposed rule are available at *https://www.regulations.gov* for easy reference.

Request for Hearing or Appearance; Waiver

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act, 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. Interested persons may file requests for a hearing or notices of intent to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(a) or (b), and such requests must include a statement of interest in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. 21 CFR 1316.47(a). Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing together with a written statement regarding the interested person's position on the matters of fact and law involved in any hearing as set forth in 21 CFR 1308.44(c).

All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law involved in such hearing, must be sent to DEA using the address information provided above.

Legal Authority

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General on his own motion. 21 U.S.C. 811(a). This proposed action is supported by a recommendation from the then-Assistant Secretary for Health of the Department of Health and Human Services (HHS).

In addition, the United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), February 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2)–(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention indicating that a drug or other substance has been added to a schedule specified in the notification, the Secretary of HHS (Secretary),[1] after

[1] As discussed in a memorandum of understanding entered into by the Food and Drug

consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance. 21 U.S.C. 811(d)(3). In the event that the Secretary did not so consult with the Attorney General, and the Attorney General did not issue a temporary order, as provided under 21 U.S.C. 811(d)(4), the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) control. Pursuant to 21 U.S.C. 811(a)(1), the Attorney General (as delegated to the Administrator of DEA) may, by rule, add to such a schedule or transfer between such schedules any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed.

Background

DOI and DOC belong to the phenethylamine class of drugs with hallucinogenic properties, similar to 2,5-dimethoxy-4-methamphetamine (DOM), a schedule I hallucinogen. DOI and DOC have no approved medical use in the United States.

On September 26, 2018, DEA, in accordance with the provisions of 21 U.S.C. 811(b), requested HHS provide a scientific and medical evaluation as well as a scheduling recommendation for DOI and DOC. Additionally, on May 7, 2020, the Secretary-General of the United Nations advised the Secretary of State of the United States that the Commission on Narcotic Drugs (CND), during its 63rd Session in March 2020, voted to place DOC in Schedule I of the 1971 Convention (CND Dec/63/4). As a signatory to this international treaty, the United States is required, by scheduling under the CSA, to place appropriate controls on DOC to meet the minimum requirements of the treaty.

Article 2, paragraph 7(a), of the 1971 Convention sets forth the minimum requirements that the United States must meet when a substance has been added to Schedule I of the 1971 Convention. The United States must adhere to specific export and import provisions that are provided in the 1971 Convention. This requirement is accomplished by the CSA with the export and import provisions established in 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312. Under Article 16, paragraph 4, of the 1971 Convention, the United States is required to provide annual statistical reports to the International Narcotics Control Board (INCB). Using INCB Form P, the United States shall provide the following information: (1) In regard to each substance in Schedule I and II of the 1971 Convention, quantities manufactured, exported to and imported from each country or region as well as stocks held by manufacturers; (2) in regard to each substance in Schedule III and IV of the 1971 Convention, quantities manufactured, as well as quantities exported and imported; (3) in regard to each substance in Schedule II and III of the 1971 Convention, quantities used in the manufacture of exempt preparations; and (4) in regard to each substance in Schedule II–IV of the 1971 Convention, quantities used for the manufacture of non-psychotropic substances or products. Lastly, under Article 2, paragraph 7(a)(vi) of the 1971 Convention, the United States must adopt measures in accordance with Article 22 to address violations of any statutes or regulations that are adopted pursuant to its obligations under the 1971 Convention. The United States complies with this provision as persons acting outside the legal framework established by the CSA are subject to administrative, civil, and/or criminal action.

Proposed Determination To Schedule DOI and DOC

Pursuant to 21 U.S.C. 811(b), DEA gathered the necessary data on DOI and DOC and on September 26, 2018, submitted it to the then-Assistant Secretary for Health of HHS with a request for a scientific and medical evaluation of available information and a scheduling recommendation for DOI and DOC. On September 28, 2020, HHS provided to DEA a scientific and medical evaluation entitled ''Basis for the Recommendation to Control 2,5-dimethoxy-4-iodoamphetamine (DOI) and 2,5-dimethoxy-4-chloroamphetamine (DOC) and their Salts in Schedule I of the Controlled Substances Act (CSA)'' and a scheduling recommendation. Following consideration of the eight factors and findings related to these substances' abuse potential, legitimate medical use, and dependence liability, HHS recommended that DOI and DOC and their salts be controlled in schedule I of the CSA under 21 U.S.C. 812(b). In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS and all other relevant data, and completed its own eight-factor review pursuant to 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by HHS and DEA in their respective eight-factor analyses, and as considered by DEA in this proposed scheduling determination. Please note that both DEA and HHS analyses are available in their entirety under ''Supporting Documents'' of the public docket for this proposed rule at *https://www.regulations.gov* under docket number ''DEA–824.''

1. The Drug's Actual or Relative Potential for Abuse

In addition to considering the information HHS provided in its scientific and medical evaluation document for DOI and DOC, DEA also considered all other relevant data regarding actual or relative potential for abuse of DOI and DOC. The term ''abuse'' is not defined in the CSA; however, the legislative history of the CSA suggests the following four prongs in determining whether a particular drug or substance has a potential for abuse: [2]

a. Individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or

b. There is a significant diversion of the drug or other substance from legitimate drug channels; or

c. Individuals are taking the drug or other substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs; or

d. The drug is so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that it will have the same potential for abuse as such substance, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

DEA reviewed the scientific and medical evaluation provided by HHS

Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518 (March 8, 1985). The Secretary has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

[2] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., 2nd Sess. (1970) reprinted in 1970 U.S.C.C.A.N. 4566, 4603.

and all other data relevant to the abuse potential of DOI and DOC. These data as presented below demonstrate that DOI and DOC have a high potential for abuse.

a. *There is evidence that individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community.*

Data show that DOI and DOC have been encountered by law enforcement in the United States (see Factor 5), indicating DOI and DOC availability for abuse. According to HHS, individuals are using DOI and DOC for their hallucinogenic effects and taking them in amounts sufficient to create a hazard to their health.

b. *There is significant diversion of the drug or substance from legitimate drug channels.*

HHS states that DOI and DOC are not Food and Drug Administration (FDA)-approved drugs for treatment in the United States and is unaware of any country in which their use is legal. DOI and DOC are available for purchase from legitimate chemical synthesis companies because they are used in scientific research. There is no evidence of diversion from these companies.

c. *Individuals are taking the substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such substance.*

DOI and DOC are not found in FDA-approved drug products and practitioners may neither legally prescribe nor dispense these substances. Therefore, individuals are taking DOI and DOC on their own initiative, rather than based on medical advice from practitioners licensed by law to administer drugs. This is consistent with the data from law enforcement seizures and case reports indicating that individuals are taking DOI and DOC on their own initiative rather than on the medical advice of licensed practitioners.

d. *The drug is a new drug so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that the drug substance will have the same potential for abuse as such drugs, thus making it reasonable to assume that there may be significant diversion from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.*

Chemically, DOI and DOC are analogs of the schedule I hallucinogen DOM. The effects and pharmacological action of DOI and DOC are similar to those of other schedule I hallucinogens, such as DOM and lysergic acid diethylamide (LSD), which have no accepted medical use and a high abuse potential.

In drug discrimination studies (an *in vivo* test to assess drug abuse liability of test drugs in comparison to known drugs of abuse), DOI and DOC produce full substitution for the discriminative stimulus effects of DOM, LSD, and *N,N*-dimethyltryptamine (DMT, schedule I). In humans, anecdotal reports suggest that DOI and DOC produce classic hallucinogenic effects that are similar to DOM, including visual and auditory hallucinations, fatigue, headache, gastrointestinal distress, insomnia and anxiety. HHS notes that use of DOC in combination with other drugs is associated with emergency department admissions and one death.

Due to the psychological and cognitive disturbances associated with DOI and DOC, as with other schedule I hallucinogens, it is reasonable to assume that DOI and DOC have substantial capability to be a hazard to the health of the user and to the safety of the community.

2. Scientific Evidence of the Drug's Pharmacological Effects, if Known

In vitro testing shows that DOI and DOC bind to and act as agonists at serotonin (5-HT) 2A (5-HT_{2A}) receptors. In rats, DOI administration induced an increase in wet dog shakes and back muscle contractions. These effects were attributed to 5-HT_{2A} receptor activation, since pretreatment with a 5-HT_{2A} receptor inverse agonist blocked the effect. Agonism of the 5-HT_{2A} receptor is the primary mechanism of action of typical hallucinogenic responses, suggesting that DOI and DOC have hallucinogenic effects. Additionally, animal testing data in rats show that DOI and DOC fully substitute for DOM, LSD, and DMT discriminative stimulus effects in drug discrimination tests.

In humans, HHS reported that anecdotal reports of hallucinogenic experiences with DOI and DOC are available on online drug forums such as *www.erowid.org,* in which recreational drug users report on their experiences with all classes of substances. In these reports, DOI and DOC are reported to induce hallucinogenic effects, including prominent visual effects.

Additionally, a World Health Organization (WHO) critical review of DOC [3] mentions its hallucinogenic effects reported by those that self-experimented with DOC and notes the duration of action may last 12 to 24 hours. WHO notes that the long duration of effects is shared by other structurally related schedule I hallucinogens including DOI, 2,5-dimethoxy-4-bromoamphetamine (DOB), and DOM. DOI and DOC are commonly administered orally and/or sublingually when encountered in the form of blotters.

3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance

DOI and DOC are centrally-acting hallucinogens and part of the phenethylamine hallucinogen family and share structural similarities with schedule I phenethylamine hallucinogens such as DOM. DOI (CAS 42203–78–1) has a molecular formula of $C_{11}H_{16}INO_2$ and a molecular weight of 321.16 g/mol. The hydrochloride salt of DOI has a melting point of 201 °C. DOC (CAS 123431–31–2) has a molecular formula of $C_{11}H_{16}ClNO_2$ and a molecular weight of 229.70 g/mol. The hydrochloride salt of DOC has a melting point of 193–194.5 °C. DOI and DOC are white, odorless, and crystalline solids.

4. Its History and Current Pattern of Abuse

The history and current pattern of abuse of DOI and DOC are described in law enforcement reports and anecdotal reports by drug abusers. In the United States, law enforcement entities initially encountered DOI and DOC in 2005, according to the National Forensic Laboratory Information System (NFLIS).[4] See Factor 5 for additional information. DOI and DOC are encountered in various forms (*e.g.,* powder, tablets, capsules, liquid, or on blotter paper).

Anecdotal reports on the internet indicate that individuals are using substances they identified as DOI and DOC for their hallucinogenic effects. Importantly, it is impossible to know if the street drugs sold to an individual as DOI or DOC are actually the substances they are marketed as in the absence of chemical analysis or evaluation of biological fluids following ingestion. However, in animal drug discrimination studies, DOI and DOC produced effects that are similar to the effects elicited by schedule I hallucinogens such as DOM, LSD, and DMT.

A July 2019 report from the European Monitoring Centre for Drugs and Drug Addiction included data from their

[3] World Health Organization (WHO). 2019a. Critical Review Report: DOC (4-Chloro-2,5-dimethoxyamfetamine) Expert Committee on Drug Dependence, Forty-second Meeting. Geneva.

[4] NFLIS is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States. NFLIS data were queried on February 23, 2021.

toxicology portal, and indicated that 16 non-fatal intoxications associated with DOC had been reported internationally between 2008 and 2017. In 2019, the United Nations Office on Drugs and Crime reported three deaths associated with DOC (one each in 2015 and 2018; information about the third is unknown).

5. The Scope, Duration, and Significance of Abuse

Data from NFLIS indicate that DOI and DOC were found in samples starting in 2005, in the United States. Specifically, there were 40 NFLIS reports for DOI from 2005 through February 2021, and 785 NFLIS reports for DOC during the same period. DOI has been encountered in 14 states, whereas DOC has been encountered in 38 states. In response to abuse and safety concerns, DOI has been controlled in Florida.

Abuse of DOI and DOC has been characterized as causing acute public health and safety issues worldwide. WHO reports that DOC has been available in Europe since 2001. Based on available abuse data, public health risk, and drug trafficking data, the WHO recommended to the United Nations (UN) that DOC be controlled internationally. In March 2020, the UN Commission on Narcotic Drugs voted to place DOC into Schedule I of the 1971 Convention.

6. *What, if Any, Risk There Is to the Public Health*

DOI and DOC share similar mechanisms of action with and produce similar physiological and subjective effects (see Factor 2 for more information) as other schedule I hallucinogens, such as DOM, DMT, and LSD. Thus, DOI and DOC pose the same risks to public health as similar hallucinogens. Predominantly, the risks to public health are borne by users (*i.e.,* hallucinogenic effects, sensory distortion, impaired judgement, strange or dangerous behaviors), but they can affect the general public, as with driving under the influence. To date, there are no reports of distressing responses or death associated with DOI in medical literature. There have been three published reports, in 2008, 2014, and 2015, of adverse events associated with DOC including, but not limited to, seizures, agitation, tachycardia, hypertension, and death of one individual. Since DOI is structurally similar to DOC and produces similar effects to DOC, it is likely to produce serious adverse effects similar to DOC. Thus, serious adverse events that may include death represent a risk to the individual drug users and to public health.

7. Its Psychic or Physiological Dependence Liability

According to HHS, the physiological dependence liability of DOI and DOC in animals and humans is not reported in scientific and medical literature. Thus, it is not possible to determine whether DOI and DOC produce physiological dependence following acute or chronic administration.

According to HHS, DOI, DOC, and other related phenethylamine hallucinogens (such as the schedule I substance DOM) are highly abusable substances. Drug discrimination studies in animals indicate that DOI and DOC fully substitute to the discriminative stimulus effects of schedule I hallucinogens DOM, LSD, and DMT. HHS notes that hallucinogens are not usually associated with physical dependence, likely due to the rapid development of tolerance precluding daily administration. Hallucinogen abusers may develop psychological dependence as evidenced by the continued use of these substances despite knowledge of their potential toxic and adverse effects.

8. Whether the Substance Is an Immediate Precursor of a Substance Already Controlled Under the CSA

DOI and DOC are not immediate precursors of any controlled substance of the CSA as defined by 21 U.S.C. 802(23).

Conclusion

Based on consideration of the scientific and medical evaluation and accompanying recommendation of HHS, and on DEA's own eight-factor analysis, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of DOI and DOC. As such, DEA proposes to schedule DOI and DOC as controlled substances under the CSA.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule, per 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the then-Assistant Secretary for Health of HHS and review of all other available data, the Administrator of DEA, pursuant to 21 U.S.C. 812(b)(1), finds that:

(1) DOI and DOC have a high potential for abuse that is comparable to other schedule I substances, such as the phenethylamine hallucinogen DOM;

(2) FDA has not approved a marketing application for a drug product containing DOI or DOC for any therapeutic indication. In addition, DEA and HHS know of no clinical studies or petitioners claiming an accepted medical use in the United States. Therefore, DOI and DOC have no currently accepted medical use in treatment in the United States.[5]

(3) There is a lack of accepted safety for use of DOI and DOC under medical supervision. The use of DOC is associated with serious adverse consequences including deaths. Since DOI is structurally similar to DOC and produces effects similar to DOC, it is likely that DOI may produce serious adverse events similar to DOC. Because DOI and DOC have no approved medical use and have not been investigated as new drugs, their safety for use under medical supervision has not been determined. Therefore, there is a lack of accepted safety for use of DOI and DOC under medical supervision.

Based on these findings, the Administrator of DEA concludes that DOI and DOC warrant control in schedule I of the CSA. More precisely, because of their hallucinogenic effects, and because they may produce hallucinogenic-like tolerance and dependence in humans, DEA proposes to place DOI and DOC, including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical description, in 21 CFR 1308.11(d) (the hallucinogenic substances category of schedule I).

Requirements for Handling DOI and DOC

If this rule is finalized as proposed, DOI and DOC would be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal

[5] Although there is no evidence suggesting that DOI and DOC have a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: i. The drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. 57 FR 10499 (1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994).

sanctions applicable to the manufacture, distribution, reverse distribution, import, export, engagement in research, conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) or desires to handle DOI or DOC would be required to register with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312, as of the effective date of a final scheduling action. Any person who currently handles DOI or DOC and is not registered with DEA would need to submit an application for registration and may not continue to handle DOI and DOC as of the effective date of a final scheduling action unless DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312.

2. Disposal of Stocks. Any person unwilling or unable to obtain a schedule I registration would be required to surrender or transfer all quantities of currently held DOI and DOC to a person registered with DEA before the effective date of a final scheduling action, in accordance with all applicable Federal, State, local, and tribal laws. As of the effective date of a final scheduling action, DOI and DOC would be required to be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* DOI and DOC would be subject to schedule I security requirements and would need to be handled and stored pursuant to 21 U.S.C. 823 and in accordance with 21 CFR 1301.71–1301.76, as of the effective date of a final scheduling action. Non-practitioners handling DOI and DOC would also need to comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

4. *Labeling and Packaging.* All labels and packaging for commercial containers of DOI and DOC would need to be in compliance with 21 U.S.C. 825, and be in accordance with 21 CFR part 1302, as of the effective date of a final scheduling action.

5. *Quota.* Only registered manufacturers would be permitted to manufacture DOI and DOC in accordance with quotas assigned pursuant to 21 U.S.C. 826, and in accordance with 21 CFR part 1303, as of the effective date of a final scheduling action.

6. *Inventory.* Every DEA registrant who possesses any quantity of DOI and DOC on the effective date of the final scheduling action would be required to take an inventory of DOI and DOC on hand at that time, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who registers with DEA on or after the effective date of the final scheduling action would be required to take an initial inventory of all stocks of controlled substances (including DOI and DOC) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant would be required to take a new inventory of all controlled substances (including DOI and DOC) on hand every two years, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant would be required to maintain records and submit reports for DOI and DOC, or products containing DOI and DOC, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317, as of the effective date of a final scheduling action. Manufacturers and distributors would need to submit reports regarding DOI and DOC to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312, as of the effective date of a final scheduling action.

8. *Order Forms.* Every DEA registrant who distributes DOI and DOC would be required to comply with the order form requirements, pursuant to 21 U.S.C. 828, and 21 CFR part 1305, as of the effective date of a final scheduling action.

9. *Importation and Exportation.* All importation and exportation of DOI and DOC would need to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312, as of the effective date of a final scheduling action.

10. *Liability.* Any activity involving DOI and DOC not authorized by, or in violation of, the CSA or its implementing regulations would be unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 and 13563, Regulatory Planning and Review, and Improving Regulation and Regulatory Review

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed 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.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of E.O. 13175. It does not 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.

Paperwork Reduction Act

This proposed action does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521.

Regulatory Flexibility Act

The Administrator of DEA, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this proposed rule, and by approving it, certifies that it will not

have a significant economic impact on a substantial number of small entities.

DEA proposes placing the substances DOI and DOC (chemical names: 2,5-dimethoxy-4-iodoamphetamine [DOI] and 2,5-dimethoxy-4-chloroamphetamine [DOC]), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, in schedule I of the CSA. This action is being taken, in part, to enable the United States to meet its obligations under the 1971 Convention for DOC. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle DOI and DOC.

According to HHS, and also by DEA's findings in this proposed rule, DOI and DOC have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and lack accepted safety for use under medical supervision. There appear to be no legitimate sources for DOI and DOC as marketed drugs in the United States, but DEA notes that these substances are available for purchase from legitimate suppliers for scientific research. There is no evidence of significant diversion of DOI and DOC from legitimate suppliers. As such, the proposed rule will not, if promulgated, result in a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the ''Regulatory Flexibility Act'' section above, DEA has determined pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.*) that this proposed action would not result in 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 1 year . . . .'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is proposed to be amended to read as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, as proposed to be amended at 86 FR 16553 (March 30, 2021), 86 FR 37719 (July 16, 2021), 86 FR 69187 (December 7, 2021), and 87 FR 2383 (January 14, 2022), add paragraphs (d)(106) and (107) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(106) 2,5-dimethoxy-4-iodoamphetamine (Other name: DOI) 7447
(107) 2,5-dimethoxy-4-chloroamphetamine (Other name: DOC) 7448

* * * * *

Anne Milgram,

Administrator.

[FR Doc. 2022–07648 Filed 4–8–22; 8:45 am]

BILLING CODE 4410–09–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3010

[Docket No. RM2022–4; Order No. 6141]

RIN 3211–AA31

Rules of Practice and Procedure

AGENCY: Postal Regulatory Commission.

ACTION: Proposed rulemaking.

SUMMARY: The Commission is proposing to add rules which revise the Commission's rules of practice and procedure regarding notices, motions, and information requests. The Commission invites public comment on the proposed rules.

DATES: *Comments are due:* May 26, 2022.

ADDRESSES: For additional information, Order No. 6141 can be accessed electronically through the Commission's website at *https://www.prc.gov.* Submit comments electronically via the Commission's Filing Online system at *https://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Relevant Statutory Requirements

Pursuant to 39 U.S.C. 503, the Commission establishes this rulemaking docket to propose amendments to the Commission's rules of practice and procedure regarding notices, motions, and information requests.

II. Background

The proposed amendments provide rules relating to motions for reconsideration of final Commission orders.[1]

[1] Motions for review of other Commission determinations may be filed in accordance with 39 CFR 3010.160.

III. Basis and Purpose of Proposed Rules

The proposed amendments revise the Commission's rules on notices, motions, and information requests, within its rules of practice and procedure, to provide rules specific to motions for reconsideration. The proposed amendments reflect the Commission's current practice of hearing timely motions for reconsideration of its final orders.

Under the proposed rules, any party may file a motion for reconsideration of a Commission final order within 15 days of the issuance of the order subject to the motion. All motions for reconsideration must briefly and specifically allege material errors of fact or law, and the relief sought, and must be confined to new questions raised by the determination or action ordered and upon which the moving party had no prior opportunity to submit arguments. Finally, no motion for reconsideration shall stay the effect of an order of the Commission unless the Commission orders otherwise.

IV. Proposed Rules

Proposed § 3010.165(a). Proposed § 3010.165(a) is added to explain eligibility among parties for filing motions for reconsideration.

Proposed § 3010.165(b). Proposed § 3010.165(b) is added to clarify the timing and content requirements for motions for reconsideration.

Proposed § 3010.165(c). Proposed § 3010.165(c) is added to explain that motions for reconsideration do not, on their own, stay the effect of the underlying order.

List of Subjects in 39 CFR Part 3010

Administrative practice and procedure, Confidential business information, Freedom of information, Sunshine Act.

Erica A. Barker,

Secretary.

For the reasons stated in the preamble, the Commission proposes to amend chapter III of title 39 of the Code of Federal Regulations as follows:

PART 3010—RULES OF PRACTICE AND PROCEDURE

■ 1. The authority citation for part 3010 continues to read as follows:

Authority: 39 U.S.C. 404(d); 503; 504; 3661.

■ 2. Add § 3010.165 to read as follows:

§ 3010.165 Motions for reconsideration.

(a) Any person may file a motion requesting reconsideration of a final order by the Commission.

(b) The motion shall be filed within 15 days of the issuance of the final order that is the subject of the motion and must:

(1) Briefly and specifically allege material errors of fact or law and the relief sought; and

(2) Be confined to new questions raised by the determination or action ordered and upon which the moving party had no prior opportunity to submit arguments.

(c) Unless the Commission orders otherwise, the filing of a motion for reconsideration shall not stay the effect of an order of the Commission.

[FR Doc. 2022–07725 Filed 4–8–22; 8:45 am]

BILLING CODE 7710–FW–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2021–0807; FRL–9680–01–R8]

Approval and Promulgation of Implementation Plans; South Dakota; Revisions to South Dakota Codified Law and Administrative Rules of South Dakota

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or the ''Agency'') is proposing approval of South Dakota's submittal requesting that EPA recognize the merger of South Dakota's Department of Agriculture (DOA) with the Department of Environment and Natural Resources (DENR) to form the new Department of Agriculture and Natural Resources (DANR) and incorporate corresponding non-substantive revisions to the South Dakota Codified Law (SDCL) and the Administrative Rules of South Dakota (ARSD) into South Dakota's State Implementation Plan. Accordingly, EPA is proposing to approve South Dakota's submittal in accordance with the Clean Air Act (CAA).

DATES: Written comments must be received on or before May 11, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2021–0807, to the Federal Rulemaking Portal: *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *www.regulations.gov.* EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically in *www.regulations.gov.* To reduce the risk of COVID–19 transmission, for this action we do not plan to offer hard copy review of the docket. Please email or call the person listed in the **FOR FURTHER INFORMATION CONTACT** section if you need to make alternative arrangements for access to the docket.

FOR FURTHER INFORMATION CONTACT: Kate Gregory, Air and Radiation Division, U.S. Environmental Protection Agency (EPA), Region 8, Mail Code 8P–ARD–QP, 1595 Wynkoop Street, Denver, Colorado 80202–1129, telephone number: (303) 312–6175, email address: *gregory.kate@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' and ''our'' means EPA. In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives such comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules section of this issue of the **Federal Register**.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Greenhouse gases, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone,

Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: April 2, 2022.

K.C. Becker,

Regional Administrator, Region 8.

[FR Doc. 2022–07411 Filed 4–8–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 220405–0084]

RIN 0648–BL17

Atlantic Highly Migratory Species; Shortfin Mako Shark Retention Limit

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS is proposing to implement a flexible shortfin mako shark retention limit with a default limit of zero in commercial and recreational Atlantic highly migratory species (HMS) fisheries. NMFS proposes to leave the default limit of zero in place unless and until changed. Changes to the retention limit could only be made based on regulatory criteria and only if consistent with an allowable retention determination made by the International Commission for the Conservation of Atlantic Tunas (ICCAT) pursuant to Recommendation 21–09. This action is necessary to implement the binding recommendation of ICCAT adopted in 2021, as authorized under the Atlantic Tunas Convention Act (ATCA), and to achieve domestic management objectives under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

DATES: Written comments must be received by May 11, 2022. NMFS will hold a public hearing via conference call and webinar for this proposed rule on April 27, 2022, from 2 p.m. to 5 p.m. EDT. For webinar registration information, see the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: Electronic copies of this proposed rule and supporting documents are available from the HMS Management Division website at *https://www.fisheries.noaa.gov/topic/atlantic-highly-migratory-species.*

You may submit comments on this document, identified by NOAA–NMFS–2022–0015, by electronic submission. Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter ''NOAA–NMFS–2022–0015'' in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the close of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Carrie Soltanoff (*carrie.soltanoff@noaa.gov*) or Guy DuBeck (*guy.dubeck@noaa.gov*) at 301–427–8503.

SUPPLEMENTARY INFORMATION: North Atlantic shortfin mako sharks are managed primarily under the authority of the Magnuson-Stevens Act (16 U.S.C. 1801 *et seq.*), as well as under ATCA (16 U.S.C. 971 *et seq.*) because they are primarily caught in fisheries for tuna and tuna-like species. Like other Atlantic highly migratory species, North Atlantic shortfin mako sharks are managed under the 2006 Consolidated Atlantic HMS Fishery Management Plan (2006 Consolidated HMS FMP) and its amendments, implemented by regulations at 50 CFR part 635.

NMFS has prepared an Environmental Assessment (EA), Regulatory Impact Review (RIR), and an Initial Regulatory Flexibility Analysis (IRFA), which analyze the anticipated environmental, social, and economic impacts of several alternatives for each of the major issues contained in this proposed rule. A brief summary of the alternatives considered and the background of this proposed rule are provided below. Additional information regarding this rule and overall Atlantic shark management can be found in the draft EA/RIR/IRFA, the 2006 Consolidated HMS FMP and its amendments, the annual HMS Stock Assessment and Fishery Evaluation (SAFE) Reports, and online at *https://www.fisheries.noaa.gov/topic/atlantic-highly-migratory-species.*

A copy of the draft EA/RIR/IRFA prepared for this proposed rule is available from NMFS (see **ADDRESSES**).

Recent ICCAT Shortfin Mako Shark Stock Assessments and Recommendations

The North Atlantic shortfin mako shark (*Isurus oxyrinchus*) is a highly migratory species that ranges across the entire North Atlantic Ocean and is caught by vessels from numerous countries. The stock is predominantly caught in association with fisheries that primarily target tunas and tuna-like species. While these sharks have been a valued component of U.S. recreational and commercial fisheries, U.S. catch represents only a small portion of the species' total catch in the North Atlantic by all reporting countries. International measures are, therefore, critical to effective conservation and management of the species.

In 2017, ICCAT's scientific body, the Standing Committee on Research and Statistics (SCRS), conducted a benchmark stock assessment for North Atlantic shortfin mako sharks. ICCAT accepted the assessment and adopted new management measures for the stock in ICCAT fisheries (Recommendation 17–08). These measures largely focused on maximizing live releases of North Atlantic shortfin mako sharks, allowing retention only in certain limited circumstances, increasing minimum size limits, and improving data collection. Further details are available in Amendment 11 to the 2006 Consolidated HMS FMP (Amendment 11; 84 FR 5358, February 21, 2019). Following the SCRS assessment, NMFS applied domestic stock status determination criteria in 2017 and determined the stock to be overfished and experiencing overfishing.

In 2019, the SCRS completed a North Atlantic shortfin mako shark stock assessment update and provided additional rebuilding information that reflected rebuilding timeframes of two mean generation times (through 2070). Following the update, ICCAT adopted Recommendation 19–06, which maintained the shortfin mako shark management measures in Recommendation 17–08 and called for the development of additional measures in order to establish a rebuilding plan with a high probability of avoiding overfishing and rebuilding the stock to biomass at maximum sustainable yield (B_{MSY}) within a timeframe that takes into account the biology of the stock.

Given that Recommendation 19–06 called for the development of additional measures in order to establish a rebuilding plan, ICCAT at the November

2021 annual meeting adopted additional management measures for North Atlantic shortfin mako sharks in Recommendation 21–09. This recommendation prohibits retention of North Atlantic shortfin mako sharks caught in association with ICCAT fisheries in 2022 and 2023. Limited retention of shortfin mako sharks may be allowed in 2023 and future years if ICCAT determines that fishing mortality is at a low enough level North Atlantic-wide to allow retention consistent with the conservation objectives of the recommendation. The recommendation aims to limit total North Atlantic-wide shortfin mako shark fishing mortality to no more than 250 metric tons (mt), which, the recommendation states, is consistent with the conservation objectives and the 2019 SCRS Kobe matrix, meaning that, at that level of fishing mortality, it is expected that overfishing would not be occurring (fishing mortality rate (F) < F_{MSY}) and the stock would not be overfished (spawning stock fecundity (SSF) > SSF_{MSY}). The SCRS will calculate the annual retention possibility each year based on reported dead discards; live releases; and, where allowed, earlier retention of shortfin mako sharks (with the SCRS providing estimates for any data gaps), and subtracting the amount of that fishing mortality from 250 mt. If applicable, the SCRS will also calculate eligible parties' individual retention allowances each year, based on the overall retention allowance and average annual catches from 2013 through 2016. The recommendation also calls on the SCRS and Panel 4 to test and confirm the appropriateness of the approach for allowing retention. The process and possible retention for 2023 will be discussed at an ICCAT Panel 4 intersessional meeting and at the annual meeting, both in November 2022.

Recommendation 21–09 also includes minimum standards for safe handling and release procedures and enhanced reporting and compliance requirements, which are consistent with existing HMS regulations and do not require additional rulemaking for U.S. implementation. The recommendation calls on the SCRS to continue to prioritize research such as identifying mating, pupping and nursery grounds, and other high concentration areas of North Atlantic shortfin mako sharks, options for spatial-temporal measures, and mitigation measures. By 2024, the SCRS will advise ICCAT on whether size restrictions are effective tools to meet required mortality reductions. Future North Atlantic shortfin mako shark stock assessments are called for in 2024, 2029, and 2034.

Recent U.S. Shortfin Mako Shark Management

Following the adoption of ICCAT Recommendation 17–08 and NMFS' determination that the North Atlantic shortfin mako shark stock is overfished with overfishing occurring, NMFS took action to implement the binding ICCAT recommendation to immediately address overfishing and begin to rebuild the shortfin mako shark stock. NMFS first published an emergency rule in 2018 (83 FR 8946, March 2, 2018; measures extended through March 2019, 83 FR 42452, August 22, 2018) followed by Amendment 11, with a final rule issued in 2019 (84 FR 5358, February 21, 2019), to reduce fishing mortality of shortfin mako sharks in HMS commercial and recreational fisheries. These rules allowed retention only in certain limited circumstances, increased minimum size limits for retention in the recreational fisheries, and improved data collection. In commercial fisheries, Amendment 11 allowed retention of shortfin mako sharks with pelagic longline gear only if the shark is dead at haulback and there is a functional electronic monitoring system on board the vessel, consistent with the ICCAT requirement. Amendment 11 also allowed retention of shortfin mako sharks caught with bottom longline or gillnet gear by persons issued a Directed or Incidental shark limited access permit (LAP) if the shark is dead at haulback, without an electronic monitoring requirement, given the small number of shortfin mako sharks that are caught in those fisheries and NMFS' determination that additional monitoring was not necessary. In recreational fisheries, Amendment 11 implemented an increase in the minimum size limit for the retention of shortfin mako sharks from 54 inches fork length (FL) (137 cm FL) to 71 inches FL (180 cm FL) for male shortfin mako sharks and 83 inches FL (210 cm FL) for female shortfin mako sharks. Amendment 11 also expanded the requirement for the use of circle hooks to all recreational shark fisheries in order to reduce post-release mortality of shortfin mako sharks (the use of circle hooks was already required in recreational shark fisheries south of Chatham, MA, and for all pelagic longline and bottom longline vessels).

At the time of the 2017 shortfin mako shark stock assessment and adoption of Recommendation 17–08, U.S. catches represented approximately 14 percent, on average, of total North Atlantic shortfin mako catch. The measures in the emergency rule and Amendment 11 were successful at reducing overall U.S. shortfin mako shark catch by 90 percent from 2013–2017 average levels, to approximately 3 percent of total North Atlantic shortfin mako shark catch in 2020.

Proposed Measures

In order to meet domestic management objectives, implement Recommendation 21–09, and acknowledge the possibility of future retention, NMFS is proposing to implement a flexible shortfin mako shark retention limit with a default limit of zero in commercial and recreational HMS fisheries. Consistent with current ICCAT provisions, the retention limit would be established as zero until Atlantic-wide catch levels are below 250 mt, a level that has a high probability of ending overfishing and starting to rebuild the stock. ICCAT determined that this measure was needed to bring catch levels down to or below that amount by all ICCAT parties, and thus was an important measure contributing to conservation and management of the stock. The shortfin mako shark retention limit per trip of zero would be in place unless and until changed after consideration of regulatory criteria and consistent with any ICCAT retention allowances pursuant to Recommendation 21–09. The retention limit per trip would apply to commercial vessels issued a Directed or Incidental shark LAP using pelagic longline, bottom longline, or gillnet gear, and to recreational HMS permit holders (those who hold HMS Angling or Charter/Headboat permits, and Atlantic Tunas General category and Swordfish General Commercial permits when participating in a registered HMS tournament). Under the default limit of zero and existing prohibitions for other gear types (see §§ 635.21(a)(4) and 635.24(a)(4)(i) and (iii)), all commercial and recreational fishermen would be required to release all shortfin mako sharks, whether dead or alive at haulback.

During the fishing year, based on consideration of the inseason trip limit adjustment criteria (§ 635.24(a)(8)) and to the extent any future retention is allowable as determined by ICCAT consistent with Recommendation 21–09, NMFS could increase the shortfin mako shark retention limit from the default, or subsequently decrease the retention limit, for the commercial fishery, the recreational fishery, or both. If a retention limit greater than zero is implemented for the commercial fishery, the current commercial shortfin mako shark restrictions would apply,

including allowing retention of shortfin mako sharks caught using only gillnet, bottom longline, or pelagic longline gear on properly-permitted vessels, if the sharks are dead at haulback, and requiring vessels with pelagic longline gear to have a functional electronic monitoring system to retain shortfin mako sharks. Similarly, if a retention limit greater than zero is implemented for the recreational fishery, the current recreational shortfin mako shark restrictions would apply, including minimum size limits of 71 inches FL (180 cm FL) for male and 83 inches FL (210 cm FL) for female shortfin mako sharks. For vessels that hold both a commercial shark permit and a permit with a shark endorsement, the current requirements at §§ 635.22(c)(7) and 635.24(a)(4)(iii) would apply. Vessels that hold such combinations of permits are prohibited from selling shortfin mako sharks, are required to follow the recreational limits, and cannot sell any sharks if retaining shortfin mako sharks. While no upper retention limit is being set in this action, any increase in retention limit would need to be consistent with ICCAT recommendations and could only be implemented after considering the regulatory criteria.

The flexible retention limit as proposed would apply in the HMS bottom longline and gillnet fisheries for sharks, although those fisheries are not considered to be ICCAT fisheries, which are defined as fisheries for tuna or tuna-like species under the current ICCAT Convention. This approach is consistent with the approach taken in Amendment 11, where NMFS determined it was appropriate to implement parallel management measures in the non-ICCAT shark fisheries given that the stock remained overfished with overfishing occurring. This approach would ensure consistency in HMS regulations, which will provide clarity for both the regulated community and for enforcement purposes and thus ensure more effective implementation. NMFS did not, however, implement the ICCAT requirement that electronic monitoring be onboard in these fisheries, because bottom longline and gillnet fisheries have minimal interactions with this species, and electronic monitoring was unnecessary to track such interactions effectively. Under this rule, after considering the measures implemented under Amendment 11 that considered the requirements of the Magnuson-Stevens Act, the status of shortfin mako sharks, and the need for consistency, NMFS is proposing to apply a flexible retention limit with a default of zero to these gears.

Under this proposed rule, research and sampling of shortfin mako sharks would continue to be allowed under exempted fishing permits (EFPs) and scientific research permits (SRPs) (see §§ 635.27(b)(4) and 635.32). Collection of shortfin mako sharks under display permits would not be allowed, and collection of shortfin mako sharks for research under EFPs and/or SRPs would be considered on a case-by-case basis. Collection of shortfin mako sharks under EFPs and/or SRPs could include sampling or limited retention where needed for scientific research. Only non-lethal sampling would be permitted on shortfin mako sharks that are alive at haulback. NMFS intends to limit any EFPs and/or SRPs to closely monitored studies and to limit the number of such permits and the number of sharks that may be sampled and/or retained. In recent years (2018–2021), NMFS has issued eight EFPs and related permits per year on average that include shortfin mako sharks, and zero to one shortfin mako sharks were retained per year under those permits. When retention is otherwise prohibited, any retention pursuant to an EFP and/or SRP would be accounted for under the applicable shark research and display quota. If retention is otherwise permitted consistent with ICCAT recommendations, NMFS would count any retention under EFPs and/or SRPs against the applicable ICCAT retention allowance. Research on shortfin mako sharks is critical to gathering scientific information about the stock and to help ensure that stock assessments have sufficient data. Permitted collection of shortfin mako sharks for scientific research would be consistent with the biological sampling and research needs described in Recommendation 21–09 and other relevant ICCAT recommendations, as well as research needs identified by the SCRS, including to provide data for future shortfin mako shark stock assessments. For example, Recommendations 21–09 and 13–10 provide for collection of biological samples of shortfin mako and other sharks that are dead at haulback during commercial fishing operations by scientific observers or individuals duly permitted by the ICCAT party. If NMFS receives EFP or SRP applications that are outside the scope described in this action, NMFS would provide notice to the public and solicit comments through the annual EFP notice of intent.

NMFS is also proposing a minor modification to the pelagic longline gear restrictions at § 635.21(c)(1)(iv) to further clarify the shortfin mako shark live release requirements.

In addition to the proposed measures, in the EA for this action, NMFS analyzed a no action alternative that would maintain the current commercial and recreational shortfin mako shark regulations as implemented under Amendment 11, and an alternative to place shortfin mako sharks on the prohibited sharks list in the HMS regulations (see §§ 635.24(a)(5), 635.34(c), and Table 1, section D, in appendix A to 50 CFR part 635). The EA for this action describes the impacts of those two alternatives and the preferred alternative proposed here.

Request for Comments

NMFS is requesting comments on this proposed rule which may be submitted via *www.regulations.gov* or at a public conference call/webinar. NMFS solicits comments on this action by May 11, 2022 (see **DATES** and **ADDRESSES**).

During the comment period, NMFS will hold a public hearing via conference call and webinar for this proposed action. Information on the conference call and webinar will be posted at: *https://www.fisheries.noaa.gov/action/proposed-changes-atlantic-shortfin-mako-shark-retention-limits.* Requests for sign language interpretation or other auxiliary aids should be directed to Carrie Soltanoff at *carrie.soltanoff@noaa.gov* or 301–427–8503, at least 7 days prior to the meeting.

The public is reminded that NMFS expects participants at a public webinar to conduct themselves appropriately. At the beginning of the webinar, the moderator will explain how the webinar will be conducted and how and when participants can provide comments. NMFS representative(s) will structure the conference call and webinars so that all members of the public will be able to comment, if they so choose, regardless of the controversial nature of the subject(s). Participants are expected to respect the ground rules, and those that do not may be asked to leave the webinar.

Classification

The NMFS Assistant Administrator has determined that the proposed rule is consistent with the 2006 Consolidated HMS FMP and its amendments, other provisions of the Magnuson-Stevens Act, ATCA, and other applicable law, subject to further consideration after public comment.

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

This proposed rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

An IRFA was prepared, as required by section 603 of the Regulatory Flexibility Act (RFA). The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the legal basis for this action are contained at the beginning of this section in the preamble and in the **SUMMARY** section of the preamble. A summary of the analysis follows. A copy of this analysis is available from NMFS (see **ADDRESSES**).

Section 603(b)(1) requires agencies to describe the reasons why the action is being considered. In compliance with section 603(b)(1) of the RFA, the purpose of this proposed rulemaking is, consistent with the 2006 Consolidated HMS FMP objectives, the Magnuson-Stevens Act, ATCA, and other applicable law, to analyze the impacts of the alternatives for implementing the ICCAT-recommended limit on retention of North Atlantic shortfin mako sharks.

Section 603(b)(2) of the RFA requires agencies to state the objectives of, and legal basis for, the proposed action. In compliance with section 603(b)(2) of the RFA, the objective of this proposed rulemaking is to implement ICCAT recommendation consistent with ATCA and achieve domestic management objectives under the Magnuson-Stevens Act.

Section 603(b)(3) of the RFA requires agencies to provide an estimate of the number of small entities to which the rule would apply. NMFS established a small business size standard of $11 million in annual gross receipts for all businesses in the commercial fishing industry (NAICS 11411) for RFA compliance purposes. The Small Business Administration (SBA) has established size standards for all other major industry sectors in the United States, including the scenic and sightseeing transportation (water) sector (NAICS code 487210), which includes for-hire (charter/party boat) fishing entities. The SBA has defined a small entity under the scenic and sightseeing transportation (water) sector as one with average annual receipts (revenue) of less than $8.0 million.

NMFS considers all HMS permit holders, both commercial and for-hire, to be small entities because they had average annual receipts of less than their respective sector's standard of $11 million and $8 million. Regarding those entities that would be directly affected by the proposed measures, the average annual revenue per active pelagic longline vessel is estimated to be $202,000, based on approximately 90 active vessels that produced an estimated $18.2 million in revenue in 2020, well below the NMFS small business size standard for commercial fishing businesses of $11 million. No single pelagic longline vessel has exceeded $11 million in revenue in recent years. Other non-longline HMS commercial fishing vessels typically earn less revenue than pelagic longline vessels and, thus, would also be considered small entities.

The proposed rule would apply to the 213 Shark Directed LAP holders, 256 Shark Incidental LAP holders, and 4,055 HMS Charter/Headboat permit holders, based on 2021 data. Of those HMS Charter/Headboat permit holders, 3,021 obtained shark endorsements. In 2018 and 2019, 800 HMS for-hire trips targeting shortfin mako sharks were taken per year on average (7 percent on average of total HMS for-hire trips), from Maine to Virginia as captured in Large Pelagics Survey data. These trips were taken by, on average, 10 percent of HMS for-hire charter/headboat vessels. On average, there were 44 Atlantic HMS tournaments that targeted pelagic sharks (primarily shortfin mako sharks) in 2018 through 2021. There were approximately 1,555 directed shortfin mako shark trips in registered HMS tournaments on average in 2018 through 2021. On average, 26 federally-permitted dealers per year purchased shortfin mako sharks in 2018 through 2020. NMFS has determined that the preferred alternative would not likely directly affect any small organizations or small government jurisdictions defined under RFA, nor would there be disproportionate economic impacts between large and small entities.

Section 603(b)(4) of the RFA requires agencies to describe any new reporting, record-keeping, and other compliance requirements. This proposed rule does not contain any new collection of information, reporting, or record-keeping requirements.

Under section 603(b)(5) of the RFA, agencies must identify, to the extent practicable, relevant Federal rules which duplicate, overlap, or conflict with the proposed action. Fishermen, dealers, and managers in these fisheries must comply with a number of international agreements, domestic laws, and other fishery management measures. These include, but are not limited to, the Magnuson-Stevens Act, ATCA, the High Seas Fishing Compliance Act, the Marine Mammal Protection Act, the Endangered Species Act, the National Environmental Policy Act, the Paperwork Reduction Act, and the Coastal Zone Management Act. This proposed action has been determined not to duplicate, overlap, or conflict with any Federal rules.

Under section 603(c) of the RFA, agencies must describe any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. Specifically, the RFA (5 U.S.C. 603(c)(1)–(4)) lists four general categories of significant alternatives to assist an agency in the development of significant alternatives. These categories of alternatives are: (1) Establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) use of performance rather than design standards; and, (4) exemptions from coverage of the rule, or any part thereof, for small entities.

NMFS examined each of these categories of alternatives. Regarding the first, second, and fourth categories, NMFS cannot establish differing compliance or reporting requirements for small entities or exempt small entities from coverage of the rule or parts of it because all of the businesses impacted by this rule are considered small entities and thus the requirements are already designed for small entities. NMFS does not know of any performance or design standards that would satisfy the aforementioned objectives of this rulemaking while, concurrently, complying with the Magnuson-Stevens Act. As described below, NMFS analyzed several different alternatives in this proposed rulemaking, and provides rationales for identifying the preferred alternative to achieve the desired objectives.

The alternatives considered and analyzed are described below. The IRFA assumes that each vessel will have similar catch and gross revenues to show the relative impact of the proposed action on vessels.

Alternative 1, the no action alternative, would not implement any new management measures in the commercial or for-hire shark fisheries to decrease mortality of shortfin mako sharks. In recent years, about 49,000 pounds dressed weight (dw) (22,000 kilograms dw) of shortfin mako sharks have been landed commercially on average from 2018 through 2020 and the commercial revenues from shortfin mako sharks have averaged

approximately $96,000 per year. The number of pounds of shortfin mako shark landed, revenue, and number of pelagic longline vessels that landed shortfin mako sharks was lower in 2020 compared to 2018 and 2019 (average landings in 2018 and 2019 were 55,700 pounds dw (25,000 kilograms dw), average revenue was approximately $109,600 per year, and average number of pelagic longline vessels landing shortfin mako sharks was 53). Almost all of the shortfin mako shark commercial landings, based on dealer reports, were made by pelagic longline vessels. An average of 49 pelagic longline vessels landed shortfin mako sharks from 2018 through 2020. Therefore, the average annual revenue from shortfin mako shark landings per pelagic longline vessel is approximately $1,960 per year ($96,000/49) under the current regulations. For-hire shark fishing operations by HMS Charter/Headboat permit holders as well as HMS tournament operations would also remain the same. This alternative would result in no additional economic impacts on small entities associated with these fisheries in the short- or long-term.

Alternative 2, the preferred alternative, would implement a flexible shortfin mako shark retention limit with a default limit of zero. The limit of zero would be in place unless and until changed after considering inseason trip limit adjustment criteria (§ 635.24(a)(8)) and when consistent with ICCAT retention allowances pursuant to Recommendation 21–09. This would apply to commercial vessels issued a Directed or Incidental shark LAP and to HMS Charter/Headboat permit holders. Under a retention limit of zero, HMS for-hire fishermen and commercial vessels would be required to release all shortfin mako sharks that are alive at haulback and discard all shortfin mako sharks that are dead at haulback. In recent years, about 49,000 pounds dw (22,000 kilograms dw) of shortfin mako sharks have been landed commercially on average from 2018 through 2020, and the commercial revenues from shortfin mako sharks have averaged approximately $96,000 fishery-wide per year. Almost all of the shortfin mako shark commercial landings, based on dealer reports, were made by pelagic longline vessels. An average of 49 pelagic longline vessels landed shortfin mako sharks from 2018 through 2020. Therefore, the average loss in annual revenue from shortfin mako shark landings per pelagic longline vessel that landed shortfin mako sharks would be approximately $1,960 per year ($96,000/49). However, the overall economic impacts associated with these reductions in revenue are not expected to be substantial, as shortfin mako sharks comprise less than one percent of total HMS ex-vessel revenues on average. Additionally, the magnitude of shortfin mako landings by other commercial gear types (bottom longline and gillnet) is very small. This alternative would have minor economic costs on small entities in those commercial fisheries compared to the no action alternative because these measures would reduce the number of shortfin mako sharks landed and sold by these fishing vessels. Shortfin mako sharks are rarely a target species, however, and generate much less revenue overall than other more valuable target species. In for-hire fisheries and tournaments, retention would be prohibited, and fishermen would only be authorized to catch and release shortfin mako sharks. A retention limit of zero for shortfin mako sharks is likely to be a disincentive to fishing by some portion of the for-hire shark fishery, particularly those individuals that would otherwise have planned to target and retain shortfin mako sharks. Charter/headboat operators may experience some decline in demand if shortfin mako sharks may not be retained, resulting in minor adverse economic impacts. For Atlantic HMS tournaments, the 1,555 directed shortfin mako shark trips, on average, that take place in HMS tournaments would likely no longer take place, resulting in a loss of approximately $1.1 million in expenditures, out of an estimated $85.6 million in total HMS tournament expenditures by participating teams. Overall, this alternative would have minor economic costs on small entities in the short-term compared to the no action alternative.

During the fishing year, based on the inseason trip limit adjustment criteria (§ 635.24(a)(8)), and to the extent consistent with any future retention allowance that is determined by ICCAT pursuant to Recommendation 21–09, NMFS could increase the shortfin mako shark retention limit for the commercial fishery, the recreational fishery, or both, as appropriate. If the retention limit for the commercial and recreational fisheries is greater than zero, the current shortfin mako shark regulatory requirements, described under Alternative 1, would apply. This would result in no additional economic impacts on small entities associated with this fishery in the long-term compared to the no action alternative.

Alternative 3 would place shortfin mako on the prohibited sharks list to prohibit any catch or retention of shortfin mako sharks in commercial and recreational HMS fisheries. *See* Table 1, section D, in appendix A to 50 CFR part 635 (prohibited sharks list), § 635.24(a)(5) (related vessel restrictions), and § 635.34(c) (criteria for adding species to, or removing species from, the prohibited shark species group). The overall economic impacts associated with reductions in revenue for the commercial and for-hire fisheries and HMS tournaments would be similar to those described under Alternative 2 and are not expected to be substantial, as shortfin mako sharks comprise less than one percent of total HMS ex-vessel revenues on average. This alternative would have minor economic costs on small entities in commercial fisheries because no shortfin mako sharks would be landed and sold by these fishing vessels under these measures. Shortfin mako sharks are rarely a target species, however, and generate less revenue overall than other more valuable target species. In for-hire fisheries and tournaments, retention would be prohibited, and fishermen would only be authorized to catch and release shortfin mako sharks. A prohibition on the retention of shortfin mako sharks is likely to be a disincentive for some portion of the for-hire shark fishery, particularly those individuals that would otherwise have planned to target and retain shortfin mako sharks. Charter/headboat operators may experience some decline in demand, resulting in adverse economic impacts. For Atlantic HMS tournaments, the 1,555 directed shortfin mako shark trips, on average, that take place in HMS tournaments would likely no longer take place, resulting in a loss of approximately $1.1 million in expenditures, out of an estimated $85.6 million in total HMS tournament expenditures by participating teams. Overall, Alternative 3 would have minor economic costs on small entities in the short- and long-term.

List of Subjects in 50 CFR Part 635

Fisheries, Fishing, Fishing vessels, Foreign relations, Imports, Penalties, Reporting and recordkeeping requirements, Statistics, Treaties.

Dated: April 5, 2022.

Carrie Robinson,

Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 635 is proposed to be amended as follows:

PART 635—ATLANTIC HIGHLY MIGRATORY SPECIES

■ 1. The authority citation for part 635 continues to read as follows:

Authority: 16 U.S.C. 971 *et seq.;* 16 U.S.C. 1801 *et seq.*

■ 2. In § 635.20, revise paragraph (e)(6) to read as follows:

§ 635.20 Size limits.

* * * * *

(e) * * *

(6) For shortfin mako sharks landed when the recreational retention limit specified at § 635.22(c)(8) is greater than zero, males must be at least 71 inches (180 cm) fork length, and females must be at least 83 inches (210 cm) fork length.

* * * * *

■ 3. In § 635.21, revise paragraph (c)(1)(iv) to read as follows:

§ 635.21 Gear operation and deployment restrictions.

* * * * *

(c) * * *

(1) * * *

(iv) Has pelagic longline gear on board, persons aboard that vessel are required to promptly release in a manner that causes the least harm any shortfin mako shark that is alive at the time of haulback, consistent with the requirements specified at paragraphs (a)(1) and (c)(6)(i) of this section. When the commercial retention limit specified at § 635.24(a)(4)(v) is greater than zero, any shortfin mako shark that is dead at the time of haulback may be retained provided the electronic monitoring system is installed and functioning in compliance with the requirements at § 635.9.

* * * * *

■ 4. In § 635.22, revise paragraph (c)(2) and add paragraph (c)(8) to read as follows:

§ 635.22 Recreational retention limits.

* * * * *

(c) * * *

(2) Only one shark from the following list may be retained per vessel per trip, subject to the size limits described in § 635.20(e)(2) and (4): Atlantic blacktip, Gulf of Mexico blacktip, bull, great hammerhead, scalloped hammerhead, smooth hammerhead, lemon, nurse, spinner, tiger, blue, common thresher, oceanic whitetip, porbeagle, Atlantic sharpnose, finetooth, Atlantic blacknose, Gulf of Mexico blacknose, and bonnethead.

* * * * *

(8) At the start of each fishing year, the default shortfin mako shark retention limit of zero sharks per vessel per trip will apply. During the fishing year, NMFS may adjust the default shortfin mako shark trip limit per the inseason trip limit adjustment criteria listed in § 635.24(a)(8). Any retention within the trip limit is subject to the size limits described in § 635.20(e)(6).

* * * * *

■ 5. In § 635.24:

■ a. Add a heading for paragraph (a)(4);

■ b. Revise paragraphs (a)(4)(i) and (iii);

■ c. Add paragraph (a)(4)(v);

■ d. Revise paragraphs (a)(8)(v) and (vi); and

■ e. Add paragraph (a)(8)(vii).

The additions and revisions read as follows:

§ 635.24 Commercial retention limits for sharks, swordfish, and BAYS tunas.

* * * * *

(a) * * *

(4) *Additional retention limits for sharks.* (i) Except as provided in § 635.22(c)(7), a person who owns or operates a vessel that has been issued a directed shark LAP may retain, possess, land, or sell pelagic sharks if the pelagic shark fishery is open per §§ 635.27 and 635.28. Shortfin mako sharks may be retained by persons aboard vessels using pelagic longline, bottom longline, or gillnet gear only if NMFS has adjusted the commercial retention limit above zero pursuant to paragraph (a)(4)(v) of this section and only if the shark is dead at the time of haulback and consistent with the provisions of §§ 635.21(c)(1), (d)(5), and (g)(6) and 635.22(c)(7).

* * * * *

(iii) Consistent with paragraph (a)(4)(ii) of this section, a person who owns or operates a vessel that has been issued an incidental shark LAP may retain, possess, land, or sell no more than 16 SCS and pelagic sharks, combined, per vessel per trip, if the respective fishery is open per §§ 635.27 and 635.28. Of those 16 SCS and pelagic sharks per vessel per trip, no more than 8 shall be blacknose sharks. Shortfin mako sharks may only be retained under the commercial retention limits by persons using pelagic longline, bottom longline, or gillnet gear only if NMFS has adjusted the commercial retention limit above zero pursuant to paragraph (a)(4)(v) of this section and only if the shark is dead at the time of haulback and consistent with the provisions at § 635.21(c)(1), (d)(5), and (g)(6). If the vessel has also been issued a permit with a shark endorsement and retains a shortfin mako shark, recreational retention limits apply to all sharks retained and none may be sold, per § 635.22(c)(7).

* * * * *

(v) At the start of each fishing year, the default shortfin mako shark retention limit of zero sharks will apply. During the fishing year, NMFS may adjust the default shortfin mako shark trip limit per the inseason trip limit adjustment criteria listed in paragraph (a)(8) of this section.

* * * * *

(8) * * *

(v) Variations in seasonal distribution, abundance, or migratory patterns of the relevant shark species based on scientific and fishery-based knowledge;

(vi) Effects of catch rates in one part of a region or sub-region precluding vessels in another part of that region or sub-region from having a reasonable opportunity to harvest a portion of the relevant quota; and/or

(vii) Any shark retention allowance set by ICCAT, the amount of remaining allowance, and the expected or reported catch rates of the relevant shark species, based on dealer and other harvest reports.

* * * * *

■ 6. In § 635.27, revise paragraph (b)(4)(i) and add paragraph (b)(4)(v) to read as follows:

§ 635.27 Quotas.

* * * * *

(b) * * *

(4) * * *

(i) The base annual quota for persons who collect LCS other than sandbar, SCS, pelagic sharks other than shortfin mako, blue sharks, porbeagle sharks, or prohibited species under a display permit or EFP is 57.2 mt ww (41.2 mt dw).

* * * * *

(v) No persons may collect shortfin mako sharks under a display permit. Collection of shortfin mako sharks for research under EFPs and/or scientific research permits (SRPs) may be considered on a case-by-case basis and any associated mortality would be deducted from the shark research and display quota if shortfin mako shark retention is otherwise prohibited or counted against U.S. allowable retention levels established at ICCAT when retention is allowed.

* * * * *

[FR Doc. 2022–07659 Filed 4–8–22; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 87, No. 69
Monday, April 11, 2022

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–FTPP–22–0013]

Information Collection for USDA/DOJ Complaint Portal: FarmerFairness.gov

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), this notice announces the Agricultural Marketing Service's (AMS) intention to request approval, from the Office of Management and Budget, for an information collection package for the web form to be used for the collection of complaints and tips from the public through the *FarmerFairness.gov* web portal. The U.S. Department of Agriculture (USDA) and the Department of Justice (DOJ) launched a web portal to allow farmers, ranchers and interested persons to report a complaint or submit information regarding potential violations of the Packers and Stockyards (P&S) Act or other federal anti-trust laws. USDA and DOJ will assess information collected to determine appropriate jurisdiction and any follow up actions. The joint USDA/DOJ web portal, *FarmerFairness.gov,* is subject to the reporting and recordkeeping requirements under the P&S Act.

DATES: Comments on this notice must be received by June 10, 2022 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit comments concerning this notice by using the electronic process available at *https://www.regulations.gov/.* All comments should reference the document number and the date and page number of this issue of the **Federal Register**. All comments submitted in response to this notice will be posted without change, including any personal information provided, at *https://www.regulations.gov/* and will be included in the record and made available to the public.

FOR FURTHER INFORMATION CONTACT: S. Brett Offutt, Chief Legal Officer/Policy Advisor, Packers and Stockyards Division, USDA AMS Fair Trade Practices Program, 1400 Independence Ave. SW, stop 3601, Washington, DC 20250; Phone: (202) 690–4355; or Email: *s.brett.offutt@usda.gov.*

SUPPLEMENTARY INFORMATION:

Agency: AMS, USDA.

Title: FarmerFairness.gov USDA/DOJ Complaint Web Portal.

OMB Number: 0581–0333.

Expiration Date of Approval: May 31, 2022.

Type of Request: Extension and revision of a currently approved information collection.

Abstract: The P&S Act and the regulations issued under the P&S Act authorize the collection of information for the purpose of enforcing the P&S Act and regulations and for conducting studies requested by Congress. The laws and regulations relating to competition in the meat and poultry industries confer separate and overlapping jurisdiction to the U.S. Department of Agriculture and the U.S. Department of Justice. Farmers, ranchers, and other interested persons may not be aware of this and may not know to whom or how to file a complaint or tip if they suspect a violation of those laws or regulations. This joint complaint portal allows those farmers, ranchers and interested persons to go to one website to submit information and USDA and DOJ will determine the appropriate jurisdiction and any follow up actions. This information collection is necessary for PSD and DOJ to monitor and examine complaints regarding financial, competitive, and trade practices in the livestock, meat packing and poultry industries. The purpose of this notice is to solicit comments from the public concerning PSD's information collection.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 1.5 hours per response.

Respondents: Livestock auction markets, livestock dealers, packer buyers, meat packers, live poultry dealers, Livestock and poultry organizations, farmers, ranchers, and other interested persons.

Estimated Number of Respondents: 110.

Estimated Total Annual Responses: 1.5 hours.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 165 hours.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Melissa Bailey,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2022–07629 Filed 4–8–22; 8:45 am]

BILLING CODE P

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 May 11, 2022 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.

Animal and Plant Health Inspection Service

Title: Special Need Request Under the Plant Protection Act.

OMB Control Number: 0579–0291.

Summary of Collection: The Plant Protection Act (PPA) (7 U.S.C. 7701 *et seq.*) authorizes the Secretary of Agriculture to restrict the importation, entry, or interstate movement of plants, plant products, and other articles to prevent the introduction of plant pests into the United States or their dissemination within the United States. This authority has been delegated to the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture, which administers regulations to implement the PPA. Regulations governing the interstate movement of plants, plant products, and other articles are contained in 7 CFR part 301, ''Domestic Quarantine Notices.'' These regulations in ''Subpart-Preemption and Special Need Requests'' allow States or political subdivisions of States to request approval from APHIS to impose prohibitions or restrictions on the movement in interstate commerce of specific articles that pose a plant health risk that are in addition to the prohibitions and restrictions imposed by APHIS.

Need and Use of the Information: APHIS believes that specific information—such as a pest data detection survey with a pest risk analysis that shows that a pest is not present in a State, or if already present, the current distribution in the State, and that the pest would harm or injure the environment and/or agricultural resources of the State or political subdivision—is needed and would be considered along with more general information available to APHIS for the Administrator to be able to determine whether to grant or deny a request for a special need exemption.

The special needs request are submitted with the required information and cover letter from a requesting State to the Deputy Administrator of Plant Protection and Quarantine (PPQ). The required information includes: Survey. The results of a scientifically sound survey that shows that the pest of concern is not in the State or subdivision of the State, or that shows the distribution of the pest, Risk of entry. A pest risk assessment or scientific data that shows that the pest could enter the area, Harm, or injury. Information that shows that if the pest entered or spread in the State, it would harm agricultural or environmental resources. Quantitative estimates of the potential injury are preferred, Special basis. Evidence that the area has special or unique characteristics that make it more vulnerable to harm or injury, such as unique fauna or flora, special historical or cultural interest, etc., Requested restrictions; and Details about what specifically is requested, why it is necessary, why it will work and how it will help.

The administrator's determination would be based upon his or her review of the information submitted by the State or political subdivision in support of its request and would consider any comments received. If this information was not collected or collected less frequently, it would create vulnerabilities which would cripple APHIS' ability to prevent the introduction or spread of plant pests and diseases in the United States.

Description of Respondents: State, Local or Tribal Government.

Number of Respondents: 1.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 160.

Dated: April 6, 2022.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–07689 Filed 4–8–22; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request; Reinstatement

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 and other forms of information technology.

Comments regarding this information collection received by May 11, 2022 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.

Forest Service

Title: Equal Opportunity Compliance Review Reporting Tool.

OMB Control Number: 0596–0215.

Summary of Collection: All Federal agencies and the entities receiving Federal financial assistance are prohibited from discriminating in the delivery of programs and services. Agencies must comply with equal opportunity laws, Title VI of the Civil Rights Act of 1964, as amended; Title IX of the Education Amendments Act of 1972; The Age Discrimination Act of 1975, as amended; Section 504 of the

Rehabilitation Act of 1973, as amended; and Executive orders prohibiting discrimination in the delivery of all programs and services to the public. Federal agencies and entities receiving Federal Financial Assistance are prohibited from discriminating. Federal Financial Assistance is defined as, ''Federal monies given by grants, cooperative agreements, commercial special use permits, training, loan/temporary assignment of Federal personnel, loan/use of Federal property at below market value.''

The equal opportunity laws require agencies to conduct compliance reviews to ensure that entities receiving Federal Financial Assistance from the government are adhering to the nondiscrimination statues. The statutes require that prior to awarding support or issuing permits, the Federal government shall conduct pre-award reviews to ensure that potential recipients understand their responsibilities to provide services equitable pursuant to the law. Thereafter, during the partnership with the agency, ongoing monitoring will take place to ensure the public is being served without any barriers or discrimination.

Need and Use of the Information: Forest Service employees will use form FS–1700–6, Equal Opportunity Compliance Review Record, to document demographics (race, ethnicity, and gender) and collect information regarding actions taken by recipients of Federal financial assistance to ensure the public receives services without discrimination or barriers to access, and that recipients' employees understand their customer services role.

Collection will occur during face-to-face meetings or telephone interviews conducted by Forest Service employees as part of the pre-award and post award process. The pre-award interview will take place prior to the award of a grant, signing of a cooperative agreement, letting of commercial special use permit, or similar activity. The post award interview will take place once every 5 years, or upon report/discovery of discrimination.

The information collected will only be shared with other Federal agencies who share in the financial assistance activities with the Forest Service. Monitoring reviews have been a responsibility of the Federal government since 1964. Without the ability to monitor recipients of Federal financial assistance, the Forest Service would not be able to ensure compliance with laws and statutes. The Agency would not be aware of potential violations, thereby resulting in potential discriminatory practices.

Description of Respondents: Business or other for-profit; Not-for-profit Institutions; State, Local or Tribal Government.

Number of Respondents: 9,500.

Frequency of Responses: Recordkeeping; Reporting: Annually.

Total Burden Hours: 18,756.

Dated: April 6, 2022.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–07701 Filed 4–8–22; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

North Wisconsin Resource Advisory Committee

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of meeting.

SUMMARY: The North Wisconsin Resource Advisory Committee (RAC) will hold a virtual meeting by phone and/or video conference. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act as well as to make recommendations on recreation fee proposals for sites on the Chequamegon-Nicolet National Forest within Ashland, Bayfield, Florence, Forest, Oconto, Price, Sawyer, and Taylor Counties, consistent with the Federal Lands Recreation Enhancement Act. RAC information and virtual meeting information can be found at the following website: *https://www.fs.usda.gov/main/cnnf/workingtogether/advisorycommittees.*

DATES: The meeting will be held on May 4, 2022, 9:00 a.m.–3:00 p.m., Central Daylight Time.

All RAC meetings are subject to cancellation. For status of the meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting is open to the public and will be held virtually via telephone and/or video conference. Virtual meeting participation details can be found on the website listed under **SUMMARY** or can be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received upon request.

FOR FURTHER INFORMATION CONTACT: Adam Felts, Designated Federal Officer (DFO), by phone at 715–362–1335 or email at *adam.felts@usda.gov* or Penny McLaughlin, RAC Coordinator, at 715–362–1322 or email at *penny.mclaughlin@usda.gov.*

Individuals who use telecommunication devices for the deaf and hard of hearing (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Hear from Title II project proponents and discuss Title II project proposals;
2. Make funding recommendations on Title II projects; and
3. Schedule additional meeting(s).

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should make a request in writing by April 15, 2022, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Penny McLaughlin, 500 Hanson Lake Road, Rhinelander, WI, 54501 or by email to *penny.mclaughlin@usda.gov.*

Meeting Accommodations: Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodation. For access to proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case-by-case basis.

Equal opportunity practices, in line with USDA policies, will be followed in all membership appointments to the RAC. To help ensure that recommendations of the RAC have taken into account the needs of the diverse groups served by the Department, membership shall include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

The USDA prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, political beliefs, income derived from a public assistance program, or reprisal or retaliation for prior civil rights activity in any program or activity conducted or funded by USDA (not all bases apply to all programs).

Dated: April 5, 2022.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2022–07674 Filed 4–8–22; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Shasta County Resource Advisory Committee

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of meeting.

SUMMARY: The Shasta County Resource Advisory Committee (RAC) will hold a virtual meeting by phone and/or video conference. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act as well as make recommendations on recreation fee proposals for sites on the Shasta-Trinity National Forest within Shasta County. RAC information can be found at the following website: *https://www.fs.usda.gov/main/stnf/workingtogether/advisorycommittees.*

DATES: The meeting will be held on April 27, 2022, 9:00 a.m.–12:00 p.m., Pacific Daylight Time.

All RAC meetings are subject to cancellation. For status of the meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

ADDRESSES: The meeting is open to the public and will be held virtually via telephone and/or video conference. Virtual meeting participation details can be found on the website listed under **SUMMARY** or can be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT.**

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Shasta Lake Ranger Station. Please call ahead at 530–275–1587 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Lejon Hamann, RAC Coordinator, by phone at 530–410–1935 or via email at *lejon.hamann@usda.gov.*

Individuals who use telecommunication devices for the deaf and hard of hearing (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours per day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: The purpose of the meetings are to cover the following:

1. Roll call;
2. Comments from the Designated Federal Officer (DFO);
3. Approve minutes from last meeting;
4. Discuss, recommend, and approve projects;
5. Public comment period; and
6. Closing comments from the DFO.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by the Friday before the meeting, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Lejon Hamann, RAC Coordinator, 3644 Avtech Parkway, Redding, California 96002 or by email to *lejon.hamann@usda.gov.*

Meeting Accommodations: Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodation. For access to proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case-by-case basis.

Equal opportunity practices, in line with USDA policies, will be followed in all membership appointments to the RAC. To help ensure that recommendations of the RAC have taken into account the needs of the diverse groups served by the Department, membership shall include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

The USDA prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, political beliefs, income derived from a public assistance program, or reprisal or retaliation for prior civil rights activity in any program or activity conducted or funded by USDA (not all bases apply to all programs).

Dated: April 6, 2022.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2022–07679 Filed 4–8–22; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Shasta County Resource Advisory Committee

AGENCY: Forest Service, (Agriculture), USDA.

ACTION: Notice of meeting.

SUMMARY: The Shasta County Resource Advisory Committee (RAC) will hold two virtual meetings by phone and/or video conference. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act as well as to make recommendations on recreation fee proposals for sites on the Shasta-Trinity National Forest within Shasta County. RAC information can be found at the following website: *https://www.fs.usda.gov/main/stnf/workingtogether/advisorycommittees.*

DATES: The meetings will be held on:

- Wednesday, May 11, 2022, 9:00 a.m.–12:00p.m., Pacific Daylight Time; and
- Wednesday, May 25, 2022, 9:00 a.m.–12:00p.m., Pacific Daylight Time.

All RAC meetings are subject to cancellation. For status of the meetings prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meetings are open to the public and will be held virtually via telephone and/or video conference.

Virtual meeting participation details can be found on the website listed under **SUMMARY** or can be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Shasta Lake Ranger Station. Please call ahead at 530–275–1587 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Lejon Hamann, RAC Coordinator, by phone at 530–410–1935 or via email at *lejon.hamann@usda.gov*.

Individuals who use telecommunication devices for the deaf and hard of hearing (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours per day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: The purpose of the meetings are to review the following:

1. Comments from the Designated Federal Officer (DFO);
2. Approve minutes from last meeting;
3. Discuss, recommend, approve Title II projects;
4. Public comment period; and
5. Closing comments from the DFO.

The meetings are open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by the Friday before the scheduled meeting(s) to be scheduled on the agenda for a particular meeting. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Lejon Hamann, RAC Coordinator, 3644 Avtech Parkway, Redding, California 96002 or by email to *lejon.hamann@usda.gov*.

Meeting Accommodations: Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodation. For access to proceedings, please contact the person listed in the section titled for **FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case-by-case basis.

Equal opportunity practices, in line with USDA policies, will be followed in all membership appointments to the RAC. To help ensure that recommendations of the RAC have taken into account the needs of the diverse groups served by the Department, membership shall include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

The USDA prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, political beliefs, income derived from a public assistance program, or reprisal or retaliation for prior civil rights activity in any program or activity conducted or funded by USDA (not all bases apply to all programs).

Dated: April 5, 2022.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2022–07675 Filed 4–8–22; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Fremont and Winema Resource Advisory Committee

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of meeting.

SUMMARY: The Fremont and Winema Resource Advisory Committee (RAC) will hold a virtual meeting by phone and/or video conference. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act as well as make recommendations on recreation fee proposals for sites on the Fremont—Winema National Forest within Klamath and Lake Counties, consistent with the Federal Lands Recreation Enhancement Act. RAC information and virtual meeting information can be found at the following website: *https://www.fs.usda.gov/main/fremont-winema/workingtogether/advisorycommittees*.

DATES: The meeting will be held on May 5, 2022, 9:00 a.m.–4:00 p.m., Pacific Daylight Time.

All RAC meetings are subject to cancellation. For status of the meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting is open to the public and will be held virtually via telephone and/or video conference. Virtual meeting participation details can be found on the website listed under **SUMMARY** or can be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received upon request.

FOR FURTHER INFORMATION CONTACT: Mike Ramsey, Designated Federal Officer (DFO), by phone at 541–219–2062 or email at *michael.ramsey@usda.gov* or Avery Kool, RAC Coordinator, at 541–219–0372 or email at *avery.kool@usda.gov*.

Individuals who use telecommunication devices for the deaf and hard of hearing (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Hear from Title II project proponents and discuss Title II project proposals;
2. Make funding recommendations on Title II projects; and
3. Schedule the next meeting.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should make a request in writing by May 4, 2022, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Avery Kool, Fremont-Winema National Forest, 303 OR–31, Paisley, OR 97636; or by email to *avery.kool@usda.gov*.

Meeting Accommodations: Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodation. For access to proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case-by-case basis.

Equal opportunity practices, in line with USDA policies, will be followed in all membership appointments to the RAC. To help ensure that recommendations of the RAC have taken into account the needs of the diverse groups served by the Department, membership shall include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

The USDA prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, political beliefs, income derived from a public assistance program, or reprisal or retaliation for prior civil rights activity in any program or activity conducted or funded by USDA (not all bases apply to all programs).

Dated: April 5, 2022.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2022–07673 Filed 4–8–22; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Dixie Resource Advisory Committee

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of meeting.

SUMMARY: The Dixie Resource Advisory Committee (RAC) will hold a virtual meeting by phone and/or video conference. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act as well as to make recommendations on recreation fee proposals for sites on the Dixie National Forest within Garfield, Iron, Kane, and Washington Counties, consistent with the Federal Lands Recreation Enhancement Act. RAC information and virtual meeting information can be found at the following website: *https://www.fs.usda.gov/main/dixie/workingtogether/advisorycommittees.*

DATES: The meeting will be held on May 26, 2022, 9:00 a.m.–12:00 p.m., Mountain Daylight Time.

All RAC meetings are subject to cancellation. For status of the meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held virtually via telephone and/or video conference. Details on how members of the public can join the meeting can be found at the website link in the above **SUMMARY.**

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received upon request.

FOR FURTHER INFORMATION CONTACT: Steven O'Neil, Designated Federal Officer (DFO), by phone at 435–865–3753 or email at *steven.oneil1@usda.gov* or Kevin S. Abel, RAC Coordinator, at 435–592–4866 or email at *kevin.abel@usda.gov.*

Individuals who use telecommunication devices for the deaf and hard of hearing (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Elect a committee chairperson;
2. Review Title II project proponents and discuss Title II project proposals;
3. Make funding recommendations on Title II projects;
4. Approve meeting minutes; and
5. Schedule the next meeting, if needed.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should make a request in writing by May 10, 2022, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Steven O'Neil, Dixie National Forest, 820 N. Main, Cedar City UT 84721 or by email to *steven.oneil1@usda.gov.*

Meeting Accommodations: Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodation. For access to proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case-by-case basis.

Equal opportunity practices, in line with USDA policies, will be followed in all membership appointments to the RAC. To help ensure that recommendations of the RAC have taken into account the needs of the diverse groups served by the Department, membership shall include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

The USDA prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, political beliefs, income derived from a public assistance program, or reprisal or retaliation for prior civil rights activity in any program or activity conducted or funded by USDA (not all bases apply to all programs).

Dated: April 5, 2022.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2022–07678 Filed 4–8–22; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

North Wisconsin Resource Advisory Committee

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of meeting.

SUMMARY: The North Wisconsin Resource Advisory Committee (RAC) will hold a virtual meeting by phone and/or video conference. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act as well as to make recommendations on recreation fee proposals for sites on the Chequamegon-Nicolet National Forest within Ashland, Bayfield, Florence, Forest, Oconto, Price, Sawyer, and Taylor Counties, consistent with the Federal Lands Recreation Enhancement Act. RAC information and virtual meeting information can be found at the

following website: *https://www.fs.usda.gov/main/cnnf/workingtogether/advisorycommittees*.

DATES: The meeting will be held on April 27, 2022, 9:00 a.m.–3:00 p.m., Central Daylight Time.

All RAC meetings are subject to cancellation. For status of the meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting is open to the public and will be held virtually via telephone and/or video conference. Virtual meeting participation details can be found on the website listed under **SUMMARY** or can be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received upon request.

FOR FURTHER INFORMATION CONTACT: Adam Felts, Designated Federal Officer (DFO), by phone at 715–362–1335 or email at *adam.felts@usda.gov* or Penny McLaughlin, RAC Coordinator, at 715–362–1322 or email at *penny.mclaughlin@usda.gov*.

Individuals who use telecommunication devices for the deaf and hard of hearing (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Hear from Title II project proponents and discuss Title II project proposals;
2. Make funding recommendations on Title II projects; and
3. Schedule additional meeting(s).

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should make a request in writing by April 15, 2022, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Penny McLaughlin, 500 Hanson Lake Road, Rhinelander, WI, 54501 or by email to *penny.mclaughlin@usda.gov*.

Meeting Accommodations: Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodation. For access to proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case-by-case basis.

Equal opportunity practices, in line with USDA policies, will be followed in all membership appointments to the RAC. To help ensure that recommendations of the RAC have taken into account the needs of the diverse groups served by the Department, membership shall include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

The USDA prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, political beliefs, income derived from a public assistance program, or reprisal or retaliation for prior civil rights activity in any program or activity conducted or funded by USDA (not all bases apply to all programs).

Dated: April 5, 2022.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2022–07670 Filed 4–8–22; 8:45 am]

BILLING CODE 3411–15–P

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

Notice of Public Meeting

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Notice of public meeting.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (Access Board or Board) is hosting a virtual public meeting to obtain further information on the appropriate low-height specification for transfer surfaces for medical diagnostic equipment.

DATES: The public meeting will take place May 12, 2022, 2:00 to 4:00 p.m. Eastern Time.

ADDRESSES: The virtual meeting will be open to the public and held via the Zoom Webinar Platform (*https://www.zoomgov.com/webinar/register/WN_GFoTS44-R7qWdh6GF0xLPg*). Requests to speak during the meeting must be submitted via email to Rose Marie Bunales at *bunales@access-board.gov* by May 11, 2022. Please type ''Request to Speak'' in the email subject line. Speakers will be limited to three minutes during the virtual meeting. Written comments may be submitted until May 27, 2022. Submit written comments via email to *mde@access-board.gov*.

FOR FURTHER INFORMATION CONTACT: To register to attend this virtual meeting, visit: *https://www.zoomgov.com/webinar/register/WN_GFoTS44-R7qWdh6GF0xLPg*. For further information, contact Bobby Stinnette of the Access Board by email at *stinnette@access-board.gov* or by phone at 202–272–0021. Communication access via real-time translation and sign language interpretation will be provided. To request additional reasonable accommodations for the virtual meeting please contact Bobby Stinnette by May 5, 2022.

SUPPLEMENTARY INFORMATION:

Background

Section 510 of the Rehabilitation Act charges the Access Board with developing and maintaining accessibility standards for medical equipment used by health care providers for diagnostic purposes, including examination tables and chairs, weight scales, and imaging equipment. 29 U.S.C. 794f. In January 2017, the Board issued a final rule establishing accessibility standards for medical diagnostic equipment (MDE Standards). 82 FR 2810 (codified at 36 CFR part 1195). The MDE Standards set forth minimum technical criteria to ensure that medical diagnostic equipment in physician's offices, clinics, emergency rooms, hospitals, and other medical settings is independently accessible to, and usable by, individuals with disabilities.

The MDE Standards address the height and adjustability of MDE equipment that patients who use wheelchairs must transfer onto, including examination tables and chairs, procedure tables, and imaging equipment with tables. It is important that the height of these transfer surfaces align with a patient's wheelchair seat height to facilitate a safe transfer between diagnostic equipment and mobility devices. Transfer surfaces that align with the seat heights of mobility devices reduce the effort needed by patients to transfer since they do not have to lift their body weight to make up the difference between the two surfaces.

In the Notice of Proposed Rulemaking for the MDE Standards, the Board sought public comment on whether the

height of transfer surfaces should be adjustable within a range of 17 inches minimum and 25 inches maximum. 77 FR 6916, 6922 (Feb. 9, 2012). These dimensions were based on findings from a major study on the human measures of people who use wheeled mobility devices in the United States conducted by the University of Buffalo Center for Inclusive Design and Environmental Access (IDeA Center) with funding from the Access Board and the National Institute for Disability, Independent Living, and Rehabilitation Research. Completed in 2010, the Anthropometry of Wheeled Mobility Project collected anthropometric data on 495 subjects who use wheelchairs, power chairs, and scooters. Researchers measured wheelchair seat height, occupied length, turning radii, reach ranges, and other dimensions (Steinfeld, E., Paquet, V., D'Souza, C., Joseph, C., and Maisel, J. ''Anthropometry of Wheeled Mobility: Final Report'' (2010), *available at http://idea.ap.buffalo.edu/wp-content/uploads/sites/110/2020/01/AnthropometryofWheeledMobilityProject_FinalReport.pdf*).

Findings from this project indicated that the occupied seat heights for people who use wheeled mobility devices vary considerably. Seat heights ranged from 16.3 inches to 23.9 inches for manual wheelchair users, 16.2 inches to 28.9 inches for power wheelchair users, and 18.8 inches to 25.3 inches for scooter users. Based on this data, researchers concluded that a transfer surface that is adjustable from a height of 17 inches minimum to 25 inches maximum would accommodate the 5th to the 95th percentile range of those who used wheeled mobility aids (*Id.,* Section 4.3.2, p. 89).

In an analysis of the data on seat height, researchers further determined that a low transfer height of 17 inches would exclude 6% of manual wheelchairs in the project database. According to this analysis, ''[i]ncreasing the minimum above 17 in. even two inches . . . would exclude a significant proportion of the manual wheelchair group, in particular, over 30% of the females in the sample.'' D'Souza, C., Steinfeld, E., ''Analysis of Seat Height for Wheeled Mobility Devices'' (July 19, 2011), *available at http://idea.ap.buffalo.edu/wp-content/uploads/sites/110/2019/08/23.pdf.*

In the Notice for Proposed Rulemaking, the Board sought comment on the height and adjustability of transfer surfaces and whether transfer surface heights should be adjustable from a low transfer position of 17 inches to a high transfer position of 25 inches. 77 FR at 6922–6933. Most commenters supported a requirement for adjustability and a high transfer surface height of 25 inches but disagreed on what the low transfer height should be. *Id.*

On July 5, 2012, the Access Board organized an advisory committee representing stakeholders to provide recommendations on how the MDE Standards should be finalized based on the public comments received. 77 FR 39656. The MDE Accessibility Standards Advisory Committee, like the public commenters, was divided on the low transfer surface height and was unable to reach consensus regarding a minimum low transfer surface height specification. MDE Accessibility Standards Advisory Committee Report, 70, *available at https://www.regulations.gov/document/ATBCB-2013-0009-0001.* Advisory committee members submitted minority reports supporting their views.

Minority reports submitted by the disability advocates and academics supported a minimum low height of 17 inches to ensure as many independent transfers as possible. They noted that a 17-inch low height provides the greatest number of individuals the opportunity to transfer independently. *See* Minority Reports from Boston Center for Independent Living Inc., National Network for ADA Centers, and Medical Diagnostic Equipment Advisory Committee. *Id.*

The minority reports submitted by manufacturers supported a minimum low height of 19 inches. They asserted that examination tables and chairs that can meet the 19-inch height are available but that there were no products on the market that met the 17-inch height. *See* Minority Reports from the Brewer Company, LLC, Hologic, Inc., Midmark Corporation, MITA Advisory Committee Members, and Recommendation of 19-inch Lower Adjustable Height as the Minimum Accessibility Standard (Joint Report). Manufacturers also expressed concern about the potential impacts of a 17-inch low height on diagnostic imaging medical equipment with tables, such as x-ray scanners, CTs, PETs and MRIs. A reduction in the low transfer surface height of a few inches may involve significant re-engineering and require FDA retesting and recertification according to these reports. See Minority Report of GE Healthcare, Phillips Healthcare, Siemens Healthcare, and Hologic, Inc. *Id.*

On January 9, 2017, the Access Board issued the MDE final rule, in which the Board specified that transfer surfaces be adjustable from a low transfer position at a height of 17–19 inches to a high transfer position at a height of 25 inches. It also required that the transfer surface be adjustable to four unspecified heights between the high and low transfer height separated by a minimum of one inch. 36 CFR part 1195, Appendix, M301.2.1 & M302.2.2. The 17–19 inch low transfer height was set as a temporary range with a five-year sunset provision. *Id.* As explained in the preamble to the final rule, the Board took this approach because ''there was insufficient information to designate a single minimum low height requirement at this time. Specifically, there [was] insufficient data on the extent to which and how many individuals would benefit from a transfer height lower than 19 inches.'' 82 FR at 2816.

During the five-year sunset period, the Board said it would further study this issue and collect additional information. *Id.* On February 3, 2022, the Board issued a direct final rule to extend the sunset provision until January 10, 2025, to provide additional time to complete its research and the required rulemaking processes to establish a final specification for the low transfer surface height. 87 FR 6037.

In 2021, the Board commissioned a secondary analysis of the Anthropometry of Wheeled Mobility database and wheelchair seat height. This analysis was undertaken because some segments of the population in the Anthropometry of Wheeled Mobility Project test sample were over- or under-represented. Specifically, the test population was younger in age and included more men than women compared to the estimated U.S. population. In addition, the researchers intentionally oversampled powered wheelchair users, which tend to have seat heights higher than manual wheelchairs, in order to capture the sizes and space requirements of this group. (''Anthropometry of Wheeled Mobility: Final Report,'' Section 3.1, pp. 36–37).

In this 2021 study, researchers statistically resampled data on occupied seat heights for manual and powered wheelchair users to create virtual samples that were proportionally representative of the total population of wheelchair users in the United States in terms of device type (manual wheelchairs or powered wheelchairs), gender, and age category (18 to 64 years or 65 years and older). Based on demographically representative sampling, the study estimates that 4.5% of wheelchair users have a seat height equal to or less than 17 inches, 21% had a seat height equal to or less than 18 inches, and 42% had a seat height equal to or less than 19 inches. (D'Souza, C.,

(January 28, 2022), ''Analysis of Low Wheelchair Seat Heights and Transfer Surfaces for Medical Diagnostic Equipment: Final Report'' *available at https://www.access-board.gov/research/human/wheelchair-seat-height/*).

Announcement of Public Meeting

In light of these latest findings from the resampling analysis, the Access Board has decided to hold a public hearing to gather additional information on the low transfer height for MDE transfer surfaces from disability advocates, manufacturers of MDE, researchers and other stakeholders and interested parties. The Board is particularly interested in information on what the low height is for adjustable MDE products that are currently on the market and any changes or innovations in their design and engineering that may have occurred since the Board issued the MDE standards in 2017. The Board is aware of at least some examination tables and chairs that can adjust to a height of 17 inches or less. The Board is also interested in updated information on the incremental costs for the design or redesign and manufacture of examination tables and chairs and diagnostic imaging medical equipment with tables that can provide a low transfer height of 17 inches.

Christopher Kuczynski,

General Counsel, U.S. Access Board.

[FR Doc. 2022–07724 Filed 4–8–22; 8:45 am]

BILLING CODE 8150–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Wyoming Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Wyoming Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a virtual business meeting via Webex at 1 p.m. MT on Monday, May 9, 2022, to discuss civil rights concerns in the state.

DATES: The meeting will take place on Monday, May 9, 2022, from 1 p.m.–2:30 p.m. MT.

Link to Join (Audio/Visual): https://tinyurl.com/2p92mtv3

Telephone (Audio Only): Dial (800) 360–9505 USA Toll Free; Access Code: 2760 040 0750

FOR FURTHER INFORMATION CONTACT: Kayla Fajota, DFO, at *kfajota@usccr.gov* or (434) 515–2395.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the conference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at (800) 877–8339 and providing the Service with the conference details found through registering at the web link above. To request additional accommodations, please email *kfajota@usccr.gov* at least ten (10) days prior to the meeting.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Liliana Schiller at *lschiller@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Wyoming Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at the above phone number.

Agenda

I. Welcome & Roll Call
II. Introductions
III. Overview of Project Process & Concept Stage
IV. Discussion: Potential Topic Choice
V. Public Comment
VI. Adjournment

Dated: April 6, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–07662 Filed 4–8–22; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the West Virginia Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the West Virginia Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold project planning meetings at the times identified in the **DATES** section below. The purpose of these meetings is to continue planning and discussing the Committee's civil rights project on disparate school discipline policies and practices in West Virginia public schools. Each planning meeting will last for approximately one hour.

DATES: Tuesday, May 3, at 11:30 a.m. ET; Tuesday, June 7, at 11:30 a.m. ET; Tuesday, July 5, at 11:30 a.m. ET; Tuesday, August 2, at 11:30 a.m. ET; and Tuesday, September 6, at 11:30 a.m. ET

Meeting Link (Audio/Visual): https://bit.ly/3wZHG1b

Telephone (Audio Only): Dial 1–800–360–9505 USA Toll Free; Access code: 2764 230 7047

FOR FURTHER INFORMATION CONTACT: Ivy Davis, DFO, and Director of the Eastern Regional Office (ERO, at *ero@usccr.gov* or 1–202–376–7533).

SUPPLEMENTARY INFORMATION: Members of the public can listen to these discussions. Committee meetings are available to the public through the above call-in number. Any interested member of the public may call this number and listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Individuals who are deaf, deafblind and hard of hearing may follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments via

email. The comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed. The email subject line should state: Atten: WV and sent to this email address: *ero@usccr.gov.* Persons who desire additional information may contact the Eastern Regional Office at *ero@usccr.gov.*

Records generated from this meeting may be inspected and reproduced at the Eastern Regional Programs, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, West Virginia Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Eastern Regional Office at the above email address.

Agenda

I. Roll Call
II. Welcome
III. Project Planning
IV. Other Matters
V. Next Meeting
VI. Public Comments
VII. Adjourn

Dated: April 6, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–07663 Filed 4–8–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–52–2022]

Foreign-Trade Zone 84—Houston, Texas Application for Subzone Coreworks Heat Exchangers, LLC, Waller, Texas

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Port of Houston Authority, grantee of FTZ 84, requesting subzone status for the facility of Coreworks Heat Exchangers, LLC (Coreworks), located in Waller (Waller County), Texas. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on April 5, 2022.

The proposed subzone (10.82 acres) is located at 1300 Alegacy Place in Waller (Waller County), Texas. At the proposed subzone, Coreworks would be able to conduct the production activity already authorized for the company for its existing facility in Katy, Texas. No additional authorization for production activity has been requested at this time. The proposed subzone would be subject to the existing activation limit of FTZ 84.

In accordance with the FTZ Board's regulations, Camille Evans of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is May 23, 2022. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to June 6, 2022.

A copy of the application will be available for public inspection in the ''Online FTZ Information Section'' section of the FTZ Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Camille Evans at *Camille.Evans@trade.gov.*

Dated: April 6, 2022.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2022–07658 Filed 4–8–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–025; C–533–862]

Polyethylene Terephthalate Resin From the People's Republic of China and India: Continuation of Countervailing Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of the determinations by the Department of Commerce (Commerce) and the U.S. International Trade Commission (ITC) that revocation of the countervailing duty (CVD) orders on polyethylene terephthalate (PET) resin from the People's Republic of China (China) and India would likely lead to continuation or recurrence of net countervailable subsidies and material injury to an industry in the United States, Commerce is publishing this notice of continuation of the CVD orders.

DATES: Applicable April 11, 2022.

FOR FURTHER INFORMATION CONTACT: Emily Bradshaw or Yang Jin Chun, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3896 or (202) 482–5760, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 6, 2016, Commerce published in the **Federal Register** the CVD orders on PET resin from China and India.[1] On March 31, 2021, Commerce published the notice of initiation of the sunset reviews of the *Orders,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] Commerce conducted expedited (120-day) sunset reviews of these *Orders,* pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2).

As a result of its reviews, Commerce determined, pursuant to sections 751(c)(1) and 752(c) of the Act, that revocation of the *Orders* would likely lead to continuation or recurrence of countervailable subsidies.[3] Commerce, therefore, notified the ITC of the magnitude of the net countervailable subsidy rates likely to prevail should the *Orders* be revoked.[4] On April 4, 2022, the ITC published its determination, pursuant to section 751(c) of the Act, that revocation of the *Orders* would likely lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[5]

Scope of the Orders

The merchandise covered by these *Orders* is polyethylene terephthalate (PET) resin having an intrinsic viscosity of at least 0.70, but not more than 0.88, deciliters per gram. The scope includes blends of virgin PET resin and recycled PET resin containing 50 percent or more virgin PET resin content by weight,

[1] *See Certain Polyethylene Terephthalate Resin from India and the People's Republic of China: Countervailing Duty Order (India) and Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order (People's Republic of China),* 81 FR 27978 (May 6, 2016) (*Orders*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 86 FR 16701 (March 31, 2021).

[3] *See Polyethylene Terephthalate Resin from the People's Republic of China and India: Final Results of the Expedited First Sunset Reviews of the Countervailing Duty Orders,* 86 FR 38982 (July 23, 2021) (*Final Sunset Reviews*), and accompanying Issues and Decision Memorandum (IDM).

[4] *See Final Sunset Reviews* IDM at 8.

[5] *See Polyethylene Terephthalate (PET) Resin from Canada, China, India, and Oman,* 87 FR 19531 (April 4, 2022).

provided such blends meet the intrinsic viscosity requirements above. The scope includes all PET resin meeting the above specifications regardless of additives introduced in the manufacturing process. The merchandise subject to these *Orders* is properly classified under subheading 3907.60.00.30 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the merchandise covered by these *Orders* is dispositive.[6]

Continuation of the Orders

As a result of the determinations by Commerce and the ITC that revocation of the *Orders* would likely lead to continuation or recurrence of countervailable subsidies and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act and 19 CFR 351.218(a), Commerce hereby orders the continuation of the *Orders.* U.S. Customs and Border Protection will continue to collect CVD cash deposits at the rates in effect at the time of entry for all imports of subject merchandise. The effective date of the continuation of the *Orders* will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act and 19 CFR 351.218(c)(2), Commerce intends to initiate the next sunset reviews of the *Orders* no later than 30 days prior to the fifth anniversary of the effective date of continuation.

Notification to Interested Parties

These five-year (sunset) reviews and this notice are in accordance with sections 751(c) and 751(d)(2) of the Act and published pursuant to section 777(i)(1) of the Act and 19 CFR 351.218(f)(4).

Dated: April 5, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–07721 Filed 4–8–22; 8:45 am]

BILLING CODE 3510–DS–P

[6] *See Polyethylene Terephthalate Resin from the People's Republic of China and India: Final Results of the Expedited First Sunset Reviews of the Countervailing Duty Orders,* 86 FR 38982 (July 23, 2021).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–890]

Wooden Bedroom Furniture From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) continues to determine that the sole respondent under review, Hui Zhou Tian Mei Investment Co., Ltd. (aka Hui Zhou Tian Mei Furniture Co., Ltd.) (Tian Mei), is not eligible for a separate rate and is therefore a part of the China-wide entity. The period of review (POR) is January 1, 2020 through December 31, 2020.

DATES: Applicable April 11, 2022.

FOR FURTHER INFORMATION CONTACT: Krisha Hill, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4037.

SUPPLEMENTARY INFORMATION:

Background

On October 7, 2021, Commerce published in the **Federal Register** the preliminary results of the 2020 administrative review of the antidumping duty (AD) order on wooden bedroom furniture (WBF) from the People's Republic of China (China).[1] We invited interested parties to comment on the *Preliminary Results.* On February 1, 2022, Commerce extended the deadline to issue the final results of this review until April 5, 2022.[2] A full description of case events that occurred since issuance of the *Preliminary Results,* is in the Issues and Decision Memorandum.[3]

[1] *See Wooden Bedroom Furniture from the People's Republic of China: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review; 2020,* 86 FR 55809 (October 7, 2021) (*Preliminary Results*).

[2] *See* Memorandum, ''Antidumping Duty Administrative Review of Wooden Bedroom Furniture from the People's Republic of China: Extension of Deadline for Final Results of Antidumping Duty Administrative Review,'' dated February 1, 2022.

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review: Wooden Bedroom Furniture from the People's Republic of China; 2020,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Scope of the Order

The product covered by the *Order* is wooden bedroom furniture, subject to certain exceptions.[4] Imports of subject merchandise are classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 9403.50.9042, 9403.50.9045, 9403.50.9080, 9403.90.7005, 9403.90.7080, 9403.50.9041, 9403.60.8081, 9403.20.0018, 9403.90.8041, 7009.92.1000 or 7009.92.5000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the *Order* is dispositive.[5]

Methodology

Commerce conducted this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act). For a discussion of the comment received, *see* the Issues and Decision Memorandum.[6] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Review

Consistent with the *Preliminary Results,* we continue to determine that the sole respondent under review, Tian Mei, did not establish its eligibility for a separate rate and is part of the China-wide entity. No parties commented on this decision.

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this

[4] *See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Wooden Bedroom Furniture from the People's Republic of China,* 70 FR 329 (January 4, 2005) (*Order*).

[5] For a complete description of the scope of the *Order, see Wooden Bedroom Furniture from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2018,* 85 FR 7731 (February 11, 2020); *see also* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review: Wooden Bedroom Furniture from the People's Republic of China,'' dated October 2, 2019.

[6] *See* Issues and Decision Memorandum.

review. No earlier than 35 days after the date of publication of this notice in the **Federal Register**, Commerce intends to instruct CBP to liquidate any entries of subject merchandise from Tian Mei that entered the United States during the POR at the China-wide rate (*i.e.,* 216.01 percent). If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of this notice in the **Federal Register** for all shipments of subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice, as provided by section 751(a)(2)(C) of the Act: (1) For previously investigated or reviewed China and non-China exporters which are not under review in this review, but which received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the exporter's existing cash deposit rate; (2) for all China exporters of subject merchandise that do not have a separate rate, the cash deposit rate will be the China-wide entity rate (*i.e.,* 216.01 percent); and (3) for all non-China exporters of subject merchandise that do not have their own rate, the cash deposit rate will be the rate applicable to the China exporter(s) that supplied that non-China exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties/and or countervailing duties prior to liquidation of the relevant entries during the POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Orders

This notice also serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under the APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results of administrative review in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(5) and 19 CFR 351.213(h)(1).

Dated: April 5, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2022–07728 Filed 4–8–22; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–817]

Certain Oil Country Tubular Goods From the Socialist Republic of Vietnam: Final Results of Antidumping Duty Administrative Review; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) finds that certain oil country tubular goods (OCTG) from the Socialist Republic of Vietnam (Vietnam) were sold in the United States at less than normal value for the period of review (POR) September 1, 2019, through August 31, 2020.

DATES: Applicable April 11, 2022.

FOR FURTHER INFORMATION CONTACT: Fred Baker, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2924.

SUPPLEMENTARY INFORMATION:

Background

On January 28, 2021, Commerce published the *Preliminary Results*.[1] On November 8, 2021, we received case briefs from Maverick Tube Corporation, Tenaris Bay City, Inc., and IPSCO Tubulars, Inc. (collectively, the petitioners) and from SeAH Steel VINA Corporation (SeAH VINA) and Pusan Pipe America, Inc. (Pusan Pipe) (collectively, SSV).[2] On November 15, 2021, the petitioners and SSV submitted rebuttal briefs.[3] On March 16, 2022, Commerce rejected the case briefs of the petitioners and SSV because they contained new factual information after the deadline for such information.[4] The petitioners and SSV submitted redacted versions of their case briefs on March 18, 2022.[5] On January 28, 2022, we extended the deadline for the final results of this review until April 5, 2022.[6]

For a complete description of the events that followed the *Preliminary Results* of this administrative review,

[1] *See Certain Oil Country Tubular Goods from the Socialist Republic of Vietnam: Preliminary Results of Antidumping Duty Administrative Review,* 86 FR 55807 (October 7, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Petitioners' Letter, ''Oil Country Tubular Goods from the Socialist Republic of Vietnam: Case Brief of Maverick Tube Corporation, Tenaris Bay City, Inc., and IPSCO Tubulars Inc.,'' dated November 8, 2021; and SSV's Letter, ''Administrative Review of the Antidumping Duty Order on Certain Oil Country Tubular Goods from Vietnam—Case Brief of SeAH Steel VINA Corporation and Pusan Pipe America, Inc.,'' dated November 8, 2021.

[3] *See* Petitioners' Letter, ''Oil Country Tubular Goods from the Socialist Republic of Vietnam: Rebuttal Brief of Maverick Tube Corporation, Tenaris Bay City, Inc., and IPSCO Tubulars Inc.,'' dated November 15, 2021; *see also* SSV's Letter, ''Administrative Review of the Antidumping Duty Order on Certain Oil Country Tubular Goods from Vietnam—Rebuttal Brief of SeAH Steel VINA Corporation and Pusan Pipe America, Inc.,'' dated November 15, 2021.

[4] *See* Commerce's Letters, ''Antidumping Duty Administrative Review of Oil Country Tubular Goods from the Socialist Republic of Vietnam; 2019–20: Rejection of Case Brief Filed by Maverick Tube Corporation, Tenaris Bay City, Inc., and IPSCO Tubulars, Inc., and Request for Resubmission of Its Case Brief,'' dated March 16, 2022; and ''Antidumping Duty Administrative Review of Oil Country Tubular Goods from the Socialist Republic of Vietnam; 2019–20: Rejection of Case Brief of SeAH Steel VINA Corporation and Pusan Pipe America, Inc., and Request for Resubmission of Its Case Brief,'' dated March 16, 2022.

[5] *See* Petitioners' Letter, ''Oil Country Tubular Goods from the Socialist Republic of Vietnam: Resubmission of Case Brief,'' dated March 18, 2022; and SSV's Letter, ''Administrative Review of the Antidumping Order on Oil Country Tubular Goods from Vietnam—Redacted Case Brief of SeAH Steel VINA Corporation and Pusan Pipe America, Inc.,'' dated March 18, 2022.

[6] *See* Memorandum, ''Oil Country Tubular Goods from the Socialist Republic of Vietnam: Extension of Deadline for Final Results of Antidumping Duty Administrative Review,'' dated January 28, 2022.

see the Issues and Decision Memorandum, dated concurrently with these final results and hereby adopted by this notice.[7] Commerce is conducting an administrative review of the antidumping duty order on OCTG from Vietnam [8] in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The merchandise covered by the *Order* is OCTG from Vietnam. For a full description of the merchandise covered by the scope of the *Order, see* the Issues and Decision Memorandum.

Analysis of Comments Received

Commerce addressed all issues raised in the case and rebuttal briefs in the Issues and Decision Memorandum. A list of the issues that parties raised and to which we responded in the Issues and Decision Memorandum is attached to this notice as the appendix. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on our review of the record and comments received from interested parties regarding the *Preliminary Results,* we made certain changes to the margin calculation for SSV. For a discussion of the issues, *see* the Issues and Decision Memorandum.

Separate Rates

No parties commented on our preliminary separate rate findings. Therefore, we have continued to grant SSV separate rate status.

Final Results of Review

Commerce determines that the following weighted-average dumping margin exists for the period September 1, 2019, through August 31, 2020:

Exporter	Weighted-average dumping margin (percent)
SeAH Steel VINA Corporation [9]	1.49

Disclosure

Commerce intends to disclose the calculations performed for these final results of review within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(1), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

Consistent with its recent notice,[10] 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).

Where the respondent's weighted-average dumping margin is zero or *de minimis,* or where an importer- (or customer-) specific *ad valorem* or per-unit rate is zero or *de minimis,* Commerce will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[11] For entries that were not reported in the U.S. sales database submitted by an exporter individually examined during this review, but that entered under the case number of that exporter (*i.e.,* at the individually-examined exporter's cash deposit rate), Commerce will instruct CBP to liquidate such entries at the Vietnam-wide rate (*i.e.,* 111.47 percent).[12]

For the individually-examined respondent whose weighted-average dumping margin is above *de minimis* (*i.e.,* 0.50 percent), Commerce will calculate importer-specific assessment rates on the basis of the ratio of the total amount of antidumping duties calculated for each importer's examined sales and the total entered value of the sales, in accordance with 19 CFR 351.212(b)(1).

Additionally, if Commerce determines that an exporter under review had no shipments of subject merchandise, any suspended entries that entered under the exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the Vietnam-wide rate.[13]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise from Vietnam entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For SeAH VINA, a cash deposit rate of 1.49 percent; (2) for previously investigated or reviewed Vietnamese and non-Vietnamese exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the exporter-specific rate published for the most-recently completed segment of this proceeding in which the exporter was reviewed; (3) for all Vietnamese exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the rate established for the Vietnam-wide entity, which is 111.47 percent; [14] and (4) for all non-Vietnamese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Vietnamese exporter that supplied that non-Vietnamese exporter with the

[7] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review of Certain Oil Country Tubular Goods from the Socialist Republic of Vietnam,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[8] *See Certain Oil Country Tubular Goods from India, the Republic of Korea, Taiwan, the Republic of Turkey, and the Socialist Republic of Vietnam: Antidumping Duty Orders; and Certain Oil Country Tubular Goods from the Socialist Republic of Vietnam: Amended Final Determination of Sales at Less Than Fair Value,* 79 FR 53691 (September 10, 2014) (*Order*).

[9] Commerce initiated a review of both SeAH VINA and Pusan Pipe, but the record shows that Pusan Pipe is a U.S. importer of OCTG that is affiliated with SeAH VINA and does not produce OCTG. *See* SSV's Letter, ''Administrative Review of the Antidumping Duty Order on Certain Oil Country Tubular Goods from Vietnam—Response to the Department's November 4 Questionnaire,'' dated December 4, 2020 at 1. Therefore, we have not calculated a rate for Pusan Pipe.

[10] *See Notice of Discontinuation Policy to Issue Liquidation Instructions After 15 Days in Applicable Antidumping and Countervailing Duty Administrative Proceedings,* 86 FR 3995 (January 15, 2021).

[11] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012).

[12] *See Certain Oil Country Tubular Goods from India, the Republic of Korea, Taiwan, the Republic of Turkey, and the Socialist Republic of Vietnam: Antidumping Duty Orders; and Certain Oil Country Tubular Goods from the Socialist Republic of Vietnam: Amended Final Determination of Sales at Less Than Fair Value,* 79 FR 53691 (September 10, 2014).

[13] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

[14] *See Order.*

subject merchandise. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers Regarding the Reimbursement of Duties

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during the review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, 19 CFR 351.213, and 19 CFR 351.221(b)(5).

Dated: April 5, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2022–07722 Filed 4–8–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–888]

Certain Carbon and Alloy Steel Cut-to-Length Plate From the Republic of Korea: Final Results and Partial Rescission of Countervailing Duty Administrative Review; 2019; Correction

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

ACTION: Notice; correction.

SUMMARY: On February 7, 2022, the Department of Commerce (Commerce) published a notice in the **Federal Register**, in which Commerce announced the final results of the 2019 administrative review of the countervailing duty (CVD) order on certain carbon and alloy steel cut-to-length plate (CTL plate) from the Republic of Korea (Korea). This notice inadvertently contained an incorrect rate for all other producers/exporters.

FOR FURTHER INFORMATION CONTACT: Faris Montgomery, 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) 482–1537.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of February 7, 2022, in FR Doc 2022–02490, on page 6844, in the first column, Commerce included an incorrect all-others rate of 4.31 percent in the first paragraph of the ''Cash Deposit Rates.'' The correct all-others rate is 3.72 percent. The correct citation for this rate is *Certain Carbon and Alloy Steel Cut-To-Length Plate from the Republic of Korea: Notice of Court Decision Not in Harmony With Final Countervailing Duty Determination, and Notice of Amended Final Countervailing Duty Determination,* 84 FR 64459 (November 22, 2019).

Background

On February 7, 2022, Commerce inadvertently published an incorrect rate in the final results of the 2019 administrative review of the CVD order on CTL plate from Korea.[1] In the final results, Commerce incorrectly listed the all-others rate as 4.31 percent, while the correct all-others rate is 3.72 percent.[2] This notice serves as a notification of, and correction to, this inadvertent error. With the issuance of this notice of correction, we confirm that the all-others rate is 3.72 percent.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i) of the Tariff Act of 1930, as amended, and 19 CFR 351.221(b)(5).

Dated: April 5, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–07676 Filed 4–8–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

United States Travel and Tourism Advisory Board: Meeting of the United States Travel and Tourism Advisory Board

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice of an open meeting.

SUMMARY: The United States Travel and Tourism Advisory Board (Board or TTAB) will hold a meeting on Monday, April 25, 2022. The Board advises the Secretary of Commerce on matters relating to the U.S. travel and tourism industry. The purpose of the meeting is for Board members to discuss the current state of the travel and tourism industry in the United States and priority issues for the industry, and for the Secretary of Commerce to charge the Board with developing recommendations in key areas. The final agenda will be posted on the Department of Commerce website for the Board at *https://www.trade.gov/ttab-*

[1] *See Certain Carbon and Alloy Steel Cut-to-Length Plate from the Republic of Korea: Final Results and Partial Recission of Countervailing Duty Administrative Review; 2019,* 87 FR 6842 (February 7, 2022).

[2] *See Certain Carbon and Alloy Steel Cut-to-Length Plate from the Republic of Korea: Notice of Court Decision Not in Harmony with Final Countervailing Duty Determination, and Notice of Amended Final Countervailing Duty Determination,* 84 FR 64459 (November 22, 2019).

meetings at least two days prior to the meeting.

DATES: Monday, April 25, 2022, 4:00 p.m.–5:30 p.m. EDT. The deadline for members of the public to register for the meeting or to submit written comments for dissemination prior to the meeting is 5:00 p.m. EDT on Wednesday, April 20, 2022.

ADDRESSES: The meeting will be held virtually. The access information will be provided by email to registrants. Requests to register (including to speak or for auxiliary aids) and any written comments should be submitted by email to *TTAB@trade.gov.*

FOR FURTHER INFORMATION CONTACT: Jennifer Aguinaga, the United States Travel and Tourism Advisory Board, National Travel and Tourism Office, U.S. Department of Commerce; telephone: 202–482–2404; email: *TTAB@trade.gov.*

SUPPLEMENTARY INFORMATION:

Public Participation: The meeting will be open to the public and will be accessible to people with disabilities. Any member of the public requesting to join the meeting is asked to register in advance by the deadline identified under the **DATES** caption. Requests for auxiliary aids must be submitted by the registration deadline. Last minute requests will be accepted but may not be possible to fill. There will be fifteen (15) minutes allotted for oral comments from members of the public joining the meeting. To accommodate as many speakers as possible, the time for public comments may be limited to three (3) minutes per person. Members of the public wishing to reserve speaking time during the meeting must submit a request at the time of registration, as well as the name and address of the proposed speaker. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the International Trade Administration may conduct a lottery to determine the speakers. Speakers are requested to submit a written copy of their prepared remarks by 5:00 p.m. EDT on Wednesday, April 20, 2022, for inclusion in the meeting records and for circulation to the members of the Board.

In addition, any member of the public may submit pertinent written comments concerning the Board's affairs at any time before or after the meeting. Comments may be submitted to Jennifer Aguinaga at the contact information indicated above. EDT on Wednesday, April 20, 2022, to ensure transmission to the Board prior to the meeting. Comments received after that date and time will be transmitted to the Board but may not be considered during the meeting. Copies of Board meeting minutes will be available within 90 days of the meeting.

This Notice is published pursuant to the Federal Advisory Committee Act, as amended (FACA), 5 U.S.C., app., 9(c). It has been determined that the Committee is necessary and in the public interest. The Committee was established pursuant to Commerce's authority under 15 U.S.C. 1512, established under the FACA, as amended, 5 U.S.C. app., and with the concurrence of the General Services Administration.

Jennifer Aguinaga,

Designated Federal Officer, United States Travel and Tourism Advisory Board.

[FR Doc. 2022–07645 Filed 4–8–22; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB947]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meetings and Request for Comments

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meetings and request for comments.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold five public hearings (including one webinar) and accept written comments regarding an action intended to rebuild the Atlantic mackerel stock.

DATES: The hearings will be held between April 25, 2022 and May 2, 2022. Written comments must be received by May 9, 2022. See **SUPPLEMENTARY INFORMATION** for details, including the dates and times for all hearings.

ADDRESSES: See **SUPPLEMENTARY INFORMATION** for hearing details.

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; *www.mafmc.org.*

Written comments may be submitted to:

- *Email to: jdidden@mafmc.org* (use subject ''Mackerel Rebuilding'').
- *Via webform at: https://www.mafmc.org/comments/mackerel-rebuilding.*
- *Mail to:* Chris Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, 800 North State Street, Suite 201, Dover, DE 19901. Mark the outside of the envelope ''Mackerel Rebuilding.''

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The Council will hold five public hearings and accept written comments regarding an action intended to rebuild the Atlantic mackerel stock. Potential management measures include commercial quotas, recreational bag limits, a 3-inch commercial minimum mesh requirement, and permitting clarifications. The action would also continue to set a river herring and shad catch cap for the mackerel fishery. A public hearing document with additional details can be found at *https://www.mafmc.org/actions/atlantic-mackerel-rebuilding-amendment.*

Hearing 1—New Bedford, Massachusetts, Monday, April 25, 2022, 6 p.m.–9 p.m., Fairfield Inn and Suites, 185 MacArthur Drive, New Bedford, MA 02740, phone: (774) 634–2000;

Hearing 2—Plymouth, Massachusetts, Tuesday, April 26, 2022, 6 p.m.–9 p.m., Hilton Garden Inn, 4 Home Depot Drive, Plymouth, MA 02360, phone: (508) 830–0200;

Hearing 3—Portsmouth, New Hampshire, Wednesday, April 27, 2022, 6 p.m.–8 p.m., Urban Forestry Center. 45 Elwyn Rd, Portsmouth, NH 03801; phone: (603) 431–6774;

Hearing 4—Brunswick, Maine, Thursday, April 28, 2022, 5:30 p.m.–8 p.m., Curtis Memorial Library (Morrell Meeting Room), 23 Pleasant Street, Brunswick, ME 04011, phone: (207) 725–5242; and

Hearing 5—Webinar: Monday, May 2, 2022, 6 p.m.–10 p.m. Connection details can be found at the Council's website calendar or *https://www.mafmc.org/actions/atlantic-mackerel-rebuilding-amendment.*

Written comments are accepted at the hearings or via the submission methods described above, by May 9, 2022.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to Shelley Spedden, (302) 526–5251, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 6, 2022.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–07695 Filed 4–8–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB898]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Marine Site Characterization Surveys Offshore of New Jersey

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; request for comments on proposed Renewal incidental harassment authorization (IHA).

SUMMARY: NMFS received a request from Ocean Wind LLC (Ocean Wind) for the Renewal of their currently active incidental harassment authorization (IHA) to take marine mammals incidental to marine site characterization survey activities off the coast of New Jersey in the areas of the Bureau of Ocean Energy Management (BOEM) Commercial Lease of Submerged Lands for Renewable Energy Development on the Outer Continental Shelf (OCS)–A 0498 (Lease Area) and federal and state waters along potential export cable routes (ECRs) to landfall locations between Raritan Bay (part of the New York Bight) and Delaware Bay. These activities are identical to those covered in the current authorization, which expires on May 9, 2022. Pursuant to the Marine Mammal Protection Act, prior to issuing the currently active IHA, NMFS requested comments on both the proposed IHA and the potential for renewing the initial authorization if certain requirements were satisfied. The Renewal requirements have been satisfied, and NMFS is now providing an additional 15-day comment period to allow for any additional comments on the proposed Renewal not previously provided during the initial 30-day comment period.

DATES: Comments and information must be received no later than April 26, 2022.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service and should be submitted via email to *ITP.Harlacher@noaa.gov*.

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments, including all attachments, must not exceed a 25-megabyte file size. Attachments to comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. All comments received are a part of the public record and will generally be posted online at *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Jenna Harlacher, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the original application, Renewal request, and supporting documents (including NMFS **Federal Register** notices of the original proposed and final authorizations, and the previous IHA), as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act*. In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The Marine Mammal Protection Act (MMPA) prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, an incidental harassment authorization is issued.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to here as ''mitigation measures''). Monitoring and reporting of such takings are also required. The meaning of key terms such as ''take,'' ''harassment,'' and ''negligible impact'' can be found in section 3 of the MMPA (16 U.S.C. 1362) and the agency's regulations at 50 CFR 216.103.

NMFS' regulations implementing the MMPA at 50 CFR 216.107(e) indicate that IHAs may be renewed for additional periods of time not to exceed one year for each reauthorization. In the notice of proposed IHA for the initial authorization (86 FR 17783; April 06, 2021), NMFS described the circumstances under which we would consider issuing a Renewal for this activity, and requested public comment on a potential Renewal under those circumstances. Specifically, on a case-by-case basis, NMFS may issue a one-time one-year Renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical, or nearly identical, activities as described in the Detailed Description of Specified Activities section of the initial IHA issuance notice is planned or (2) the activities as described in the Description of the Specified Activities and Anticipated Impacts section of this notice would not be completed by the time the initial IHA expires and a Renewal would allow for completion of the activities beyond that described in the **DATES** section of the notice of issuance of the initial IHA, provided all of the following conditions are met:

1. A request for renewal is received no later than 60 days prior to the needed Renewal IHA effective date (recognizing that the Renewal IHA expiration date cannot extend beyond one year from expiration of the initial IHA).

2. The request for renewal must include the following:

- An explanation that the activities to be conducted under the requested Renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (*e.g.,* reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take).

• A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

3. Upon review of the request for Renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

An additional public comment period of 15 days (for a total of 45 days), with direct notice by email, phone, or postal service to commenters on the initial IHA, is provided to allow for any additional comments on the proposed Renewal. A description of the Renewal process may be found on our website at: *www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-harassment-authorization-renewals*. Any comments received on the potential Renewal, along with relevant comments on the initial IHA, have been considered in the development of this proposed IHA Renewal, and a summary of agency responses to applicable comments is included in this notice. NMFS will consider any additional public comments prior to making any final decision on the issuance of the requested Renewal, and agency responses will be summarized in the final notice of our decision.

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 proposed action (*i.e.,* the issuance of an incidental harassment authorization) 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 NOAA Administrative Order 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 preliminarily determined that the issuance of the proposed IHA Renewal qualifies to be categorically excluded from further NEPA review.

We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the IHA Renewal request.

History of Request

On May 10, 2021, NMFS issued an IHA to Ocean Wind to take marine mammals incidental to marine site characterization survey activities off the coast of New Jersey in the areas of the Commercial Lease of Submerged Lands for Renewable Energy Development on the Outer Continental Shelf (OCS–A 0498) and along potential submarine cable routes to landfall locations in New Jersey (86 FR 6465), effective from May 10, 2021 through May 09, 2022. On February 18, 2022, NMFS received an application for the Renewal of that initial IHA. As described in the application for Renewal IHA, the activities for which incidental take is requested are identical to those covered in the initial authorization. As required, the applicant also provided a preliminary monitoring report (available at *www.fisheries.noaa.gov/action/incidental-take-authorization-ocean-wind-llc-marine-site-characterization-surveys-new-jersey*) which confirms that the applicant has implemented the required mitigation and monitoring, and which also shows that no impacts of a scale or nature not previously analyzed or authorized have occurred as a result of the activities conducted.

Description of the Specified Activities and Anticipated Impacts

Ocean Wind proposes to conduct a second year of high-resolution geophysical (HRG) marine site characterization surveys in the Lease Area and along potential ECRs to landfall locations in New Jersey, between Raritan Bay (part of the New York Bight) and Delaware Bay. The location, timing, and nature of the activities, including the types of equipment planned for use, are identical to those described in the original IHA. The purpose of the marine site characterization surveys are to obtain an assessment of seabed (geophysical, geotechnical, and geohazard), ecological, and archeological conditions within the footprint of a planned offshore wind facility development. Surveys are also conducted to support engineering design and to map unexploded ordnance. Underwater sound resulting from Ocean Wind's site characterization survey activities, specifically HRG surveys, has the potential to result in incidental take of marine mammals in the form of Level B harassment.

In their 2020 IHA application, Ocean Wind estimated it would conduct surveys at a rate of 70 kilometers (km) per survey day. Ocean Wind defined a survey day as a 24-hour activity day. Based on the planned 24-hours operations, the number of estimated survey days varies between the Lease Area and ECR area, with 142 vessel survey days expected in the Lease Area and 133 vessel survey days in the ECR area, with a total of 275 survey days. A maximum of 2 vessels would operate concurrently in areas where 24-hr operations would be conducted, with an additional third vessel potentially conducting daylight-only survey effort in shallow-water areas. The Renewal IHA would authorize harassment of marine mammals for a second year of identical survey activities to be completed in one year, in the same area, using survey methods identical to those described in the initial IHA application; therefore, the anticipated impacts on marine mammals and the affected stocks also remain the same.

Accordingly, the amount of take requested for the Renewal IHA is also identical to that authorized in the initial IHA. All active acoustic sources and mitigation and monitoring measures would remain exactly as described in the **Federal Register** notices of the initial proposed IHA (86 FR 17783; April 06, 2021) and issued initial final IHA (86 FR 26465; May 14, 2021).

The following documents are referenced in this notice and include important supporting information:

• Initial final IHA (86 FR 26465; May 14, 2021);

• Initial proposed IHA (86 FR 17783; April 06, 2021); and

• 2021 IHA application, references cited, and previous public comments received (available at *www.fisheries.noaa.gov/action/incidental-take-authorization-ocean-wind-llc-marine-site-characterization-surveys-new-jersey*).

Detailed Description of the Activity

A detailed description of the marine site characterization survey activities for which incidental take is proposed here may be found in the **Federal Register** notice of the proposed IHA (86 FR 17783; April 06, 2021) for the initial authorization. Ocean Wind plans to complete the survey activities analyzed in the initial IHA by the date the IHA expires (May 09, 2022). The surveys Ocean Wind proposes to conduct under this renewal would be a second year of identical surveys in the same area. The general location and nature of the activities, including the types of equipment planned for use, are identical

to those described in the previous notices. The proposed Renewal IHA would be effective from the date of issuance to May 09, 2023 (one year from the expiration of the initial IHA).

Description of Marine Mammals

A description of the marine mammals in the area of the activities for which authorization of take is proposed here, including information on abundance, status, distribution, and hearing, may be found in the **Federal Register** notice of the proposed IHA for the initial authorization (86 FR 17783; April 06, 2021). NMFS has reviewed the preliminary monitoring data from the initial IHA, recent draft Stock Assessment Reports, information on relevant Unusual Mortality Events, and other scientific literature. Newly available information is described below.

The draft 2021 Stock Assessment Reports (SARs, available online at: *www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports*) provide updated information for several stocks. Estimated abundance has increased for the U.S. population of gray seals (from 27,131 (CV=0.19) to 27,300 (CV=0.22)). Abundance estimates have decreased for Risso's dolphins (from 35,493 (CV=0.19 to 35,215 (CV=0.19)) and harbor seals (from 75,834 (CV=0.15) to 61,336 (CV=0.08)). Abundance estimates for North Atlantic right whales have also been updated in the draft 2021 SAR, which states that right whale abundance has decreased from 412 to 368 (95% CI 356–378) individuals (Hayes *et al.,* 2021).

Roberts *et al.* (2021) provided updated modeling methodology (statistical methods for characterizing model uncertainty) with updated monthly densities of North Atlantic right whales since the time of the initial IHA. This model also incorporated additional data from spring 2019 which added transect and sighting data. The new model results slightly increased density estimates for North Atlantic right whales in southern New England, but these results do not meaningfully impact the information supporting exposure estimation in the survey area here.

NMFS has preliminarily determined that neither this nor any other new information affects which species or stocks have the potential to be affected or the pertinent information contained in the supporting documents for the initial IHA.

Potential Effects on Marine Mammals and Their Habitat

A description of the potential effects of the specified activity on marine mammals and their habitat for the activities for which the authorization of take is proposed here may be found in the **Federal Register** notice for the proposed initial IHA (86 FR 17783; April 06, 2021). NMFS has reviewed the preliminary monitoring data from the ongoing survey work under the initial, currently active, IHA, recent draft Stock Assessment Reports, updates to the NARW density model (Roberts *et al.,* 2021), information on relevant Unusual Mortality Events, and other scientific literature, and determined that neither this nor any other new information affects our initial analysis of impacts on marine mammals and their habitat.

Estimated Take

A detailed description of the methods and inputs used to estimate take for the specified activity are found in the notices of the proposed (86 FR 17783; April 06, 2021) and final (86 FR 26465; May 14, 2021) initial IHAs. The acoustic source types, as well as source levels applicable to this renewal authorization, methods of take, and methodology of estimating take remain unchanged from the initial IHA. Accordingly, the stocks taken, type of take (*i.e.,* Level B harassment only), and amount of take remain unchanged from what was previously authorized in the previously issued IHA. The amount of take proposed for authorization in this renewal is indicated below in Table 1.

TABLE 1—TAKE PROPOSED FOR AUTHORIZATION AND PROPORTION OF POPULATION POTENTIALLY AFFECTED

Species	Abundance estimate [1]	Takes by Level B harassment	% Population
North Atlantic right whale—*Eubalaena glacialis*	368	9	2.44
Humpback whale—*Megaptera novaeangliae*	1,396	2	0.14
Fin whale—*Balaenoptera physalus*	6,802	6	0.09
Sei whale—*Balaenoptera borealis*	6,292	1	0.02
Minke whale—*Balaenoptera acutorostrata*	21,968	2	0.01
Sperm whale—*Physeter macrocephalus*	4,349	3	0.07
Long-finned pilot whale—*Globicephala melas*	39,215	2	0.01
Common bottlenose dolphin (offshore)—*Tursiops truncatus*	62,851	262	0.42
Common bottlenose dolphin (migratory)—*Tursiops truncatus*	6,639	1,410	21.24
Short-finned pilot whale—*Globicephala macrorhynchus*	28,924	2	0.01
Atlantic white-sided dolphin—*Lagenorhynchus acutus*	93,233	16	0.02
Atlantic spotted dolphin—*Stenella frontalis*	39,921	3	0.01
Risso's dolphin—*Stenella frontalis*	35,215	30	0.09
Common dolphin—*Delphinus delphis*	172,974	124	0.07
Harbor porpoise—*Phocoena phocoena*	95,543	91	0.10
Harbor seal—*Phoca vitulina*	61,336	11	0.02
Gray seal—*Halichoerus grypus*	451,431	11	0.00

W.N.A. = Western North Atlantic.

[1] Abundance estimates have been updated from the initial IHA (86 FR 26465; May 14, 2021) using the 2021 Draft SARs (Hayes *et al.,* 2021).

Description of Proposed Mitigation, Monitoring and Reporting Measures

The proposed mitigation, monitoring, and reporting measures included as requirements in this authorization are identical to those included in the **Federal Register** notice announcing the issuance of the initial IHA (86 FR 26465; May 14, 2021), and the discussion of the least practicable adverse impact included in that document remains applicable. All mitigation, monitoring and reporting measures in the initial IHA are carried over to this proposed Renewal IHA and summarized below.

- *Exclusion Zones (EZ):* Marine mammal EZs would be established around the HRG survey equipment and

monitored by PSOs during marine site characterization surveys as follows: A 500-m EZ for North Atlantic right whales during use of all acoustic sources, and a 100-m EZ for all other marine mammals during use of impulsive acoustic sources (*e.g.,* boomers and/or sparkers).

- *Ramp-up:* A ramp-up procedure would be used for HRG equipment capable of adjusting energy levels at the start or re-start of survey activities.
- *Shutdown of HRG Equipment:* If an HRG source is active and a marine mammal is observed within or entering a relevant EZ (as described above), an immediate shutdown of the HRG survey equipment would be required. If a species for which authorization has not been granted, or, a species for which authorization has been granted but the authorized number of takes have been met, approaches or is observed within the Level B harassment zone (48 m, non-impulsive; 141 m impulsive), shutdown would occur.
- *Vessel strike avoidance measures:* Vessel strike measures include, but are not limited to, separation distances for large whales (500 m North Atlantic right whales, 100 m other large whales; 50 m other cetaceans and pinnipeds), restricted vessel speeds, and operational maneuvers.
- *Protected Species Observers (PSOs):* A minimum of one NMFS-approved PSO would be on duty and conducting visual observations at all times during daylight hours (*i.e.,* from 30 minutes prior to sunrise through 30 minutes following sunset) and two active duty PSOs will be on watch during all nighttime operations.
- *Reporting:* Ocean Wind would submit a final technical report within 90 days following completion of the surveys. In the event that Ocean Wind personnel discover an injured or dead marine mammal, Ocean Wind shall report the incident to the Office of Protected Resources (OPR), NMFS and to the New England/Mid-Atlantic Regional Stranding Coordinator through the NOAA Fisheries Marine Mammal and Sea Turtle Stranding and Entanglement Hotline as soon as feasible. In the event of a ship strike of a marine mammal by any vessel involved in the activities covered by the authorization, Ocean Wind shall report the incident immediately to OPR, NMFS and to the New England/Mid-Atlantic Regional Stranding Coordinator through the NOAA Fisheries Marine Mammal and Sea Turtle Stranding and Entanglement Hotline.

Comments and Responses

As noted previously, NMFS published a notice of a proposed IHA (86 FR 17783; April 06, 2021) and solicited public comments on both our proposal to issue the initial IHA for marine site characterization surveys and on the potential for a Renewal IHA, should certain requirements be met.

During the 30-day comment period, NMFS did not receive any substantive public comments on the proposed IHA (86 FR 17783; April 06, 2021). However, NMFS was later notified that a group of environmental non-governmental organizations (ENGOs) had submitted a comment letter during the comment period for the proposed initial IHA. NMFS did not receive that letter prior to issuance of the initial IHA due to an email quarantine issue. Below, we describe how we have addressed, with updated information where appropriate, any comments contained in that letter that specifically pertain to the Renewal of the 2021 IHA.

Comment: The commenters objected to NMFS' process to consider extending any 1-year IHA with a truncated 15-day comment period as contrary to the MMPA.

Response: NMFS' IHA Renewal process meets all statutory requirements. All IHAs issued, whether an initial IHA or a Renewal IHA, are valid for a period of not more than 1 year. And the public has at least 30 days to comment on all proposed IHAs, with a cumulative total of 45 days for IHA Renewals. As noted above, the Request for Public Comments section in the initial IHA made clear that the agency was seeking comment on both the initial proposed IHA and the potential issuance of a Renewal for this project. Because any Renewal (as explained in the Request for Public Comments section in the initial IHA) is limited to another year of identical or nearly identical activities in the same location (as described in the Description of Proposed Activity section in the initial IHA) or the same activities that were not completed within the one-year period of the initial IHA, reviewers have the information needed to effectively comment on both the immediate proposed IHA and a possible 1-year Renewal, should the IHA holder choose to request one.

While there are additional documents submitted with a Renewal request, for a qualifying Renewal these are limited to documentation that NMFS will make available and use to verify that the activities are identical to those in the initial IHA, are nearly identical such that the changes would have either no effect on impacts to marine mammals or decrease those impacts, or are a subset of activities already analyzed and authorized but not completed under the initial IHA. NMFS will also confirm, among other things, that the activities will occur in the same location; involve the same species and stocks; provide for continuation of the same mitigation, monitoring, and reporting requirements; and that no new information has been received that would alter the prior analysis. The renewal request also contains a preliminary monitoring report, but that is to verify that effects from the activities do not indicate impacts of a scale or nature not previously analyzed. The additional 15-day public comment period provides the public an opportunity to review these few documents, provide any additional pertinent information and comment on whether they think the criteria for a renewal have been met. NMFS also will provide direct notice of the proposed Renewal to those who commented on the initial IHA, to provide an opportunity to submit any additional comments. Between the initial 30-day comment period on these same activities and the additional 15 days, the total comment period for a renewal is 45 days.

In addition to the IHA Renewal process being consistent with all requirements under section 101(a)(5)(D), it is also consistent with Congress's intent for issuance of IHAs to the extent reflected in statements in the legislative history of the MMPA. Through the provision for Renewals in the regulations, description of the process and express invitation to comment on specific potential Renewals in the Request for Public Comments section of each proposed IHA, the description of the process on NMFS' website, further elaboration on the process through responses to comments such as these, posting of substantive documents on the agency's website, and provision of 30 or 45 days for public review and comment on all proposed initial IHAs and Renewals respectively, NMFS has ensured that the public ''is invited and encouraged to participate fully in the agency decision-making process.''

For more information, NMFS has published a description of the Renewal process on our website (available at *www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-harassment-authorization-renewals*).

Preliminary Determinations

The survey activities proposed by Ocean Wind are identical to those analyzed in the initial IHA, including the planned number of days and general

location of activity (*i.e.,* OCS–A 0498 and OCS–A 0532), as are the method of taking and the effects of the action. Therefore, the amount of take proposed for authorization is unchanged from that authorized in the initial IHA. The potential effects of Ocean Wind's activities remain limited to Level B harassment in the form of behavioral disturbance. No serious injury or mortality of marine mammal is anticipated. In analyzing the effects of the activities in the initial IHA, NMFS determined that Ocean Wind's activities would have a negligible impact on the affected species or stocks and that the authorized take numbers of each species or stock were small relative to the relevant stocks (*e.g.,* less than one-third of the abundance of all stocks). The proposed mitigation measures and monitoring and reporting requirements as described above are identical to the initial IHA.

NMFS has preliminarily concluded that there is no new information suggesting that our analysis or findings should change from those reached for the initial IHA. Based on the information and analysis contained here and in the referenced documents, NMFS has preliminarily determined the following: (1) The proposed mitigation measures will affect the least practicable impact on marine mammal species or stocks and their habitat; (2) the proposed authorized takes will have a negligible impact on the affected marine mammal species or stocks; (3) the proposed authorized takes represent small numbers of marine mammals relative to the affected stock abundances; (4) Ocean Wind activities would not have an unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by this action, and; (5) appropriate monitoring and reporting requirements are proposed for inclusion.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (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, in this case with the NMFS Greater Atlantic Regional Fisheries Office (GARFO), whenever we propose to authorize take for endangered or threatened species.

The NMFS Office of Protected Resources is proposing to authorize the incidental take of four species of marine mammals that are listed under the ESA: The North Atlantic right, fin, sei and sperm whales. We requested initiation of consultation under Section 7 of the ESA with NMFS GARFO on February 04, 2021, for the issuance of the initial IHA. NMFS GARFO determined that issuance of the IHA to Ocean Wind is not likely to adversely affect the North Atlantic right, fin, sei, and sperm whale or the critical habitat of any ESA-listed species or result in the take of any marine mammals in violation of the ESA, and at this time considered the potential for a renewal. The proposed Renewal IHA provides no new information about the effects of the action, nor does it change the extent of effects of the action, or any other basis to require re-initiation of the Opinion; therefore, the incidental take statement issued for the initial IHA remains valid.

Proposed Renewal IHA and Request for Public Comment

As a result of these preliminary determinations, NMFS proposes to issue a Renewal IHA to Ocean Wind for conducting marine site characterization surveys offshore of New Jersey and along potential submarine cable routes to a landfall location in New Jersey, provided the previously described mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed and final initial IHA can be found at *www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act*. We request comment on our analyses, the proposed Renewal IHA, and any other aspect of this Notice. Please include with your comments any supporting data or literature citations to help inform our final decision on the request for MMPA authorization.

Dated: April 6, 2022.

Angela Somma,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–07715 Filed 4–8–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB881]

Fisheries of the Gulf of Mexico; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 74 Data Workshop for Gulf of Mexico Red Snapper.

SUMMARY: The SEDAR 74 assessment process of Gulf of Mexico red snapper will consist of a Data Workshop, and a series of assessment webinars, and a Review Workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 74 Data Workshop will be held from 1 p.m. on May 2, 2022, until 1 p.m. on May 6, 2022. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice.

ADDRESSES:

Meeting address: The SEDAR 74 Data Workshop will be held at the Courtyard Gulfport Beachfront, 1600 E. Beach Blvd., Gulfport, MS 39501; phone: (228) 858–6652.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571–4366; email: *Julie.neer@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data/Assessment Workshop, and (2) a series of webinars. The product of the Data/Assessment Workshop is a report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses, and describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency

representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the Data Workshop are as follows:

1. An assessment data set and associated documentation will be developed during the workshop.

2. Participants will evaluate proposed data and select appropriate sources for providing information on life history characteristics, catch statistics, discard estimates, length and age composition, and fishery dependent and fishery independent measures of stock abundance.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 6, 2022.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–07693 Filed 4–8–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB835]

Endangered and Threatened Species; Take of Anadromous Fish

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability; of a proposed evaluation for a Tribal Resource Management Plan and request for comment.

SUMMARY: Notice is hereby given that the Northwest Indian Fisheries Commission (NWIFC) has submitted a Tribal Resource Management Plan (Tribal Plan) for NMFS to evaluate. It was presented by the Bureau of Indian Affairs (BIA) on behalf of the Northwest Indian Tribes; the submission fulfills the Tribes' obligations under the protective regulations promulgated for Puget Sound (PS) Chinook salmon, Hood Canal summer-run (HCS) chum salmon, PS steelhead, and Southern (S) eulachon under the Endangered Species Act (ESA). The Tribal Plan describes research and assessment activities that may affect listed PS Chinook salmon, HCS chum salmon, PS steelhead, and S eulachon in Washington State. The proposed research is intended to increase knowledge of species listed under the Endangered Species Act (ESA) and to help guide management and conservation efforts. NMFS has completed a proposed evaluation of how well the Tribal Plan fulfills ESA criteria, and the Secretary of Commerce (Secretary) is making that proposed evaluation available for public comment.

DATES: Comments or requests for a public hearing on the applications must be received no later than 5 p.m. Pacific standard time on May 11, 2022.

ADDRESSES: Because all West Coast NMFS offices are currently closed, all written comments on the document should be sent by email to *shivonne.nesbit@noaa.gov* (please include the RTID number (XB835) in the subject line of the email). The proposed evaluation available for public comment may be viewed online at: *https://www.fisheries.noaa.gov/action/tribal-resource-management-plan-trump-northwest-indian-fisheries-commission.*

FOR FURTHER INFORMATION CONTACT: Shivonne Nesbit, Portland, OR (Ph: 503–231–6741, email: *shivonne.nesbit@noaa.gov*).

SUPPLEMENTARY INFORMATION:

Species Covered in This Notice

The following listed species are covered in this notice:

Chinook salmon (*Oncorhynchus tshawytscha*): Threatened Puget Sound (PS).

Chum salmon (*O. keta*): Threatened Hood Canal Summer-run (HCS).

Steelhead (*O. mykiss*): Threatened PS.

Eulachon (*Thaleichthys pacificus*): Threatened southern distinct population segment (DPS).

Authority

Under section 4 of the ESA, the Secretary is required to adopt such regulations as he deems necessary and advisable for the conservation of the species listed as threatened. The ESA Tribal 4(d) rule (70 FR 37160; June 28, 2005) states that the ESA section 9 take prohibitions do not apply to Tribal Plans that will not appreciably reduce the likelihood of survival and recovery for the listed species.

The Tribal Plan

The NWIFC—through the BIA and on behalf of the Northwest Indian Tribes—has submitted a Tribal Plan for scientific research and assessment activities within the range of the PS Chinook salmon, HCS chum salmon, PS steelhead, and SDPS eulachon. The Northwest Indian Tribes conduct, independently and in cooperation with other agencies, a variety of research and assessment projects. These projects provide the technical basis for managing fisheries and conserving and restoring salmon stocks and their habitat. The need for an improved understanding of salmonid survival in the freshwater and early marine life stages drives much of the current research. The Tribal Plan includes implementation, monitoring, and evaluation procedures designed to ensure that the research is consistent with the objectives of the ESA. The research activities described in the Tribal Plan would take place over a 5 year period starting in 2022.

As 50 CFR 223.209 requires, the Secretary must determine whether the activities proposed in the Tribal Plan would appreciably reduce the likelihood of survival and recovery for PS Chinook salmon, HCS chum salmon, PS steelhead, and SDPS eulachon. The Secretary must take comments on how NMFS's evaluation of the Tribal Plan fulfills the criteria in 50 CFR 223.209 when making that portion of the determination.

Dated: April 5, 2022.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2022–07661 Filed 4–8–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

U.S. Integrated Ocean Observing System (IOOS®) Advisory Committee Public Meeting

AGENCY: U.S. Integrated Ocean Observing System (IOOS®), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of open meeting.

SUMMARY: Notice is hereby given of a virtual meeting of the U.S. Integrated Ocean Observing System (IOOS®) Advisory Committee (Committee). The meeting is open to the public and an opportunity for oral and written comments will be provided.

DATES: The meeting will be held May 11, 2022, and May 13, 2022. Written public comments should be received by the Designated Federal Official by May 6, 2022.

ADDRESSES: The meeting will be held virtually. To register for the meeting and/or submit public comments, use this link *https://forms.gle/YWmTpTxE7777JVhj8* or email *Laura.Gewain@noaa.gov.* See **SUPPLEMENTARY INFORMATION** for instructions and other information about public participation.

FOR FURTHER INFORMATION CONTACT: Krisa Arzayus, Designated Federal Official, U.S. IOOS Advisory Committee, U.S. IOOS Program, 1315 East-West Highway, Silver Spring, MD 20910; Phone 240–533–9455; Fax 301–713–3281; email *krisa.arzayus@noaa.gov* or visit the U.S. IOOS Advisory Committee website at *http://ioos.noaa.gov/community/u-s-ioos-advisory-committee/.*

SUPPLEMENTARY INFORMATION: The Committee was established by the NOAA Administrator as directed by section 12304 of the Integrated Coastal and Ocean Observation System Act, part of the Omnibus Public Land Management Act of 2009 (Pub. L. 111–11), and reauthorized under the Coordinated Ocean Observations and Research Act of 2020 (Pub. L. 116–271). The Committee advises the NOAA Administrator and the Interagency Ocean Observation Committee (IOOC) on matters related to the responsibilities and authorities set forth in section 12302 of the Integrated Coastal and Ocean Observation System Act of 2009 and other appropriate matters as the Under Secretary refers to the Committee for review and advice.

The Committee will provide advice on:

(a) Administration, operation, management, and maintenance of the Integrated Coastal and Ocean Observation System (the System);

(b) expansion and periodic modernization and upgrade of technology components of the System;

(c) identification of end-user communities, their needs for information provided by the System, and the System's effectiveness in disseminating information to end-user communities and to the general public; and

(d) additional priorities, including—

(1) a national surface current mapping network designed to improve fine scale sea surface mapping using high frequency radar technology and other emerging technologies to address national priorities, including Coast Guard search and rescue operation planning and harmful algal bloom forecasting and detection that—

(i) is comprised of existing high frequency radar and other sea surface current mapping infrastructure operated by national programs and regional coastal observing systems;

(ii) incorporates new high frequency radar assets or other fine scale sea surface mapping technology assets, and other assets needed to fill gaps in coverage on United States coastlines; and

(iii) follows a deployment plan that prioritizes closing gaps in high frequency radar infrastructure in the United States, starting with areas demonstrating significant sea surface current data needs, especially in areas where additional data will improve Coast Guard search and rescue models;

(2) fleet acquisition for unmanned maritime systems for deployment and data integration to fulfill the purposes of this subtitle;

(3) an integrative survey program for application of unmanned maritime systems to the real-time or near real-time collection and transmission of sea floor, water column, and sea surface data on biology, chemistry, geology, physics, and hydrography;

(4) remote sensing and data assimilation to develop new analytical methodologies to assimilate data from the System into hydrodynamic models;

(5) integrated, multi-State monitoring to assess sources, movement, and fate of sediments in coastal regions;

(6) a multi-region marine sound monitoring system to be—

(i) planned in consultation with the IOOC, NOAA on, the Department of the Navy, and academic research institutions; and

(ii) developed, installed, and operated in coordination with NOAA, the Department of the Navy, and academic research institutions; and

(e) any other purpose identified by the Administrator or the Council.

Matters to be considered: The meeting will focus on (1) providing the Committee with programmatic updates from the U.S. IOOS program and the IOOC and (2) presentations and discussion to advance the work plan for the Committee. The latest version of the agenda will be posted at *http://ioos.noaa.gov/community/u-s-ioos-advisory-committee/.* The times and the agenda topics described here are subject to change.

Public Comment Instructions: The meeting will be open to public participation each day (check agenda on website to confirm times). The Committee expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of three (3) minutes. Written comments should be received by the Designated Federal Official by May 6, 2022, to provide sufficient time for Committee review. Written comments received after May 6, 2022, will be distributed to the Committee, but may not be reviewed prior to the meeting date. To submit written comments, please fill out the brief form at *https://forms.gle/YWmTpTxE7777JVhj8* or email your comments, your name as it appears on your driver's license, and the organization/company affiliation you represent to Laura Gewain, *Laura.Gewain@noaa.gov.*

Special accommodations: These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Krisa Arzayus, Designated Federal Official by phone (240–533–9455) or email (*Krisa.Arzayus@noaa.gov*) or to Laura Gewain (*Laura.Gewain@noaa.gov*) by April 27, 2022.

Carl C. Gouldman,

Director, U.S. Integrated Ocean Observing System Office, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2022–07697 Filed 4–8–22; 8:45 am]

BILLING CODE 3510–JE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB945]

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The New England Fishery Management Council's is convening several Scoping Meetings for Limited

Access Leasing in the Atlantic Sea Scallop Fishery to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: These meetings and webinars will be held between the dates of Wednesday, April 27, 2022 and Friday, June 24, 2022. See **SUPPLEMENTARY INFORMATION** for more details on specific dates and times.

ADDRESSES: *Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

1. *Wednesday, April 27, 2022, from 5 p.m.–6:30 p.m.,* Cruiseport, 6 Rowe Square, Gloucester, MA 01930;

2. *Wednesday, May 11, 2022, from 4 p.m.–6 p.m.,* Whaling Museum, 18 Johnny Cake Hill, New Bedford, MA 02740;

3. *Thursday, May 19, 2022, from 5 p.m.–7 p.m.,* Holiday Inn, 151 Route 72 West, Manahawkin, NJ 08050;

4. *Wednesday, May 25, 2022, from 4 p.m.–6 p.m.,* Whaling Museum, 18 Johnny Cake Hill, New Bedford, MA 02740;

5. *Thursday, May 26, 2022, from 10 a.m.–12 p.m.,* Superior Trawl Conference Room, 55 State Street, Narragansett, RI 02882;

6. *Wednesday, June 1, 2022, from 5 p.m.–7 p.m.,* DoubleTree River Front, 100 Middle Street, New Bern, NC 28560;

7. *Thursday, June 2, 2022, from 5 p.m.–7 p.m.,* Embassy Suites, 1700 Coliseum Drive, Hampton, VA 23666;

8. *Friday, June 17, 2022, from 1 p.m.–2:30 p.m.,* via webinar. Please register for the webinar here *https://attendee.gotowebinar.com/register/1197227847196646414; and*

9. *Friday, June 24, 2022, from 10 a.m.—12 p.m.,* via webinar. Please register for the webinar here *https://attendee.gotowebinar.com/register/7661183039612723725.*

Public comments: Public comment deadline is 8 a.m. EST on July 5, 2022. Mail to Thomas A. Nies, Executive Director, New England Fishery Management Council, 50 Water Street, Mill #2, Newburyport, MA 01950. Mark the outside of the envelope ''Atlantic Sea Scallop Limited Access Leasing Scoping Comments''. Comments may also be sent via fax to 978–465–3116 or submitted via email to *comments@nefmc.org* with ''Atlantic Sea Scallop Limited Access Leasing Scoping Comments'' in the subject line.

Agenda

Council staff will brief the public on Limited Access Leasing before receiving comments. The hearing will begin promptly at the time indicated above. If all attendees who wish to do so have provided their comments prior to the end time indicated, the hearing may conclude early. To the extent possible, the Council may extend hearings beyond the end time indicated above to accommodate all attendees who wish to speak.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 6, 2022.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–07694 Filed 4–8–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–OS–0042]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency'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 information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by June 10, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Human Resources Activity, 4800 Mark Center Drive, Suite 08F05, Alexandria, VA 22350, LaTarsha Yeargins, 571–372–2089.

SUPPLEMENTARY INFORMATION: In March 2019, Acting Secretary of Defense, Patrick Shanahan, requested the DoD to form a team of experts to ''take a fresh look'' at issues involving the sexual assault investigative and accountability process. The DoD established the Sexual Assault Accountability and Investigation Task Force (SAAITF) to identify, evaluate, and make

recommendations to improve the investigation and accountability process. As part of this effort, the 2019 SAAITF report called for a ''standardized survey of victim experiences, attitudes, and satisfaction.'' The Sexual Violence Support and Experiences Study (SVSES) meets this requirement and will allow the DoD Sexual Assault Prevention and Response Office (SAPRO), other DoD policy offices, and the military Services to use the input of military members to inform improvements to the response system and to address challenges military members face during the military investigation and accountability process.

Title; Associated Form; and OMB Number: Sexual Violence Support and Experience Study; OMB Control Number 0704–SVSS.

Needs and Uses: Information from the SVSES will be used by the OUSD(P&R) policy offices, and the Military Departments to improve personnel policies, programs, practices, and trainings related to sexual assault response and accountability systems in the military. It will provide the policy offices of the OUSD(P&R) with current data on (1) Service member satisfaction with sexual assault support resources; (2) the impact that the military support and justice processes have on Services members who experience sexual assault during military service (*e.g.,* their psychological health and well-being); and (3) aspects of the military support and justice process that relate to retention intention, career progression, and separation from military service.

Any Service member (Active or Reserve component) who has experienced sexual assault since joining the military will be eligible to participate in the study. Recruitment for the SVSES will include proactive outreach to Service members who previously filed an unrestricted report for sexual assault and Service members who requested to learn more about the study. The Office of People Analytics (OPA) will administer the SVSES via the web. The survey will be administered online via proprietary software developed by OPA's operations contractor. To reduce respondent burden, these online surveys will use ''smart skip'' technology to ensure respondents only answer questions that are applicable to them.

The study will not produce generalizable statistics or findings; rather, it will inform policy and program offices within the DoD about Service member satisfaction with sexual assault response resources and processes and the sexual assault accountability system. OPA will provide interim reports regarding the findings of the study to OUSD(P&R) policy offices on a biannual basis and a full report on a biennial basis. Data from the SVSES will also be used in future analyses.

Affected Public: Individuals or households.

Annual Burden Hours: 300.

Number of Respondents: 300.

Responses per Respondent: 4.

Annual Responses: 1,200.

Average Burden per Response: 15 minutes.

Frequency: Quarterly.

Dated: April 4, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–07704 Filed 4–8–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–OS–0041]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency'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 information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by June 10, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Department of Defense Education Activity, Research, Accountability & Evaluation Division, ATTN: Research Requests, 4800 Mark Center Drive, Alexandria, VA 22350–1400, Sam Gotti, 571–372–1891.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Department of Defense Education Activity Research Request Program; DoDEA Form 1304.01–F1; OMB Control Number 0704–0457.

Needs and Uses: The Department of Defense Education Activity (DoDEA) Research Study Request form is administered annually and is used to conduct research involving DoDEA schools, teachers, principals, students, and parents. DoDEA receives requests from researchers both internal to DoDEA as well as outside the Federal government or DoD, to conduct research studies in DoDEA schools and districts. This information collection is needed to aid in the systematic and consistent collection of information on proposed research in accordance with guidelines established in DoDEA Administrative Instruction 1304.01, ''Research Request Program.''

Affected Public: Individuals or households.

Annual Burden Hours: 50 hours.

Number of Respondents: 50.

Responses per Respondent: 1.

Annual Responses: 50.

Average Burden per Response: 1 hour.

Frequency: Annual.

Dated: April 4, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–07707 Filed 4–8–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2022–OS–0010]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)), Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by May 11, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela Duncan, 571–372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Armed Forces Workplace and Equal Opportunity Survey; OMB Control Number 0704–WEOS.

Type of Request: Regular.

Number of Respondents: 62,100.

Responses per Respondent: 1.

Annual Responses: 62,100.

Average Burden per Response: 30 minutes.

Annual Burden Hours: 31,050 hours.

Needs and Uses: The statutory requirements direct the DoD to conduct surveys to solicit information on racial and ethnic issues, including issues relating to harassment, discrimination, and the climate in the Armed Forces for forming professional relationships among members of various racial and ethnic groups. Specifically, surveys conducted under Title 10 U.S.C. 481 shall be conducted to solicit information on the following:

- Indicators of positive and negative trends for professional and personal relationships among members of all racial and ethnic groups.
- The effectiveness of DoD policies designed to improve relationships among all racial and ethnic groups.
- The effectiveness of current processes for complaints on, and investigations into, racial and ethnic discrimination.

Moreover, in the 2020 National Defense Authorization Act (NDAA) as modified by the 2021 NDAA, the DoD was further directed to conduct a survey to assess whether or not military members witnessed or experienced extremism in their workplace, as well as whether or not those experiences were reported. To reduce survey burden, the Department identified the Workplace and Equal Opportunity (WEO) survey as the most appropriate existing survey vehicle to collect this information. As such, the 2022 WEO survey will be the first survey to collect and report on this new statutory requirement. Prior to including the new exposure to extremism metric on the 2022 WEO, the Department engaged in a year-long robust metric development and validation study to ensure results are collected consistently, and also to ensure results accurately measure the experiences required by law and IAW DoDI 1325.06 which define prohibited extremist activities for military members. The statutory and policy requirements for the WEO can be found in the following:

- FY03 NDAA
- FY20 NDAA, Section 593
- FY21 NDAA, Section 553
- 10 U.S.C., Section 481
- 10 U.S.C., Section 136
- 10 U.S.C., Section 1782
- 10 U.S.C., Section 2358
- DoD Instruction (DoDI) 1100.13, ''Surveys of DoD Personnel''
- DoD Instruction (DoDI) 1350.02, ''DoD Military Equal Opportunity Program''
- Immediate Actions to Improve Diversity & Inclusion (Esper, 2020)

Overall, the results of the survey will assess progress, identify shortfalls, and revise policies and programs as needed, related to issues directly affecting military members. Data from this survey will be presented to the OUSD(P&R), Congress, and DoD policy and program offices to assess and improve policies, programs, practices, and training related to racial/ethnic relations in the Armed Forces informed by current and statistically reliable information. Analysis will include the Office of People Analytics' standard products: An executive report highlighting key findings, a trends/tabulations report (a set of relative frequency distributions of each question, and cross-tabulations of survey questions by key stratifying variables), briefing slides, and a statistical methodology report. Ad hoc analyses requested by the policy office sponsors and other approved organizations may be conducted and published as needed and based on available staff.

Affected Public: Individuals or households.

Frequency: Biennially.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: April 4, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–07703 Filed 4–8–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2022–SCC–0007]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Streamlined Clearance Process for Discretionary Grants

AGENCY: Office of the Secretary (OS), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension without change of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before May 11, 2022.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information

collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox. Comments may also be sent to *ICDocketmgr@ed.gov.*

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Alfreida Pettiford, 202–453–7718.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Streamlined Clearance Process for Discretionary Grants.

OMB Control Number: 1894–0001.

Type of Review: An extension without change of a currently approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 1.

Total Estimated Number of Annual Burden Hours: 3.

Abstract: Section 3505(a)(2) of the PRA of 1995 provides the OMB Director authority to approve the streamlined clearance process proposed in this information collection request. This information collection request was originally approved by OMB in January of 1997. This information collection streamlines the clearance process for all discretionary grant information collections which do not fit the generic application process. The streamlined clearance process continues to reduce the clearance time for the U.S. Department of Education's (ED's) discretionary grant information collections by two months or 60 days. This is desirable for two major reasons: It would allow ED to provide better customer service to grant applicants and help meet ED's goal for timely awards of discretionary grants. § 3474.20(d) adds the requirement for grantees to develop a dissemination plan for copyrighted work under open licensing. Information contained in the narrative of an application will be captured in the Evidence of Effectiveness Form.

Dated: April 6, 2022.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–07691 Filed 4–8–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board Chairs

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) Chairs. The Federal Advisory Committee Act requires that public notice of this online virtual meeting be announced in the **Federal Register**.

DATES: Tuesday, May 3, 2022; 1:00 p.m.–5:00 p.m. CDT; Wednesday, May 4, 2022; 10:00 a.m.–3:00 p.m. CDT.

ADDRESSES: This hybrid meeting will be open to the public in-person and virtually (observation only). To attend, please contact Alyssa Harris by email, *Alyssa.Harris@em.doe.gov,* no later than 5:00 p.m. EDT on Monday, April 25, 2022.

Those participating in-person will meet at: The Carson Center—Myre River Room, 100 Kentucky Avenue, Paducah, KY 42003.

FOR FURTHER INFORMATION CONTACT: Alyssa Harris, EM SSAB Federal Coordinator. U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585. Email: *Alyssa.Harris@em.doe.gov.* Telephone: (202) 586–7627.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda Topics

Tuesday, May 3, 2022

- EM Program Update
- Chairs Round Robin
- Public Comment
- EM SSAB Recommendation Status
- Administration Priorities Presentation
- Board Business/Open Discussion

Wednesday, May 4, 2022

- Office of Technology Development Overview
- Budget Update
- Public Comment
- Board Business/Open Discussion

Public Participation: The meeting is open to the public in-person and virtually. To provide a safe meeting environment with social distancing, seating may be limited; attendees should register for attendance by sending an email to *Alyssa.Harris@em.doe.gov* no later than 5:00 p.m. ET on Wednesday, April 27, 2022. The EM SSAB 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 note this when registering. Public comments will be accepted during the meeting for in-person participants and via email for virtual participants prior to and after the meeting. Comments received in writing no later than 5:00 p.m. EDT on Wednesday, April 27, 2022 will be read aloud during the meeting. Comments will also be accepted after the meeting by no later than 5:00 p.m. EDT on Wednesday, May 11, 2022 to be included in the official meeting record. Please send comments to Alyssa Harris at *Alyssa.Harris@em.doe.gov.* The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business.

Minutes: Minutes will also be available at the following website: *https://energy.gov/em/listings/chairs-meetings.*

Signed in Washington, DC, on April 5, 2022.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2022–07564 Filed 4–8–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[Case Number 2022–002, EERE–2017–BT–WAV–0027]

Energy Conservation Program: Extension of Interim Waiver to AHT Cooling Systems GmbH and AHT Cooling Systems USA Inc. From the Department of Energy Commercial Refrigerator, Freezer, and Refrigerator-Freezer Test Procedure

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

ACTION: Notification of extension of interim waiver.

SUMMARY: The U.S. Department of Energy (''DOE'') is granting an interim waiver extension (Case No. 2022–002) to AHT Cooling Systems GmbH and AHT Cooling Systems USA Inc. (''AHT'') from specified portions of the DOE Commercial Refrigerators, Freezers, and Refrigerator-Freezers (collectively ''commercial refrigeration equipment'' or ''CRE'') test procedure for determining the energy consumption of the specified AHT CRE basic models. Under this extension, AHT is required to test and rate the specified basic models in accordance with the alternate test procedure specified in the interim waiver.

DATES: The Extension of Interim Waiver is effective on April 11, 2022.

FOR FURTHER INFORMATION CONTACT:

Ms. Julia Hegarty, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Email: *AS_Waiver_Requests@ee.doe.gov.*

Mr. Pete Cochran, U.S. Department of Energy, Office of the General Counsel, Mail Stop GC–33, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585–0103. Telephone: (202) 586–9496. Email: *peter.cochran@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: In accordance with Title 10 of the Code of Federal Regulations (10 CFR 431.401(g)), DOE gives notice of the issuance of an Extension of Interim Waiver as set forth below. The Extension of Interim Waiver extends the Interim Waiver granted to AHT on May 26, 2017 (82 FR 24330, ''May 2017 Interim Waiver'') to include the AHT basic models specified in this interim waiver extension, as requested by AHT on January 20, 2022.[1] AHT must test and rate the specifically identified CRE basic models in accordance with the alternate test procedure specified in the May 2017 Interim Waiver. AHT's representations concerning the energy consumption of the specified basic models must be based on testing according to the provisions and restrictions in the alternate test procedure set forth in the May 2017 Interim Waiver, and the representations must fairly disclose the test results. Distributors, retailers, and private labelers are held to the same requirements when making representations regarding the energy consumption of this equipment. (42 U.S.C. 6314(d))

DOE makes decisions on waiver extensions, including interim waiver extensions, for only those basic models specifically set out in the request, not future models that may be manufactured by the petitioner. AHT may submit a new or amended petition for waiver and request for grant of interim waiver, as appropriate, for additional basic models of CRE. Alternatively, if appropriate, AHT may request that DOE extend the scope of a waiver or interim waiver to include additional basic models employing the same technology as the basic models set forth in the original petition consistent with 10 CFR 431.401(g).

Case Number 2020–023

Extension of Interim Waiver

I. Background and Authority

The Energy Policy and Conservation Act, as amended (''EPCA''),[1] authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part C[2] of EPCA established the Energy Conservation Program for Certain Industrial Equipment, which sets forth a variety of provisions designed to improve energy efficiency for certain types of industrial equipment. This equipment includes Commercial Refrigerators, Freezers, and Refrigerator-Freezers (collectively ''commercial refrigeration equipment'' or ''CRE''), the focus of this document. (42 U.S.C. 6311(1)(E))

The energy conservation program under EPCA consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA include definitions (42 U.S.C. 6311), energy conservation standards (42 U.S.C. 6313), test procedures (42 U.S.C. 6314), labeling provisions (42 U.S.C. 6315), and the authority to require information and reports from manufacturers (42 U.S.C. 6316).

The Federal testing requirements consist of test procedures that manufacturers of covered equipment must use as the basis for: (1) Certifying to DOE that their equipment complies with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6316(a); 42 U.S.C. 6295(s)), and (2) making representations about the efficiency of that equipment (42 U.S.C. 6314(d)). Similarly, DOE must use these test procedures to determine whether the equipment complies with relevant standards promulgated under EPCA. (42 U.S.C. 6316(a); 42 U.S.C. 6295(s))

Under 42 U.S.C. 6314, EPCA sets forth the criteria and procedures DOE is required to follow when prescribing or amending test procedures for covered equipment. EPCA requires that any test procedures prescribed or amended under this section must be reasonably designed to produce test results which reflect the energy efficiency, energy use or estimated annual operating cost of covered equipment during a representative average use cycle and requires that test procedures not be unduly burdensome to conduct. (42 U.S.C. 6314(a)(2)) The test procedure for CRE is contained in 10 CFR part 431, subpart C, appendix B—*Amended Uniform Test Method for the Measurement of Energy Consumption of Commercial Refrigerators, Freezers, and Refrigerator-Freezers* (''Appendix B'').

Any interested person may submit a petition for waiver from DOE's test procedure requirements. 10 CFR 431.401(a)(1). DOE will grant a waiver from the test procedure requirements if DOE determines either that the basic model for which the waiver was requested contains a design characteristic that prevents testing of the basic model according to the prescribed test procedures, or that the prescribed test procedures evaluate the basic model in a manner so unrepresentative of its true energy or water consumption characteristics as to provide materially

[1] AHT's request is available at *https://www.regulations.gov/document/EERE-2017-BT-WAV-0027-0017*. The specified basic models are: IBIZA 145 (U) NAM1–IC, IBIZA 210 (U) NAM1–IC, MALTA 185 (U) NAM1–IC, MANHATTAN XL 210 (U) NAM1–IC, MIAMI 210 (U) NAM1–IC, MIAMI 250 (U) NAM1–IC, MIAMI XL EC 185 (U) NAM1–IC, PARIS 210 (U) NAM1–IC, PARIS EC 185 (U) NAM1–IC, SYDNEY EC 223 (U) NAM1–IC, SYDNEY XL 210 (U) NAM1–IC, IBIZA 145 (U) NAM1–R, IBIZA 210 (U) NAM1–R, MALTA 185 (U) NAM1–R, MANHATTAN XL 210 (U) NAM1–R, MIAMI 210 (U) NAM1–R, MIAMI 250 (U) NAM1–R, MIAMI XL EC 185 (U) NAM1–R, PARIS 210 (U) NAM1–R, PARIS EC 185 (U) NAM1–R, SYDNEY EC 223 (U) NAM1–R, SYDNEY XL 210 (U) NAM1–R.

[1] All references to EPCA in this document refer to the statute as amended through the Infrastructure Investment and Jobs Act, Public Law 117–58 (Nov. 15, 2021).

[2] For editorial reasons, upon codification in the U.S. Code, Part C was redesignated as Part A–1.

inaccurate comparative data. 10 CFR 431.401(f)(2). DOE may grant the waiver subject to conditions, including adherence to alternate test procedures. *Id.*

A petitioner may request that DOE extend the scope of a waiver or an interim waiver to include additional basic models employing the same technology as the basic model(s) set forth in the original petition. 10 CFR 431.401(g). DOE will publish any such extension in the **Federal Register**. *Id.*

II. Request for an Extension of Interim Waiver: Assertions and Determinations

On May 26, 2017, DOE issued an Interim Waiver in Case Number CR–006 granting AHT an interim waiver to test its AHT basic models specified in that interim waiver using an alternate test procedure. 82 FR 24330 (''May 2017 Interim Waiver'').[3] AHT stated that their basic models defrost less frequently than once every 24 hours. The DOE test procedure, by reference to ANSI/ASHRAE Standard 72–2005, ''Method of Testing Commercial Refrigerators and Freezers'' (''ASHRAE 72–2005''), requires beginning the test period at the start of a defrost cycle and recording data for 24 hours. AHT stated that the DOE test procedure would overstate the energy usage from the defrosting function. 82 FR 24330, 24335.

Based on its review, including the information provided by AHT, DOE initially determined that the current test procedure at Appendix B would evaluate the CRE basic models specified in the May 2017 Interim Waiver in a manner so unrepresentative of their true energy consumption characteristics as to provide materially inaccurate comparative data. *Id.* at 82 FR 24332–24333. The May 2017 Interim Waiver specifies that AHT must test and rate the subject basic models such that the energy consumption be determined using an equation that incorporates the energy consumption of two modified tests. The first modified test would be a 24-hour test without a defrost cycle starting in steady state conditions with eight hours of door openings. The second modified test would include a defrost cycle starting after steady state conditions are established and continuing until the defrost cycle recovery is complete. *Id.* at 82 FR 24333.

On January 20, 2022, AHT submitted a request to extend the scope of the interim waiver, Case Number 2022–002, to the specified additional AHT basic models.[4] AHT stated that these basic models have the same characteristics as the models covered by the existing interim waiver.

DOE has reviewed AHT's interim waiver extension request and operating instructions for the subject basic models and determined that the CRE basic models identified in AHT's request incorporate the same design characteristics as those basic models covered under the interim waiver in Case Number CR–006 such that the test procedure evaluates these basic models in a manner that is unrepresentative of their actual energy use. For the same reasons set forth in the May 2017 Interim Waiver, DOE understands that the model lines identified in AHT's request are not capable of defrosting once every 24 hours as simulated by the DOE test procedure. *See* 82 FR 24330, 24332–24333. Accordingly, DOE is extending the interim waiver in Case Number CR–006 to the CRE basic models identified by AHT in its interim waiver extension request.

III. Order

After careful consideration of all the material submitted by AHT in this matter, it is *ordered* that:

(1) AHT must, as of the date of publication of this Extension of Interim Waiver in the **Federal Register**, test and rate the following AHT brand commercial refrigerator and commercial ice-cream freezer basic models with the alternate test procedure as set forth in paragraph (2):

Brand	Basic model
AHT ..	IBIZA 145 (U) NAM1–IC.
AHT ..	IBIZA 210 (U) NAM1–IC.
AHT ..	MALTA 185 (U) NAM1–IC.
AHT ..	MANHATTAN XL 210 (U) NAM1–IC.
AHT ..	MIAMI 210 (U) NAM1–IC.
AHT ..	MIAMI 250 (U) NAM1–IC.
AHT ..	MIAMI XL EC 185 (U) NAM1–IC.
AHT ..	PARIS 210 (U) NAM1–IC.
AHT ..	PARIS EC 185 (U) NAM1–IC.
AHT ..	SYDNEY EC 223 (U) NAM1–IC.
AHT ..	SYDNEY XL 210 (U) NAM1–IC.
AHT ..	IBIZA 145 (U) NAM1–R.
AHT ..	IBIZA 210 (U) NAM1–R.
AHT ..	MALTA 185 (U) NAM1–R.
AHT ..	MANHATTAN XL 210 (U) NAM1–R.
AHT ..	MIAMI 210 (U) NAM1–R.
AHT ..	MIAMI 250 (U) NAM1–R.
AHT ..	MIAMI XL EC 185 (U) NAM1–R.
AHT ..	PARIS 210 (U) NAM1–R.
AHT ..	PARIS EC 185 (U) NAM1–R.
AHT ..	SYDNEY EC 223 (U) NAM1–R.
AHT ..	SYDNEY XL 210 (U) NAM1–R.

(2) The alternate test procedure for the AHT basic models referenced in paragraph (1) of this Order is the test procedure for CRE prescribed by DOE at 10 CFR part 431, subpart C, appendix B, except the test period shall be selected as follows:

The first part of the test shall be a 24-hour test starting in steady-state conditions and including eight hours of door opening (according to ASHRAE Standard 72). The energy consumed in this test, $ET1$, shall be recorded.

The second part of the test shall be a defrost cycle, including any operation associated with a defrost. The start and end points of the defrost cycle test period shall be determined according to the instructions for consumer refrigerators and refrigerator-freezers outlined in 10 CFR part 430, subpart B, appendix A, section 4.2.1.1 (for cycling compressor systems) or section 4.2.1.2 (for non-cycling compressor systems). The energy consumed in this test, $ET2$, and duration, t_{DI}, shall be recorded.

Based on the measured energy consumption in these two tests, the daily energy consumption (DEC) in kWh shall be calculated as:

[3] In the May 2017 Interim Waiver DOE declined to grant AHT an interim waiver as it pertained to AHT's petition regarding multi-mode operation. 82 FR 24330, 24332. That denial is not relevant to AHT's request for an extension or this Order extending the interim waiver granted in the May 2017 Interim Waiver.

[4] The specified basic models are: IBIZA 145 (U) NAM1–IC, IBIZA 210 (U) NAM1–IC, MALTA 185 (U) NAM1–IC, MANHATTAN XL 210 (U) NAM1–IC, MIAMI 210 (U) NAM1–IC, MIAMI 250 (U) NAM1–IC, MIAMI XL EC 185 (U) NAM1–IC, PARIS 210 (U) NAM1–IC, PARIS EC 185 (U) NAM1–IC, SYDNEY EC 223 (U) NAM1–IC, SYDNEY XL 210 (U) NAM1–IC, IBIZA 145 (U) NAM1–R, IBIZA 210 (U) NAM1–R, MALTA 185 (U) NAM1–R, MANHATTAN XL 210 (U) NAM1–R, MIAMI 210 (U) NAM1–R, MIAMI 250 (U) NAM1–R, MIAMI XL EC 185 (U) NAM1–R, PARIS 210 (U) NAM1–R, PARIS EC 185 (U) NAM1–R, SYDNEY EC 223 (U) NAM1–R, SYDNEY XL 210 (U) NAM1–R.

$$DEC = ET1 \times \frac{(1440 - t_{NDI})}{1440} + \frac{ET2}{3.5}$$

and

$$t_{NDI} = \frac{t_{DI}}{3.5}$$

Where:

DEC = daily energy consumption, kWh;
*ET*1 = energy consumed during the first part of the test, in kWh;
*ET*2 = energy consumed during the second part of the test, in kWh;
t_{NDI} = normalized length of defrosting time per day, in minutes;
t_{DI} = length of time of defrosting test period, in minutes;
3.5 = time between defrost occurrences, in days; and
1440 = conversion factor, minutes per day.

(3) *Representations.* AHT may not make representations about the energy use of a basic model listed in paragraph (1) of this Order for compliance, marketing, or other purposes unless that basic model has been tested in accordance with the provisions of paragraph (2) of this Order and such representations fairly disclose the results of such testing.

(4) This Extension of Interim Waiver shall remain in effect according to the provisions of 10 CFR 431.401.

(5) This Extension of Interim Waiver is issued on the condition that the statements, representations, and documentation provided by AHT are valid. If AHT makes any modifications to the defrost controls of these basic models, the interim waiver will no longer be valid and AHT will either be required to use the current Federal test method or submit a new application for a test procedure waiver. DOE may rescind or modify this Extension of Interim Waiver (and/or the underlying Order issued in Case Number CR–006) at any time if it determines the factual basis underlying the petition for extension of interim waiver (and/or the underlying Order issued in Case Number CR–006) is incorrect, or the results from the alternate test procedure are unrepresentative of a basic model's true energy consumption characteristics. 10 CFR 431.401(k)(1). Likewise, AHT may request that DOE rescind or modify the Extension of Interim Waiver (and/or the underlying Order issued in Case Number CR–006) if AHT discovers an error in the information provided to DOE as part of its petition, determines that the interim waiver is no longer needed, or for other appropriate reasons. 10 CFR 431.401(k)(2).

(6) AHT remains obligated to fulfill all applicable requirements set forth at 10 CFR part 429.

Signing Authority

This document of the Department of Energy was signed on April 5, 2022, by Kelly J. Speakes-Backman, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on April 6, 2022.

Treena V. Garrett,

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

[FR Doc. 2022–07665 Filed 4–8–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[Case Number 2022–001, EERE–2017–BT–WAV–0041]

Energy Conservation Program: Extension of Waiver to AHT Cooling Systems GmbH and AHT Cooling Systems USA Inc. From the Department of Energy Commercial Refrigerator, Freezer, and Refrigerator-Freezer Test Procedure

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

ACTION: Notice of decision and order: Extension of waiver.

SUMMARY: The U.S. Department of Energy (''DOE'') gives notice of a Decision and Order (Case No. 2022–001) that grants AHT Cooling Systems GmbH and AHT Cooling Systems USA Inc. (''AHT'') a waiver extension from specified portions of the DOE Commercial Refrigerators, Freezers, and Refrigerator-Freezers (collectively ''commercial refrigeration equipment'' or ''CRE'') test procedure for determining the energy consumption of the specified AHT CRE basic models. AHT is required to test and rate the specified basic models in accordance with the alternate test procedure specified in this Decision and Order.

DATES: The Decision and Order is effective on April 11, 2022. The Decision and Order will terminate upon the compliance date of any future amendment to the test procedure for CRE located in 10 CFR part 431, subpart C, appendix B that addresses the issues presented in this waiver. At such time, AHT must use the relevant test procedure for the specified basic models of CRE for any testing to demonstrate compliance with standards, and any other representations of energy use.

FOR FURTHER INFORMATION CONTACT:

Ms. Julia Hegarty, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Email: *AS_Waiver_Requests@ee.doe.gov*.

Mr. Pete Cochran, U.S. Department of Energy, Office of the General Counsel, Mail Stop GC–33, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585–0103. Telephone: (202) 586–9496. Email: *peter.cochran@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: In accordance with Title 10 of the Code of Federal Regulations (10 CFR 431.401(g)), DOE gives notice of the Decision and Order as set forth below. The Decision and Order extends the waiver that was granted to AHT on October 30, 2018 (83 FR 54581, ''October 2018 Decision and Order'') to include the AHT basic models specified in this waiver, as requested by AHT on January 20, 2022.[1] AHT must test and

[1] AHT's request is available at *https://www.regulations.gov/docket?D=EERE-2017-BT-WAV-0041*. The specified basic models are: IBIZA 145 (U) NAM1–F, IBIZA 210 (U) NAM1–F, MALTA

Continued

rate the specifically identified CRE basic models in accordance with the alternate test procedure specified in the Decision and Order. AHT's representations concerning the energy consumption of the specified basic models must be based on testing according to the provisions and restrictions in the alternate test procedure set forth in the Decision and Order, and the representations must fairly disclose the test results. Distributors, retailers, and private labelers are held to the same requirements when making representations regarding the energy consumption of this equipment. (42 U.S.C. 6314(d))

DOE makes decisions on waiver extensions for only those basic models specifically set out in the request, not future models that may be manufactured by the petitioner. AHT may submit a new or amended petition for waiver and request for grant of interim waiver, as appropriate, for additional basic models of CRE. Alternatively, if appropriate, AHT may request that DOE extend the scope of a waiver to include additional basic models employing the same technology as the basic models set forth in the original petition consistent with 10 CFR 431.401(g).

Case Number 2020–025

Extension of Waiver

I. Background and Authority

The Energy Policy and Conservation Act, as amended (''EPCA''),[1] authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part C [2] of EPCA established the Energy Conservation Program for Certain Industrial Equipment, which sets forth a variety of provisions designed to improve energy efficiency for certain types of industrial equipment. This equipment includes Commercial Refrigerators, Freezers, and Refrigerator-Freezers (collectively ''commercial refrigeration equipment'' or ''CRE''), the focus of this document. (42 U.S.C. 6311(1)(E))

Under 42 U.S.C. 6314, EPCA sets forth the criteria and procedures DOE is required to follow when prescribing or amending test procedures for covered equipment. EPCA requires that any test procedures prescribed or amended under this section must be reasonably designed to produce test results which reflect the energy efficiency, energy use or estimated annual operating cost of covered equipment during a representative average use cycle and requires that test procedures not be unduly burdensome to conduct. (42 U.S.C. 6314(a)(2)) The test procedure for CRE is contained in 10 CFR part 431, subpart C, appendix B—*Amended Uniform Test Method for the Measurement of Energy Consumption of Commercial Refrigerators, Freezers, and Refrigerator-Freezers* (''Appendix B'').

Any interested person may submit a petition for waiver from DOE's test procedure requirements. 10 CFR 431.401(a)(1). DOE will grant a waiver from the test procedure requirements if DOE determines either that the basic model for which the waiver was requested contains a design characteristic that prevents testing of the basic model according to the prescribed test procedures, or that the prescribed test procedures evaluate the basic model in a manner so unrepresentative of its true energy or water consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 431.401(f)(2). DOE may grant the waiver subject to conditions, including adherence to alternate test procedures. *Id.*

A petitioner may request that DOE extend the scope of a waiver or an interim waiver to include additional basic models employing the same technology as the basic model(s) set forth in the original petition. 10 CFR 431.401(g). DOE will publish any such extension in the **Federal Register**. *Id.*

II. Request for an Extension of Waiver: Assertions and Determinations

On October 30, 2018, DOE issued a Decision and Order in Case Number 2017–007 granting AHT a waiver to test its AHT basic models specified in that Order using an alternate test procedure. 83 FR 54581 (''October 2018 Decision and Order''). AHT stated that the basic models listed in the petition do not have a defrost cycle when operated in freezer mode, and therefore cannot be tested under Appendix B, which references defrosts for the start of the test period and door-opening period.

Based on its review, including the information provided by AHT, DOE determined that the CRE basic models specified in the October 2018 Decision and Order contain a design characteristic that prevents testing the basic models according to the prescribed test procedure at Appendix B. 83 FR 54581, 54582. The October 2018 Decision and Order specifies that AHT must test and rate the subject basic models according to Appendix B, but with the test period starting after the unit achieves steady state conditions and the door-opening period starting 3 hours after the start of the test period. *Id* at 83 FR 54583.

On January 20, 2022, AHT submitted a request to extend the scope of the waiver, Case Number 2022–001, to specified additional AHT basic models.[3] AHT stated that these basic models have the same characteristics as the models covered by the existing waiver.

DOE has reviewed AHT's waiver extension request and operating instructions for the subject basic models and determined that the CRE basic models identified in AHT's request incorporate the same design characteristics as those basic models covered under the waiver in Case Number 2017–007 (*i.e.,* lack of defrost cycle when operated in freezer mode), which prevents testing the basic models according to the prescribed test procedure at Appendix B. DOE also determined that the alternate procedure specified in Case Number 2017–007 will allow for the accurate measurement of the energy use of the CRE basic models identified by AHT in its waiver extension request, while alleviating the testing problems associated with AHT's implementation of DOE's applicable commercial refrigeration equipment test procedure for the specified basic models.

III. Order

After careful consideration of all the material submitted by AHT in this matter, it is *ordered* that:

(1) AHT must, as of the date of publication of this Extension of Waiver in the **Federal Register**, test and rate the following AHT brand commercial freezer basic models (which do not have defrost cycle capability when operated in freezer mode) with the alternate test procedure as set forth in paragraph (2):

Brand	Basic model
AHT ..	IBIZA 145 (U) NAM1–F.
AHT ..	IBIZA 210 (U) NAM1–F.
AHT ..	MALTA 185 (U) NAM1–F.
AHT ..	MANHATTAN XL 210 (U) NAM1–F.
AHT ..	MIAMI 210 (U) NAM1–F.
AHT ..	MIAMI 250 (U) NAM1–F.
AHT ..	MIAMI XL EC 185 (U) NAM1–F.
AHT ..	PARIS 210 (U) NAM1–F.

185 (U) NAM1–F, MANHATTAN XL 210 (U) NAM1–F, MIAMI 210 (U) NAM1–F, MIAMI 250 (U) NAM1–F, MIAMI XL EC 185 (U) NAM1–F, PARIS 210 (U) NAM1–F, PARIS EC 185 (U) NAM1–F, SYDNEY EC 223 (U) NAM1–F, SYDNEY XL 210 (U) NAM1–F.

[1] All references to EPCA in this document refer to the statute as amended through the Infrastructure Investment and Jobs Act, Public Law 117–58 (Nov. 15, 2021).

[2] For editorial reasons, upon codification in the U.S. Code, Part C was redesignated as Part A–1.

[3] The specified basic models are: IBIZA 145 (U) NAM1–F, IBIZA 210 (U) NAM1–F, MALTA 185 (U) NAM1–F, MANHATTAN XL 210 (U) NAM1–F, MIAMI 210 (U) NAM1–F, MIAMI 250 (U) NAM1–F, MIAMI XL EC 185 (U) NAM1–F, PARIS 210 (U) NAM1–F, PARIS EC 185 (U) NAM1–F, SYDNEY EC 223 (U) NAM1–F, SYDNEY XL 210 (U) NAM1–F.

Brand	Basic model
AHT ..	PARIS EC 185 (U) NAM1–F.
AHT ..	SYDNEY EC 223 (U) NAM1–F.
AHT ..	SYDNEY XL 210 (U) NAM1–F.

(2) The alternate test procedure for the AHT basic models referenced in paragraph (1) of this Order is the test procedure for CRE prescribed by DOE at 10 CFR part 431, subpart C, appendix B, except that the test period shall be selected as detailed below. All other requirements of Appendix B and DOE's regulations remain applicable.

The test shall begin when steady state conditions occur (per ASHRAE Standard 72–2005, Section 3, definitions, which defines steady state as ''the condition where the average temperature of all test simulators changes less than 0.2 °C (0.4 °F) from one 24-hour period or refrigeration cycle to the next''). Additionally, the door-opening requirements shall be as defined in ASHRAE 72–2005 Section 7.2, with the exception that the eight-hour period of door openings shall begin three hours after the start of the test. Ambient temperature, test simulator temperatures, and all other data shall be recorded at three-minute intervals beginning at the start of the test and throughout the 24-hour testing period.

(3) *Representations.* AHT may not make representations about the energy use of a basic model listed in paragraph (1) of this Order for compliance, marketing, or other purposes unless that basic model has been tested in accordance with the provisions of paragraph (2) of this Order and such representations fairly disclose the results of such testing.

(4) This Extension of Waiver shall remain in effect according to the provisions of 10 CFR 431.401.

(5) This Extension of Waiver is issued on the condition that the statements, representations, and documentation provided by AHT are valid. If AHT makes any modifications to the controls or capabilities (*e.g.,* adding automatic defrost to freezer mode) of these basic models, the waiver will no longer be valid and AHT will either be required to use the current Federal test method or submit a new application for a test procedure waiver. DOE may rescind or modify this Extension of Waiver (and/or the underlying Order issued in Case Number 2017–007) at any time if it determines the factual basis underlying the petition for extension of waiver (and/or the underlying Order issued in Case Number 2017–007) is incorrect, or the results from the alternate test procedure are unrepresentative of a basic model's true energy consumption characteristics. 10 CFR 431.401(k)(1). Likewise, AHT may request that DOE rescind or modify the Extension of Waiver (and/or the underlying Order issued in Case Number 2017–007) if AHT discovers an error in the information provided to DOE as part of its petition, determines that the waiver is no longer needed, or for other appropriate reasons. 10 CFR 431.401(k)(2).

(6) AHT remains obligated to fulfill all applicable requirements set forth at 10 CFR part 429.

Signing Authority

This document of the Department of Energy was signed on April 5, 2022, by Kelly J. Speakes-Backman, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on April 6, 2022.

Treena V. Garrett,

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

[FR Doc. 2022–07668 Filed 4–8–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

National Nuclear Security Administration

Secretarial Determination of No Adverse Impact on the Domestic Uranium Mining, Conversion, and Enrichment Industries To Support Mo-99 Production

AGENCY: National Nuclear Security Administration (NNSA), Department of Energy (DOE).

ACTION: Notice.

SUMMARY: On November 24, 2021, the Secretary of Energy issued a determination (''Secretarial Determination'') covering the sale, lease, or transfer of up to 750 kilograms uranium (kgU) of high-assay low enriched uranium (HALEU) (above 5 but less than 20 wt. percent uranium-235) per calendar year to support the development and establishment of molybdenum-99 (Mo-99) production capabilities. For the reasons set forth in the Department's ''Analysis of Potential Impacts of Certain Uranium Transactions on the Domestic Uranium Mining, Conversion, and Enrichment Industries,'' which is incorporated into the Secretarial Determination, the Secretary determined that these transactions will not have an adverse material impact on the domestic uranium mining, conversion, or enrichment industry.

FOR FURTHER INFORMATION CONTACT: Requests for additional information may be sent to Brett Cox: *officeofconversion@nnsa.doe.gov* or (202) 287–5191.

SUPPLEMENTARY INFORMATION:

Authority and Background

The Department of Energy (''the Department'') holds limited inventories of uranium in various forms and quantities that have been declared as excess and are not dedicated to U.S. national security missions. Within DOE, the National Nuclear Security Administration (NNSA) manages these inventories. NNSA down-blends excess highly-enriched uranium (HEU) to high-assay low-enriched uranium (HALEU)—a subset of low enriched uranium (LEU), enriched above the commercial level of 5 wt-% and below 20 wt-% of the isotope U–235. Common applications of such high-assay materials are as fuels for domestic and foreign research reactors and as target materials for the production of medical isotopes.

This notice involves the sale, lease, or transfer of HALEU to support domestic molybdenum-99 (Mo-99) producers. These sales, leases, and transfers fulfill a directive in the American Medical Isotopes Production Act of 2012 (Pub. L. 112–239, Division C, Title XXXI, Subtitle F, 42 U.S.C. 2065) for the Department to establish a program to make HALEU available, through lease contracts, for the production of Mo-99 for medical uses. These sales, leases, and transfers also support U.S. nuclear nonproliferation initiatives, by down-blending HEU and encouraging the use of LEU in civilian applications in lieu of HEU.

These sales, leases or transfers are conducted in accordance with the Atomic Energy Act of 1954 (42 U.S.C. 2011 *et seq.,* ''AEA''), as amended, and other applicable law. Specifically, Title I, Chapters 6 and 14 of the AEA authorize DOE to sell or transfer special nuclear material, including HALEU. The United States Enrichment Corporation (USEC) Privatization Act (Pub. L. 104–

134, 42 U.S.C. 2297h *et seq.*) places certain limitations on DOE's authority to sell or transfer uranium from its excess uranium inventory. Specifically, under section 3112(d) of the USEC Privatization Act (42 U.S.C. 2297h–10(d)), DOE may make certain sales or transfers of natural uranium or LEU if the Secretary determines that the sales or transfers ''will not have an adverse material impact on the domestic uranium mining, conversion or enrichment industry, taking into account the sales of uranium under the Russian Highly Enriched Uranium Agreement and the Suspension Agreement.''

On November 23, 2021, the Secretary of Energy issued a determination covering the sale, lease, or transfer of up to 750 kgU of HALEU per calendar year to support the development and establishment of Mo-99 production capabilities. For the reasons set forth in the Department's ''Analysis of Potential Impacts of Certain Uranium Transactions on the Domestic Uranium Mining, Conversion, and Enrichment Industries,'' which is incorporated into the Secretarial Determination, the Secretary determined that these transactions will not have an adverse material impact on the domestic uranium mining, conversion, or enrichment industry. In accordance with section 306(a) of Division D, Title III of the *Consolidated and Further Continuing Appropriations Act,* 2015 (Pub. L. 113–235)), this determination is valid for no more than two calendar years following the date of the Secretarial Determination.

Signing Authority

This document of the Department of Energy was signed on April 5, 2022, by Corey Hinderstein, Deputy Administrator for Defense Nuclear Nonproliferation, pursuant to delegated authority from the Secretary of Energy. The document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on April 6, 2022.

Treena V. Garrett,

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

Set forth below is the full text of the Secretarial Determination.

Secretarial Determination for the Sale, Lease, or Transfer of Certain High-Assay Low Enriched Uranium for the Next Two Years

I determine that the sale, lease, or transfer of up to 750 kgU of high-assay low enriched uranium (above 5 but less than 20 wt. percent uranium-235) per calendar year to support the development and establishment of molybdenum-99 production capabilities will not have an adverse material impact on the domestic uranium mining, conversion, or enrichment industry. I base my conclusions on the Department's *Analysis of Potential Impacts of Uranium Transfers on the Domestic Uranium Mining, Conversion, and Enrichment Industries,* which is incorporated herein. As explained in that document, I have considered, *inter alia,* the requirements of the *USEC Privatization Act of 1996* (42 U.S.C. 2297h *et seq.*), the nature of uranium markets, and the current status of the domestic uranium industries. I have also taken into account the sales of uranium under the *Russian Highly Enriched Uranium Agreement* and the *Suspension Agreement.*

Date: November 23, 2021

Jennifer Granholm,

Secretary of Energy

Set forth below is the full text of the ''*Analysis of Potential Impacts of Certain Uranium Transactions on the Domestic Uranium Mining, Conversion, and Enrichment Industries.*''

Analysis of Potential Impacts of Certain Uranium Transactions on the Domestic Uranium Mining, Conversion, and Enrichment Industries

I. Introduction

A. Legal Authority

The Department of Energy (DOE) manages its excess uranium inventory in accordance with the *Atomic Energy Act of 1954* (42 U.S.C. 2011 *et seq.*) (AEA), as amended, and other applicable laws. Specifically, Title I, Chapters 6 and 14 of the AEA authorize DOE to sell or transfer special nuclear material. Low enriched uranium (LEU) is a type of special nuclear material.

The *United States Enrichment Corporation (USEC) Privatization Act* (Pub. L. 104–134, 42 U.S.C. 2297h *et seq.*) places certain limitations on DOE's authority to sell or transfer uranium from its excess uranium inventory. Specifically, under section 3112(d) of the *USEC Privatization Act,* DOE may make certain sales or transfers of natural uranium or LEU if the Secretary determines that the sales or transfers ''will not have an adverse material impact on the domestic uranium mining, conversion or enrichment industry, taking into account the sales of uranium under the Russian Highly Enriched Uranium Agreement and the Suspension Agreement.'' (42 U.S.C. 2297h–10(d)(2)(B)). The validity of any determination under this section is limited to no more than two calendar years subsequent to the determination.[1] The *USEC Privatization Act* also covers sales or transfers of enriched uranium for governmental purposes under section 3112(e), which are not subject to the same limitations of section 3112(d).

B. Transactions Considered in This Analysis

Two types of potential transactions are considered in this analysis: (1) The lease of certain high-assay low enriched uranium (HALEU) (LEU enriched above 5 weight (wt.) % U–235, but less than 20 wt. % U–235) for the production of molybdenum-99 (Mo-99); and (2) the sale or transfer of HALEU to producers for use in medical isotope research, development, and production.

The first type of transaction is authorized under the *American Medical Isotopes Production Act* of 2012 [2] (AMIPA). AMIPA directs the Department to establish a Uranium Lease and Take Back (ULTB) program to lease LEU for irradiation to produce Mo-99 in the United States without the use of highly enriched uranium (HEU). The leased material would be used as either driver fuel for reactors employed in medical isotope production, as target material for irradiation and extraction of Mo-99, or both. The exact uses and designs vary by producer, but fission-based production usually involves fabrication of uranium targets for irradiation in a reactor, followed by chemical processing to extract the Mo-99 for packaging into a generator and delivery to a radiopharmacy.

The second type of transaction considered in this analysis is a sale or transfer of HALEU to producers for use in medical isotope research and production processes that are not under the ULTB program and do not meet the criteria of section 3112(e)(3) of the *USEC Privatization Act.* Such uranium

[1] See section 306(a) of Division D, Title III of the *Consolidated and Further Continuing Appropriations Act,* 2015 (Pub. L. 113–235).

[2] Public Law 112–239, Division C, Title XXXI, Subtitle F, 42 U.S.C. 2065.

sales or transfers would require a Secretarial Determination under section 3112(d)(2)(B) of the *USEC Privatization Act* as well as meeting the other criteria of section 3112(d)(2).

The materials considered in this analysis would be transferred during calendar years 2021 through 2023 and consist of no more than 750 kg of HALEU in any calendar year. Based on semi-annual LEU demand surveys conducted to determine domestic producers' material needs, DOE's National Nuclear Security Administration (DOE/NNSA) increased the amount being assessed in this Determination from 500 kg per calendar year for the last Determination (2019 to 2021), to 750 kg of HALEU per calendar year during this Determination period. Assuming a tails assay of 0.20 wt. % U–235, this quantity would be equivalent to approximately 28,700 kgU of natural uranium hexafluoride and approximately 33,850 separative work units (''SWU'') to produce 750 kg of HALEU at 19.75 wt. % U–235.[3]

II. Analytical Approach

The analytical approach relied on for previous Secretarial Determinations covering the sale, transfer, or lease of excess uranium for Mo-99 research and production (80 FR 65728, Oct. 27, 2015), the ULTB program (81 FR 1409, Jan. 12, 2016), and the Secretarial Determination for the Sale, Lease or Transfer of Uranium (signed and dated November 26, 2019) is repeated here and updated to the extent necessary.

This analysis evaluates the state of the domestic uranium industries and the relevant impacts if DOE goes forward with these potential transactions. DOE has developed a set of factors that this analysis considers in assessing whether DOE's uranium sales and transfers will have an ''adverse material impact'' on the domestic uranium mining, conversion, or enrichment industry:

1. Prices
2. Production at existing facilities
3. Employment levels in the industry
4. Changes in capital improvement plans and development of future facilities
5. Long-term viability and health of the industry
6. *Russian HEU Agreement* and *Russian Suspension Agreement*

While no single factor is dispositive of the issue, DOE believes that these factors are representative of the types of impacts that the proposed sale, lease, or transfer may have on the domestic uranium industries. Not every factor will necessarily be relevant on a given occasion or to a particular industry; DOE intends this list of factors only as a guide to its analysis.

III. Assessment of Potential Impacts

1. Prices

There is currently no commercial supplier for HALEU. Therefore, there is no established market price for HALEU. DOE sets a price for HALEU based on a combination of commercial market price components for LEU, plus a charge for the separative work above the 5% LEU limit reflecting the historical cost to DOE to produce this material.

The market value of 4.95% enriched LEU has risen 64% from its low point in October 2017. Industry analysts forecast a continued increase in the market value of LEU.[4] The relatively small quantities of HALEU provided by DOE have not impacted the price increases in this market.

Further, with no commercial provider for HALEU, the DOE sales and leases of HALEU would not displace production or affect prices among the commercial domestic uranium mining, conversion, or enrichment industries, and even if it did, the amount would be so small that the effects would be minimal.

2. Production at Existing Facilities

An analysis of the impact of the proposed sales and leases based on an assessment of production at existing facilities is straightforward. There is currently no commercial supplier of HALEU in the United States. Due to the lack of a sufficient near-term market, owners and operators of enrichment facilities have not developed commercial HALEU enrichment capability to produce uranium enriched to 19.75 wt. % U–235. With the closing of the Paducah Gaseous Diffusion Plant in 2013, the only operational uranium enrichment facility in the United States is the URENCO USA facility operated by Louisiana Energy Services, LLC, in Eunice, New Mexico, which is currently licensed by the Nuclear Regulatory Commission to possess uranium only up to 5.5 wt. % U–235.[5]

Further, it is not feasible for commercial Mo-99 producers to use commercially available assays of LEU (*i.e.,* LEU enriched to 5 wt. % U–235 or less) instead of HALEU. Given the specialized uses, designs, and regulatory requirements of the fuels and targets used for these isotope production purposes, use of commercial-assay LEU would prevent the reactor or target from achieving the same performance or efficiency and thus from being used for their intended purposes.

Although the DOE sales and leases of HALEU would not displace production among the commercial domestic uranium mining, conversion, or enrichment industries, even if it did, the amount would be so small that the effects would be minimal. With respect to these industries, to produce the amount of HALEU in the proposed sales and leases from primary production would require approximately 75,000 pounds of uranium concentrates (U_3O_8), 28,700 kgU of conversion services, and 33,850 SWU of enrichment services. By comparison, the entire domestic fleet of nuclear reactors in 2020 required approximately 43 million pounds of U_3O_8, 16.2 million kgU of conversion services, and about 14.8 million SWU.[6] Therefore, the feed, conversion, and SWU content of the DOE material represents 0.18%, 0.18%, and 0.23% of annual domestic requirements, respectively.

The domestic conversion industry consists of only one facility that historically produced between 10 million kgU and 12 million kgU per year and reduced its capability to 7 million kgU in 2017. Honeywell, the owner of the sole domestic conversion facility, suspended operation in 2018, but recently announced that the plant would be restarted and projected that production would begin in early 2023.[7] Thus, although there is currently no conversion occurring in the United States, there are signs of the market improving given this recent announcement.

As mentioned above, there is only one currently operating commercial enrichment facility, URENCO USA's subsidiary, Louisiana Energy Services (LES), LLC in the United States. The total capacity of that facility is 4.9 million SWU.

[3] The calculation is based on the Y–12 Standard Specification for LEU Metal Supply for Mo-99 Isotope Production, which assumes deliveries of quantities of 19.75 wt. % LEU. If any sale, lease, or transfer includes material at an assay other than 19.75 wt. %, the amount will be converted so that the total amount in any calendar year is equivalent to no more than 750 kgU at 19.75 wt. %.

[4] Energy Resources International, Inc. (ERI), *Nuclear Fuel Cycle Supply and Price Report,* ERI–2006–2101/June 2021.

[5] U.S. Nuclear Regulatory Commission, *Materials License.* License Number SNM–2010, Amendment 57, Docket Number 70–3103.

[6] The global requirements information comes from an analysis prepared by Energy Resources International, Inc. (ERI), *Nuclear Fuel Cycle Supply and Price Report,* ERI–2006–2101/June 2021.

[7] Conversion Services Market update, Energy Resources International, Inc. (ERI), *Nuclear Fuel Cycle Supply and Price Report,* ERI–2006–2101/June 2021.

3. Employment Levels in the Industry

As stated above, DOE sales and leases of HALEU would not displace production among the commercial domestic uranium mining, conversion, or enrichment industries, and therefore will not affect employment levels in these industries.

4. Changes in Capital Improvement Plans and Development of Future Facilities

Although there is currently no domestic uranium enrichment capability to produce HALEU, there have been recent noteworthy developments. In 2019, the Department entered into a cost-shared contract for a HALEU Demonstration Program with American Centrifuge Operating, LLC (ACO), a subsidiary of the U.S. company, Centrus Energy Corp. (''Centrus''). The Program has objectives to deploy a 16-machine cascade of AC–100 M centrifuges in Piketon, Ohio to produce 19.75 wt. % U–235 with US-origin enrichment technology that will result in a small quantity of HALEU for use in research and development. In June 2021, the Nuclear Regulatory Commission (NRC) approved ACO's license amendment request to produce HALEU with an enrichment assay of up to 20 wt. % U–235 at the Piketon facility.[8]

In another recent development, URENCO USA provided a notice to the NRC in April 2021 of its intent to amend the URENCO USA license to increase the enrichment level up to 10 wt. % U–235. Submittal of the initial license amendment request is expected later in 2021. URENCO USA expects to have capability to deliver HALEU up to 10 wt. % U–235 in 2024. URENCO USA also has longer term plans to produce up to 19.75 wt. % U–235.[9]

However, the relatively small amounts of material covered by this Determination have no impact on capital improvement plans and development of future facilities including mines, conversion facilities, and enrichment plants.

5. Long-Term Viability and Health of the Industry

There is currently no commercial supplier of HALEU in the United States. Therefore, there is no long-term industry impact to assess. As noted above, DOE is working with Centrus to establish a technology base which could provide greater amounts of HALEU if commercialized. Long term impacts of DOE material provided to the market will be assessable when Centrus or another HALEU enricher are closer to entering the nuclear fuel market.

6. Russian HEU Agreement and Russian Suspension Agreement

The *Russian HEU Agreement* ended in December 2013. The *Russian Suspension Agreement* (''Suspension Agreement'') was extended on October 5, 2020 (85 FR 64112) and remains in force through 2040 with annual export limits on Russian enriched uranium product sold to U.S. utilities at commercially available assays (*e.g.,* 5 wt. % U–235) through FY2027 (85 FR 64112).[10] The *Suspension Agreement* allows for the sale of up to the following amounts of U–235 per year in 2021, 2022, and 2023 respectively: 26,254 kg, 21,543 kg, and 25,471 kg. The relatively small amount of material covered by this Determination is minimal compared to domestic needs for LEU and imports from the Russian Federation.

IV. Conclusion

With respect to the six factors listed above to assess market impacts:

1. The relatively small amounts of material covered by this Determination have no impact on the price of HALEU, for which there is currently no commercial market price.

2. There are new developments in the industry, but licensing and production timelines will not be impacted in the timeframe for this Determination.

3. The relatively small amounts of material covered by this Determination have no impact on employment levels in the mining, conversion, or enrichment industries.

4. New market developments will not mature during this Determination period to a point where the market could be impacted by DOE sales or leases.

5. The relatively small amounts of material covered by this Determination have no impact on the long-term viability and health of the mining, conversion, and enrichment industries.

6. The Russian HEU Agreement and Russian Suspension Agreement are not factors because there is no HALEU currently being imported from Russia to the United States.

Thus, DOE concludes that the sale, lease, or transfer of up to 750 kg of HALEU per calendar year to support the research, development, and production of Mo-99 and other isotopes will not have an adverse material impact on the domestic uranium mining, conversion, or enrichment industry, taking into account the ended *Russian HEU Agreement* and extended *Russian Suspension Agreement.*

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BILLING CODE 6450–01–P

[8] American Centrifuge Plant and HALEU, from an analysis prepared by Energy Resources International, Inc. (ERI), *Nuclear Fuel Cycle Supply and Price Report,* ERI–2006–2101/June 2021.

[9] High-Assay LEU, Urenco, from an analysis prepared by Energy Resources International, Inc. (ERI), *Nuclear Fuel Cycle Supply and Price Report,* ERI–2006–2101/June 2021.

[10] 2020 Amendment to the Agreement Suspending the Antidumping Investigation on Uranium From the Russian Federation, **Federal Register**/Vol. 85, No. 197/Friday, October 9, 2020/Notices *https://www.federalregister.gov/documents/2020/10/09/2020-22431/2020-amendment-to-the-agreement-suspending-the-antidumping-investigation-on-uranium-from-the-russian.*

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 in Existing Proceedings

Docket Numbers: RP22–417–003.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: Tariff Amendment: TGP PCG Pooling Amendment No.3 to be effective 5/1/2022.
Filed Date: 3/31/22.
Accession Number: 20220331–5337.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–573–001.
Applicants: Golden Pass Pipeline LLC.
Description: Compliance filing: Golden Pass Pipeline LLC 2021 Operational Purchases and Sales Report—Revised to be effective N/A.
Filed Date: 4/5/22.
Accession Number: 20220405–5044.
Comment Date: 5 p.m. ET 4/18/22.

Docket Numbers: RP22–763–001.
Applicants: Columbia Gas Transmission, LLC.
Description: Tariff Amendment: OTRA Summer 2022—Errata to be effective 5/1/2022.
Filed Date: 4/5/22.
Accession Number: 20220405–5020.
Comment Date: 5 p.m. ET 4/18/22.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

Filings Instituting Proceedings

Docket Number: PR22–29–000.
Applicants: Permian Highway Pipeline LLC.

Description: Submits tariff filing per 284.123(b),(e)/: Fuel Filing 4.1.22 to be effective 4/1/2022.
Filed Date: 3/31/2022.
Accession Number: 20220331–5000.
Comments/Protests Due: 5 p.m. ET 4/21/22.

Docket Numbers: PR22–30–000.
Applicants: Black Hills/Kansas Gas Utility Company, LLC.
Description: Submits tariff filing per 284.123(b),(e)/: BHKG Revised Statement of Rates and SOC to be effective 2/1/2022.
Filed Date: 3/31/2022.
Accession Number: 20220331–5375.
Comments/Protests Due: 5 p.m. ET 4/21/22.

Docket Numbers: PR22–31–000.
Applicants: BBT Alabama, LLC.
Description: Submits tariff filing per 284.123(b)(2) + (: BBT Alabama Petition Rate Approval—Revised Statement of Operating Conditions to be effective 4/1/2022.
Filed Date: 4/1/2022.
Accession Number: 20220401–5168.
Comments/Protests Due: 5 p.m. ET 4/22/22.

Docket Numbers: PR22–32–000.
Applicants: BBT Alabama Intrastate, LLC.
Description: Submits tariff filing per 284.123(e)/.224: Alabama Intrastate (Magnolia) Cancellational of SOC to be effective 4/1/2022.
Filed Date: 4/1/2022.
Accession Number: 20220401–5219.
Comments/Protests Due: 5 p.m. ET 4/22/22.

Docket Numbers: RP22–756–000.
Applicants: Enable Gas Transmission, LLC.
Description: Annual Revenue Crediting Filing of Enable Gas Transmission, LLC.
Filed Date: 3/30/22.
Accession Number: 20220330–5266.
Comment Date: 5 p.m. ET 4/11/22.

Docket Numbers: RP22–799–000.
Applicants: Kern River Gas Transmission Company.
Description: Annual Gas Compressor Fuel Report of Kern River Gas Transmission Company.
Filed Date: 3/31/22.
Accession Number: 20220331–5566.
Comment Date: 5 p.m. ET 4/12/22.

Docket Numbers: RP22–808–000.
Applicants: Dominion Energy Overthrust Pipeline, LLC.
Description: § 4(d) Rate Filing: WIC TSA 6358 Amendment to be effective 4/4/2022.
Filed Date: 4/4/22.
Accession Number: 20220404–5146.
Comment Date: 5 p.m. ET 4/18/22.

Docket Numbers: RP22–809–000.
Applicants: Nautilus Pipeline Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rates—HEDV KLM contract 630241 to be effective 4/4/2022.
Filed Date: 4/4/22.
Accession Number: 20220404–5191.
Comment Date: 5 p.m. ET 4/18/22.

Docket Numbers: RP22–810–000.
Applicants: Rover Pipeline LLC.
Description: § 4(d) Rate Filing: Summary of Negotiated Rate Capacity Release Agreements on 4–4–22 to be effective 4/1/2022.
Filed Date: 4/4/22.
Accession Number: 20220404–5206.
Comment Date: 5 p.m. ET 4/18/22.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 5, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–07672 Filed 4–8–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–1566–000]

Guernsey Power Station 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 Guernsey Power Station 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 April 25, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: April 5, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–07671 Filed 4–8–22; 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 exempt wholesale generator filings:

Docket Numbers: EG22–81–000.
Applicants: WPL Crawfish River Solar, LLC.
Description: Self-Certification of EWG Status of WPL Crawfish River Solar, LLC.
Filed Date: 4/5/22.
Accession Number: 20220405–5112.
Comment Date: 5 p.m. ET 4/26/22.

Docket Numbers: EG22–82–000.
Applicants: WPL Bear Creek Solar, LLC.
Description: Self-Certification of EWG Status of WPL Bear Creek Solar, LLC.
Filed Date: 4/5/22.
Accession Number: 20220405–5113.
Comment Date: 5 p.m. ET 4/26/22.

Docket Numbers: EG22–83–000.
Applicants: WPL Wood County Solar, LLC.
Description: Self-Certification of EWG Status of WPL Wood County Solar, LLC.
Filed Date: 4/5/22.
Accession Number: 20220405–5119.
Comment Date: 5 p.m. ET 4/26/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER22–1433–000; ER22–1536–000.
Applicants: PJM Interconnection, L.L.C., Borough of Chambersburg, Pennsylvania.
Description: PJM Interconnection, L.L.C. submits an Informational filing to its March 31, 2022 filing of an executed Service Agreement for Network Integration Transmission Service.
Filed Date: 4/1/22.
Accession Number: 20220401–5605.
Comment Date: 5 p.m. ET 4/22/22.

Docket Numbers: ER22–1574–000.
Applicants: WPL Bear Creek Solar, LLC.
Description: Baseline eTariff Filing: WPL Bear Creek Solar MBR Application to be effective 5/15/2022.
Filed Date: 4/5/22.
Accession Number: 20220405–5082.
Comment Date: 5 p.m. ET 4/26/22.

Docket Numbers: ER22–1575–000.
Applicants: WPL Crawfish River Solar, LLC.
Description: Baseline eTariff Filing: WPL Crawfish River Solar MBR Application Filing to be effective 5/15/2022.
Filed Date: 4/5/22.
Accession Number: 20220405–5084.
Comment Date: 5 p.m. ET 4/26/22.

Docket Numbers: ER22–1576–000.
Applicants: WPL North Rock Solar, LLC.
Description: Baseline eTariff Filing: WPL North Rock Solar MBR Application Filing to be effective 5/15/2022.
Filed Date: 4/5/22.
Accession Number: 20220405–5085.
Comment Date: 5 p.m. ET 4/26/22.

Docket Numbers: ER22–1577–000.
Applicants: PacifiCorp.
Description: § 205(d) Rate Filing: UAMPS Agmt Re SSAS Rev 1 to be effective 3/30/2022.
Filed Date: 4/5/22.
Accession Number: 20220405–5088.
Comment Date: 5 p.m. ET 4/26/22.

Docket Numbers: ER22–1578–000.
Applicants: WPL Wood County Solar, LLC.
Description: Baseline eTariff Filing: WPL Wood County Solar MBR Application Filing to be effective 5/15/2022.
Filed Date: 4/5/22.
Accession Number: 20220405–5090.
Comment Date: 5 p.m. ET 4/26/22.

Docket Numbers: ER22–1579–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2022–04–05_Electric Storage Resources Pre-Implementation Filing to be effective 6/6/2022.
Filed Date: 4/5/22.
Accession Number: 20220405–5100.
Comment Date: 5 p.m. ET 4/26/22.

Docket Numbers: ER22–1581–000.
Applicants: Sun Streams 4, LLC.
Description: Tariff Amendment: Notice of Cancellation to be effective 4/6/2022.
Filed Date: 4/5/22.
Accession Number: 20220405–5128.
Comment Date: 5 p.m. ET 4/26/22.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 5, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–07677 Filed 4–8–22; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OGC–2022–0175; FRL–9570–01–OGC]

Proposed Consent Decree, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed consent decree; request for public comment.

SUMMARY: In accordance with the Clean Air Act, as amended (CAA or the Act), notice is given of a proposed consent decree in *Sierra Club et al.* v. *Regan,* No. 21–cv–6956 (N.D. Cal, September 8, 2021). On September 8, 2021, Plaintiffs Sierra Club, Environmental Integrity Project, and Natural Resources Defense Council (collectively, Plaintiffs) filed a complaint in the United States District Court for the Northern District of California, Oakland Division. Plaintiffs alleged that the Environmental Protection Agency (EPA or the Agency) failed to undertake certain non-discretionary duties in accordance with the Act to timely respond to numerous state implementation plan submissions and to issue findings of failure to submit to numerous other states who had failed to respond to an EPA finding that their state plans were substantially inadequate under the Act. The proposed consent decree would establish deadlines for EPA to act on certain submissions and establish that certain claims in the Complaint are now moot.

DATES: Written comments on the proposed consent decree must be received by May 11, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2022–0175, online at *https://www.regulations.gov* (EPA's preferred method). Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID number for this action. Comments received may be posted without change to *https://www.regulations.gov,* including any personal information provided. For detailed instructions on sending

comments and additional information on the rulemaking process, see the ''Additional Information about Commenting on the Proposed Consent Decree'' heading under the **SUPPLEMENTARY INFORMATION** section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov,* as there may be a delay in processing mail and faxes. Hand-deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

EPA continues to carefully and continuously monitor information from the CDC, local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID–19.

FOR FURTHER INFORMATION CONTACT: Seth Buchsbaum, Air and Radiation Law Office (mail code), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone (202) 564–2484; email address *buchsbaum.seth@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining a Copy of the Proposed Consent Decree

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2022–0175) contains a copy of the proposed consent decree.

The electronic version of the public docket for this action contains a copy of the proposed consent decree and is available through *https://www.regulations.gov.* You may use *https://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search.''

II. Additional Information About the Proposed Consent Decree

On June 15, 2015, EPA issued findings of substantial inadequacy pursuant to CAA section 110(k)(5) for SIP provisions applying to excess emissions during startup, shutdown, and malfunction (''SSM'') periods for 45 states and air districts. State Implementation Plans: Response to Petition for Rulemaking; Restatement and Update of EPA's SSM Policy Applicable to SIPs; Findings of Substantial Inadequacy; and SIP Calls to Amend Provisions Applying to Excess Emissions During Periods of Startup, Shutdown, and Malfunction, 80 FR 33840 (June 12, 2015). EPA accordingly issued a SIP Call requiring those 45 states and air districts to submit plan revisions to correct SSM-related deficiencies in their SIPs within 18 months, *i.e.,* by November 22, 2016 (2015 SSM SIP Call).

The proposed consent decree would establish deadlines for EPA to take action pursuant to CAA section 110(k) on certain SIP revisions that were submitted by the following states and air districts in response to the 2015 SSM SIP Call: Alaska, Arizona—Arizona Department of Environmental Quality, Arizona—Maricopa County Air Quality Department, California—Eastern Kern Air Pollution Control District, California—Imperial County Air Pollution Control District, Colorado, Delaware, Florida, Georgia, Indiana, Kansas, Kentucky, Louisiana, Maine, Michigan, Minnesota, Missouri, Mississippi, Montana, New Jersey, New Mexico, North Dakota, New Mexico—Albuquerque-Bernalillo County, Oklahoma, South Carolina, Tennessee, Virginia, Washington, and West Virginia. Plaintiffs also alleged that EPA had failed to take action on SIP revisions submitted by Texas and North Carolina in response to the SIP call; however, EPA has withdrawn the SIP Calls submitted to those states, mooting that portion of the litigation. SIP Call Withdrawal and Air Plan Approval; NC: Large Internal Combustion Engines NO_X Rule Changes, 85 FR 23700 (April 28, 2020); Withdrawal of Finding of Substantial Inadequacy of Implementation Plan and of Call for Texas State Implementation Plan Revision-Affirmative Defense Provisions, 85 FR 7232 (February 7, 2020; effective March 9, 2020).

CAA section 110(k) sets forth the process by which EPA reviews SIP submissions and revisions. 42 U.S.C. 7410(k). According to that process, EPA must determine no later than 6 months after the date by which a state is required to submit a SIP submittal whether a state has made a submission that meets the minimum completeness criteria. *Id.* 7410(k)(1)(B). EPA refers to the determination that a state has not submitted a requisite SIP submittal as a ''finding of failure to submit.'' Plaintiffs alleged in the complaint that EPA failed to make findings of failure to submit SIP revisions that remove or amend the SIP-called provisions pursuant to CAA section 110(k)(1)(B), 42 U.S.C. 7410(k)(1)(B), for twelve additional states and air districts. However, on January 12, 2022, EPA published findings of failure to submit in the **Federal Register** for those twelve states and air districts, mooting that portion of the litigation. Findings of Failure to Submit State Implementation Plan Revisions in Response to the 2015 Findings of Substantial Inadequacy and SIP Calls to Amend Provisions Applying Excess Emissions During Periods of Startup, Shutdown, and Malfunction, 87 FR 1680 (January 12, 2022).

Additionally, during the pendency of this litigation, in the ordinary course of its administrative action, EPA has taken final action on some of the SIP submissions originally at issue in the litigation.[1]

Under the terms of the proposed consent decree, EPA shall sign a notice or notices approving, disapproving, conditionally approving, or approving in part and conditionally approving or disapproving in part the SIP revisions as listed and identified in the proposed consent decree by the established deadlines. The proposed consent decree provides that if any State withdraws one of the listed SIP revisions, EPA's obligation to take such an action is terminated.

In accordance with section 113(g) of the CAA, for a period of thirty (30) days following the date of publication of this document, the Agency will accept written comments relating to the proposed consent decree. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act.

III. Additional Information About Commenting on the Proposed Consent Decree

Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2022–0175, via *https://www.regulations.gov.* Once submitted, comments cannot be edited or removed from this docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI) or other

[1] See 87 FR 7725 (February 10, 2022); 87 FR 8952 (February 17, 2022); 87 FR 14802 (March 16, 2022).

information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* For additional information about submitting information identified as CBI, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document. Note that written comments containing CBI and submitted by mail may be delayed and deliveries or couriers will be received by scheduled appointment only.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *https://www.regulations.gov* website to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment.

Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

Gautam Srinivasan,

Associate General Counsel.

[FR Doc. 2022–07655 Filed 4–8–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0484, OMB 3060–1003; FR ID 80736]

Information Collections Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before June 10, 2022. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0484.

Title: Amendments to Part 4 of the Commission's Rules Concerning Disruptions to Communications.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit; Not-for-profit institutions; State, Local or Tribal Government.

Number of Respondents and Responses: 1,065 respondents; 27,395 responses.

Estimated Time per Response: 1 hour–2 hours (average per response).

Frequency of Response: On occasion and annual reporting requirements and recordkeeping requirement.

Obligation to Respond: Mandatory and Voluntary. Statutory authority for this collection is contained in sections 1, 4(i), 4(j), 4(o), 251(e)(3), 254, 301, 303(b), 303(g), 303(r), 307, 309(a), 309(j), 316, 332, and 403 of the Communications Act of 1934, as amended, and section 706 of the Telecommunications Act of 1996, 47 U.S.C. 151, 154(i)–(j) & (o), 251(e)(3), 254, 301, 303(b), 303(g), 303(r), 332, 403, and 1302.

Total Annual Burden: 54,215 hours.

Total Annual Cost: No Cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: In accordance with 47 CFR 4.2, reports and information contained in the underlying NORS filings are presumed confidential. The filings are shared with the Department of Homeland Security through password-protected real time access to NORS. Other persons seeking disclosure must follow the procedure delineated in 47 CFR 0.457 and 0.459 of the Commission's Rules for requests for and disclosure of information. The modified collection proposed here will allow ''need to know'' agencies acting on behalf of the federal government, the 50 states, the District of Columbia, Tribal Nations, and the U.S. territories access to confidential information derived from NORS filings based on events occurring within an agency's jurisdiction, provided those agencies maintain the confidentiality of the information and report any breach of that confidentiality.

The Commission has adopted procedures allowing state, federal, local,

and Tribal agencies with a demonstrated ''need to know'' to apply for ''read-only'' access to NORS reports impacting locations where the agency has jurisdiction. To protect the confidentiality of the NORS and DIRS information disclosed to these Participating Agencies, the Commission limited the access to only those agencies who complete the registration process and then limits by geographic area the reports available to each Participating Agency. The Commission also adopted safeguards to protect the data accessed by Participating Agencies from manipulation and from distribution to unauthorized recipients.

Needs and Uses: The general purpose of the Commission's Part 4 rules is to gather sufficient information regarding disruptions to telecommunications to facilitate FCC monitoring, analysis, and investigation of the reliability and security of voice, paging, and interconnected Voice over Internet Protocol (interconnected VoIP) communications services, and to identify and act on potential threats to our Nation's telecommunications infrastructure. The Commission uses this information collection to identify the duration, magnitude, root causes, and contributing factors with respect to significant outages, and to identify outage trends; support service restoration efforts; and help coordinate with public safety officials during times of crisis. The Commission also maintains an ongoing dialogue with reporting entities, as well as with the communications industry at large, generally regarding lessons learned from the information collection in order to foster a better understanding of the root causes of significant outages and to explore preventive measures in the future so as to mitigate the potential scale and impact of such outages.

In a Second Report and Order adopted on March 18, 2021, as FCC 21–34, the Commission adopted rules allowing certain federal, state, and Tribal Nation agencies 10 (Participating Agencies) to access to certain geographically relevant outage reports filed in the Commission's Network Outage Reporting System (NORS). The information collections and record keeping provisions adopted will allow federal, state and Tribal Nation agencies (Participating Agencies) to apply for, and receive access to, NORS report in the areas where they have jurisdiction. The collection will further enable these Participating Agencies, at their election, to share NORS reports with qualified local agencies whose jurisdiction is affected by an outage, while still maintaining the confidentiality of the substantive data. The changes to the data collections fields in the NORS filings made by service providers will further facilitate the ability of Participating Agencies to access those reports relevant to their specific geographies. Finally, the changes to the information collection and associated recordkeeping requirements, including retention by participating agencies of qualification forms submitted by local agency seeking access to NORS data, as well as a list of which local agencies receive information from the Participating Agency, training materials setting clear parameters for the use of NORS data, and a list of those persons granted NORS account access, will enable auditing functions to ensure accountability in the use of NORS information and immediate reporting of breaches of access or confidentiality protocols.

OMB Control Number: 3060–1003.

Title: Communications Disaster Information Reporting System (DIRS).

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit; Not-for-profit institutions; State, Local or Tribal Government.

Number of Respondents and Responses: 400 respondents; 104,000 responses.

Estimated Time per Response: 1 hour–1.5 hours (average per response).

Frequency of Response: On occasion and annual reporting requirements and recordkeeping requirements.

Obligation to Respond: Voluntary. Statutory authority for this collection is contained in sections 1, 4(i), 4(j), 4(o), 251(e)(3), 254, 301, 303(b), 303(g), 303(r), 307, 309(a), 309(j), 316, 332, and 403 of the Communications Act of 1934, as amended, and section 706 of the Telecommunications Act of 1996, 47 U.S.C. 151, 154(i)–(j) & (o), 251(e)(3), 254, 301, 303(b), 303(g), 303(r), 332, 403, and 1302.

Total Annual Burden: 16,320 hours.

Total Annual Costs: No Cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: The Commission provides respondents with assurances that their collected filings reports will be treated with a presumption of confidentiality. As noted in the DIRS User Manual, ''[b]ecause the information that communications companies input to [their collected filings] is sensitive for national security and/or commercial reasons, [the collected filings] shall be treated as presumptively confidential upon filing.''

In accordance with 47 CFR 4.2, reports and information contained in the underlying DIRS filings are presumed confidential. The filings are shared with the Department of Homeland Security through password-protected real time access to NORS. Other persons seeking disclosure must follow the procedure delineated in 47 CFR 0.457 and 0.459 of the Commission's Rules for requests for and disclosure of information. The modified collection proposed here will allow ''need to know'' agencies acting on behalf of the federal government, the 50 states, the District of Columbia, Tribal Nations, and the U.S. territories access to confidential information derived from DIRS filings based on events occurring within an agency's jurisdiction, provided those agencies maintain the confidentiality of the information and report any breach of that confidentiality.

The Commission has adopted procedures allowing state, federal, local, and Tribal agencies with a demonstrated ''need to know'' to apply for ''read-only'' access to DIRS reports impacting locations where the agency has jurisdiction. To protect the confidentiality of the NORS and DIRS information disclosed to these Participating Agencies, the Commission limited the access to only those agencies who complete the registration process and then limits by geographic area the reports available to each Participating Agency. The Commission also adopted safeguards to protect the data accessed by Participating Agencies from manipulation and from distribution to unauthorized recipients.

Needs and Uses: The Commission launched the Disaster Information Reporting System (DIRS) in 2007 pursuant to its mandate to promote the safety of life and property through the use of wire and radio communication as required by the Communications Act of 1934, as amended. DIRS is a voluntary, efficient, and web-based system that communications companies may use to report their infrastructure status during times of crisis (*e.g.,* related to a disaster). DIRS uses a number of template forms tailored to different communications sectors (*i.e.,* wireless, wireline, broadcast, and cable) to facilitate the entry of this information. To use DIRS, a company first inputs its emergency contact information. After this, they submit information using the template form appropriate for their communications sector. In a *Second Report and Order* adopted on March 18, 2021, as FCC 21–34, the Commission adopted rules allowing certain federal, state, and Tribal Nation agencies (Participating Agencies) to access to

certain geographically relevant reports filed in the Commission's Disaster Information Reporting System (DIRS). The information collections and record keeping provisions adopted will allow Participating Agencies to apply for, and receive access to, DIRS report in the areas where they have jurisdiction. The collection will further enable these Participating Agencies, at their election, to share DIRS reports with qualified local agencies whose jurisdiction is affected by a disaster, while still maintaining the confidentiality of the substantive data. The changes to the data collections fields in the DIRS filings made by service providers will further facilitate the ability of Participating Agencies to access those reports relevant to their specific geographies. Finally, the changes to the information collection and associated recordkeeping requirements, including retention by participating agencies of qualification forms submitted by local agency seeking access to DIRS data, as well as a list of which local agencies receive information from the Participating Agency, training materials setting clear parameters for the use of DIRS data, and a list of those persons granted DIRS account access, will enable auditing functions to ensure accountability in the use of DIRS information and immediate reporting of breaches of access or confidentiality protocols.

The Commission notes that the information sharing framework established in the Second Report and Order allows for access to be granted not only for DIRS, but also to the Commission's Network Outage Reporting System (NORS). We note that the process and requirements for Participating Agencies under this framework is identical, regardless of whether they seek access to NORS, DIRS, or both. Because the Commission anticipates that NORS and DIRS access will be requested together in most cases, it believes that the estimated burden hours and costs for Participating Agencies associated with DIRS access are fully included in the estimates that it has separately submitted as part of its collection on Part 4 of the Commission's Rules Concerning Disruptions to Communications, OMB Control No. 3060–0484. To avoid double-counting the estimated burden hours and costs associated with both collections, the Commission estimates the marginal cost of the Participating Agency aspect of this collection to be zero.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2022–07630 Filed 4–8–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1271; FR ID 81140]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before June 10, 2022. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION: *OMB Control Number:* 3060–1271.

Title: Promoting Telehealth for Low-Income Consumers, COVID–19 Telehealth Program.

Form Numbers: FCC Forms 460, 461, 462, and 463.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit; Not-for-profit institutions; Federal Government; and State, Local, or Tribal governments.

Number of Respondents and Responses: 7,210 respondents; 34,553 responses.

Estimated Time per Response: 0.30–25 hours.

Frequency of Response: One-time, annual, and on occasion reporting requirements; recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in sections 1–4, 201–205, 214, 254, 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151–154, 201–205, 214, 254, 303(r), and 403, and DIVISION B of the Coronavirus Aid, Relief, and Economic Security Act, Public Law 116–136, 134 Stat. 281.

Total Annual Burden: 197,787 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: No Impact(s).

Nature and Extent of Confidentiality: The Name, Address, DUNS Number and Business Type will be disclosed in accordance with the FFATA/DATA Act reporting requirements as part of the COVID–19 Telehealth Program. Also, the COVID–19 Telehealth Program award and disbursement amounts will be made public. We intend to keep other information submitted under the COVID–19 Telehealth Program confidential to the extent permitted by law. There is no assurance of confidentiality provided to respondents as part of the Connected Care Pilot Program, the selected applicants and estimated funding will be made public. Respondents under both programs may request materials or information submitted to the Commission to be withheld from public inspection under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: On March 31, 2020, the Commission adopted a Report and Order entitled *Promoting Telehealth for Low-Income Consumers; COVID–19 Telehealth Program,* WC Docket No. 18–

213, WC Docket No. 20–89 (FCC 20–44), establishing two programs designed to assist health care providers in providing connected care services to consumers—the COVID–19 Telehealth Program and the Connected Care Pilot Program (collectively, Programs). June 2021, the Commission adopted a Second Report and Order, WC Docket No. 18–213 (FCC 21–74), that provided guidance on eligible services, competitive bidding, invoicing, and data reporting for Pilot Program participants. The information collected herein is necessary to meet the specific requirements for information that must be submitted as part of the annual and final reports to the Commission as outlined in the *Second Connected Care Report and Order,* and for the Commission to receive and evaluate data for the selected projects and ensure compliance with the Commission's rules and procedures applicable to the Connected Care Pilot Program. This submission does not make any changes to the previously approved information collections for the COVID–19 Telehealth Program and some of the previously approved requirements for the Pilot Program.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2022–07631 Filed 4–8–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

[OMB No. 3064–0207]

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to take this opportunity to comment on the renewal of the existing information collection described below (OMB Control No. 3064–0207).

DATES: Comments must be submitted on or before June 10, 2022.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *Agency Website: https://www.fdic.gov/resources/regulations/federal-register-publications/.*
- *Email: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.
- *Mail:* Manny Cabeza (202–898–3767), Regulatory Counsel, MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street NW building (located on F Street NW), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Manny Cabeza, Regulatory Counsel, 202–898–3767, *mcabeza@fdic.gov,* MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

Proposal to renew the following currently approved collection of information:

1. *Title:* Loans in Areas Having Special Flood Hazards.

OMB Number: 3064–0207.

Form Number: None.

Affected Public: Private Sector.

Burden Estimate:

BURDEN CALCULATION

[OMB No. 3064–0207]

Description	Estimated annual number of respondents	Estimated annual number of responses per respondent	Estimated hours per response	Total hours
Recordkeeping:				
Private flood Insurance (Required to obtain benefits)	3,106	1	0.500	1,553.00
Standard flood hazard determination form (Mandatory)	3,106	313	0.042	40,831.48
Retention of notice of special flood hazards and availability of Federal disaster relief assistance (Mandatory)	3,106	36	0.250	27,954.00
Disclosure:				
Notice of requirement to escrow flood insurance payments and fees (Mandatory)	470	82	0.083	3,198.82
Change in status (Mandatory)	30	2	40	2,400.00
Notice of option to escrow flood insurance payments and fees (Mandatory)	30	22	0.083	54.78
Notice to borrower to purchase flood insurance (Mandatory)	3,106	10	0.083	2,577.98
Notification to terminate flood insurance purchased on behalf of a borrower (Mandatory)	3,106	1	0.250	776.50
Notice of special flood hazards and availability of Federal disaster relief assistance (Mandatory)	3,106	36	0.250	27,954.00
Notice to Administrator of FEMA of servicer's identity (Mandatory)	3,106	18	0.083	4,640.36
Notice to Administrator of FEMA of a change in loan servicer (Mandatory)	3,106	22	0.083	5,671.56

Total Estimated Burden Hours: $117,612.48.

General Description of Collection: Each supervised lending institution is required to provide a notice of special flood hazards to a borrower acquiring a loan secured by a building on real property located in an area identified by FEMA as subject to special flood hazards, and various other notices to borrowers, servicers and FEMA. The Riegle Community Development Act

requires that each institution also provide a copy of the notice to the servicer of the loan (if different from the originating lender). Section 100239 of the Biggert-Waters Flood Insurance Reform Act of 2012 requires each federal banking agency (including the FDIC), and the Farm Credit Administration, to adopt implementing regulations to direct regulated lending institutions to accept ''private flood insurance,'' as defined by the Biggert-Waters Act. A lending institution would be required to implement policies and procedures to comply with the Biggert-Waters Act provision and verify in writing that a private insurance policy satisfies the criteria included in the definition or document findings that separate required criteria have been met when accepting a private flood insurance policy in satisfaction of the mandatory flood insurance purchase requirement of the Flood Disaster Protection Act. The institution must also maintain records to permit examination staff to ascertain how the institution has met the requirements of the regulation.

The FDIC has reviewed its previous submission related to the PRA and has updated its methodology to align with the Office of the Comptroller of the Currency's corresponding information collection (1557–0326). The decrease in the estimated annual burden of 409,935 hours is the result of this change in methodology.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on April 5, 2022.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2022–07639 Filed 4–8–22; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0552]

Safety and Performance Based Pathway Device-Specific Guidances; Guidance for Industry and Food and Drug Administration Staff; 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 two final device-specific guidance documents for the Safety and Performance Based Pathway—specifically, ''Surgical Sutures—Performance Criteria for Safety and Performance Based Pathway'' and ''Orthopedic Fracture Fixation Plates—Performance Criteria for Safety and Performance Based Pathway.'' The device-specific guidances identified in this notice were developed in accordance with the finalized guidance entitled ''Safety and Performance Based Pathway.''

DATES: The announcement of the guidances is published in the **Federal Register** on April 11, 2022.

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–2022–D–0552 for ''Surgical Sutures—Performance Criteria for Safety and Performance Based Pathway'' or ''Orthopedic Fracture Fixation Plates—Performance Criteria for Safety and Performance Based Pathway.'' 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)).

An electronic copy of the guidance documents are available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidances. Submit written requests for a single hard copy of the guidance document entitled ''Surgical Sutures—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff'' or the guidance document entitled ''Orthopedic Fracture Fixation Plates—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Jason Ryans, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1613, Silver Spring, MD 20993–0002, 301–796–4908.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA is announcing the availability of two final device-specific guidance documents for the Safety and Performance Based Pathway—specifically, ''Surgical Sutures—Performance Criteria for Safety and Performance Based Pathway'' and ''Orthopedic Fracture Fixation Plates—Performance Criteria for Safety and Performance Based Pathway.'' These device-specific guidance documents provide performance criteria for premarket notification (510(k)) submissions to support the optional Safety and Performance Based Pathway, as described in the guidance entitled ''Safety and Performance Based Pathway.'' [1] As described in that guidance, substantial equivalence is rooted in comparisons between new devices and predicate devices. However, the Federal Food, Drug, and Cosmetic Act (FD&C Act) does not preclude FDA from using performance criteria to facilitate this comparison. If a legally marketed device performs at certain levels relevant to its safety and effectiveness, and a new device meets those levels of performance for the same characteristics, FDA could find the new device as safe and effective as the legally marketed device. Instead of reviewing data from direct comparison testing between the two devices, FDA could support a finding of substantial equivalence with data demonstrating the new device meets the level of performance of an appropriate predicate device(s). Under this optional Safety and Performance Based Pathway, a submitter of a surgical suture or orthopedic fracture fixation plate device could satisfy the requirement to compare its device with a legally marketed device by, among other things, independently demonstrating that the device's performance meets performance criteria as established in the relevant above-listed guidance rather than using direct predicate comparison testing for some of the performance characteristics.

These guidances are being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (see section 701(h)(1)(C) of the FD&C Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). FDA has determined that these guidance documents present less burdensome policies that are consistent with public health. Although these guidances are being implemented immediately, FDA will consider all comments received and revise the guidance documents as appropriate.

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These guidances represent the current thinking of FDA on ''Surgical Sutures—Performance Criteria for Safety and Performance Based Pathway'' and ''Orthopedic Fracture Fixation Plates—Performance Criteria for Safety and Performance Based Pathway.'' They do not establish any rights for any person and are 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. Electronic Access

Persons interested in obtaining a copy of the guidances may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* These guidance documents are also available at *https://www.regulations.gov* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Surgical Sutures—Performance Criteria for Safety and Performance Based Pathway'' or ''Orthopedic Fracture Fixation Plates—Performance Criteria for Safety and Performance Based Pathway'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 20002 for ''Surgical Sutures—Performance Criteria for Safety and Performance Based Pathway'' or document number 19044 for ''Orthopedic Fracture Fixation Plates—Performance Criteria for Safety and Performance Based Pathway'' to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While these guidances contain no new collection of information, they do refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) is not required for these guidances. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulation and guidance have been approved by OMB as listed in the following table:

21 CFR part; guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120

[1] Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway.*

21 CFR part; guidance	Topic	OMB control No.
"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program".	Q-submissions; pre-submissions	0910–0756

Dated: April 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07684 Filed 4–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5225]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Foreign Supplier Verification Programs for Food Importers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 11, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0752. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–45, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Foreign Supplier Verification Programs (FSVP) for Food Importers—21 CFR Part 1, Subpart L

OMB Control Number 0910–0752—Extension

This information collection supports FDA regulations in 21 CFR part 1, subpart L (21 CFR 1.500 through 1.514 (§§ 1.500 through (§§ 1.514)), which help to implement section 805 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384a). Section 805 authorizes the Agency's FSVP and establishes requirements applicable to imported food. Respondents to the information collection are importers, as defined in section 805(a)(1) of the FD&C Act. The regulations are intended to provide verification that imported food is produced in compliance with statutory requirements that include the implementation of appropriate risk-based preventive controls. The regulations also establish that importers of foods must develop, maintain, and follow an FSVP that provides adequate assurances a foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 of the FD&C Act (21 U.S.C. 350g) (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (21 U.S.C. 350h) (regarding standards for produce safety), if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 (21 U.S.C. 342) (regarding adulteration) and 403(w) (21 U.S.C. 343(w)) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the FD&C Act. The regulations also provide for certain exemptions. To assist respondents with understanding the requirements we have developed Agency guidance, available at: *https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and-animals.*

Specifically, regulations in § 1.501 set forth the applicability of requirements for FSVP, while regulations in §§ 1.502 through 1.508, prescribe specific activities for developing, maintaining, and following an FSVP; as well as for evaluating compliance and for identifying and correcting hazards. Finally, regulations in § 1.509 identify required data elements applicable to food products offered for importation into the United States, while regulations in § 1.510 govern required records, providing that records be made available to FDA upon request and that records be maintained electronically. On May 10, 2021, FDA launched the FSVP Importer Portal for FSVP Records Submission as a means for importers to upload FSVP records electronically and submit them to the Agency, after receiving a request for records from FDA. The portal may be found at *https://www.access.fda.gov/,* and a user guide is available at *https://www.fda.gov/media/148312/download.*

In the **Federal Register** of January 28, 2022 (87 FR 4607), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Exemption for food for research; 1.501(c)	36,360	40	1,454,400	0.083 (5 minutes)	120,715
Identifier for filing with U.S. Customs and Border Protection; 1.509.	56,800	157	8,917,600	0.02 (1.2 minutes)	178,352
Total			10,372,000		299,067

[1] There are no capital costs or operating and maintenance costs associated with the information collection.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Controls for low-acid canned foods; 1.502(b)	2,443	4	9,772	1	9,772
Hazard determinations, controls, and audits; 1.504, 1.506, 1.511.	56,800	87.74	4,984,036	0.38 (23 minutes)	1,917,174
Written assurances for food produced under dietary supplement current good manufacturing practices; 1.511.	11,701	2.88	33,664	2.25	75,744
Document very small importer/certain small foreign supplier status; 1.512(b)(1).	50,450	1	50,450	1	50,450
Written assurances associated with very small importer/certain small foreign supplier; 1.512(b)(3).	50,450	2.79	141,084	2.25	317,439
Total			5,219,006		2,370,579

[1] There are no capital costs or operating and maintenance costs associated with the information collection.
[2] Figures have been rounded to the nearest one hundredth.

Upon evaluation of the information collection, we are retaining the currently approved burden estimates.

Dated: April 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07617 Filed 4–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3049]

E8(R1) General Considerations for Clinical Studies; International Council for Harmonisation; 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 for industry entitled ''E8(R1) General Considerations for Clinical Studies.'' The guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The guidance describes internationally accepted principles and practices for the design and conduct of clinical studies of drug and biological products. In addition, the guidance provides an overview of the types of clinical studies that may be performed and data sources used during the product's life cycle. The guidance is intended to promote the quality of the studies submitted to regulatory authorities, while allowing for flexibility. This guidance revises the guidance for industry ''E8 General Considerations for Clinical Trials'' issued in December 1997.

DATES: The announcement of the guidance is published in the **Federal Register** on April 11, 2022.

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–2019–D–3049 for ''E8(R1) General Considerations for Clinical Studies.'' 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 this 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, or 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 that 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: *Regarding the guidance:* Mark Levenson, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 21, Rm. 4626, Silver Spring, MD 20993–0002, 301–796–2097, *Mark.Levenson@fda.hhs.gov;* or Stephen Ripley, 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.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259, *Jill.Adleberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''E8(R1) General Considerations for Clinical Studies''. The guidance was prepared under the auspices of ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies,[1] standardized the reporting of important safety information, standardized marketing application submissions, and made many other improvements in the quality of global drug development and manufacturing and the products available to patients.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. Additionally, the Membership of ICH has expanded to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by involving technical experts from both regulators and industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In the **Federal Register** of August 1, 2019 (84 FR 37649), FDA published a notice announcing the availability of a draft guidance entitled ''E8(R1) General Considerations for Clinical Studies.'' The notice gave interested persons an opportunity to submit comments by September 30, 2019. After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies in October 2021.

This guidance finalizes the draft guidance issued on August 1, 2019. The revised final guidance describes internationally accepted principles and practices in the design and conduct of clinical studies of drug and biological products. Changes from the 2019 draft guidance to the final guidance include a reduced emphasis on distinct phases of clinical development, the addition of examples of novel studies, and amendments to appendices. The original ICH guidance ''E8 General Considerations for Clinical Trials,'' that was issued in 1997 has not undergone revision previously. Since the 1997 guidance was issued, clinical trial design and conduct have become more complex, impacting the time and feasibility of developing drugs. In response, the revised guidance directly addresses study quality to ensure the protection of study participants and the generation of reliable and meaningful results, while promoting study efficiency. The ICH E8(R1) guidance focuses on the identification of factors that are critical to the study quality and the management of risks to those factors. Additionally, a wider range of study designs and data sources play an increasingly important role in drug development and are not adequately addressed in the original ICH E8 guidance. Hence, the revised final guidance addresses a broad range of study designs and data sources. The revised final guidance also provides updated cross-referencing to other relevant ICH guidances that inform the design, planning, and conduct of clinical research, without reproducing the detailed material found in those guidances.

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 ''E8(R1) General Considerations for Clinical Studies.'' It does not establish any rights for any person and is not binding on FDA or the

[1] We support the principles of the ''3Rs,'' to reduce, refine, and replace animal use in testing when feasible. We encourage sponsors to consult with us if it they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method.

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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information for investigational new drug applications under have been approved under OMB control number 0910–0014; the collections of information for review of new drug applications in have been approved under OMB control number 0910–0001; and the collections of information for review of biologic licensing applications in have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: April 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07690 Filed 4–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Toni M. Brand, Ph.D. (Respondent), who was a graduate student in the Department of Human Oncology, University of Wisconsin-Madison (UWM), and subsequently a research fellow in the Department of Otolaryngology—Head and Neck Surgery, University of California San Francisco (UCSF). Respondent engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Cancer Institute (NCI), National Institutes of Health (NIH), grants P30 CA014520, K99 CA160639, T32 CA108462, and U54 CA209891, National Center for Research Resources (NCRR), NIH, grant UL1 RR025011, National Center for Translational Sciences (NCATS), NIH, grants U54 TR000021 and UL1 TR000427, National Institute of General Medical Sciences (NIGMS), NIH, grant T32 GM081061, and National Institute of Dental and Craniofacial Research (NIDCR), NIH, grant R01 DE023685. The administrative actions, including supervision for a period of four (4) years, were implemented beginning on March 23, 2022, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Wanda K. Jones, Dr. P.H., Acting Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453–8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Toni M. Brand, Ph.D., University of Wisconsin-Madison and University of California San Francisco: Based on the reports of investigations conducted by UWM and UCSF and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Toni M. Brand, who was a graduate student in the Department of Human Oncology, UWM, and subsequently a research fellow in the Department of Otolaryngology—Head and Neck Surgery, UCSF, engaged in research misconduct in research supported by PHS funds, specifically NCI, NIH, grants P30 CA014520, K99 CA160639, T32 CA108462, and U54 CA209891, NCRR, NIH, grant UL1 RR025011, NCATS, NIH, grants U54 TR000021 and UL1 TR000427, NIGMS, NIH, grant T32 GM081061, and NIDCR, NIH, grant R01 DE023685.

ORI found that Respondent engaged in research misconduct by knowingly or recklessly falsifying or fabricating western blot data, by reusing and relabeling data to represent expression of proteins in control experiments measuring the purity of cytoplasmic and nuclear cell fractionation, measurements of proteins of interest, and measurements of the same protein under different experimental conditions or loading controls, included in twenty-four (24) figures in the following grant application submitted to NIDCR, NIH, her Ph.D. Thesis Dissertation, and seven (7) published papers:

- K99 DE027699–01, ''Targeting HPV-driven immunosuppressive signaling pathways in head and neck cancer,'' submitted to NIDCR, NIH, on June 8, 2017.
- Ph.D. Thesis Dissertation, ''Investigations of Nuclear HER family receptors in cancer and resistance to cetuximab therapy,'' Department of Human Oncology, UWM, March 21, 2014 (hereafter referred to as ''Thesis'').
- Mapping C-terminal transactivation domains of the nuclear HER family receptor tyrosine kinase HER3. *PLoS One* 2013 Aug 8;8(8):e71518; doi: 10.1371/journal.pone.0071518. eCollection 2013 (hereafter referred to as ''*PLoS One* 2013'').
- Nuclear EGFR as a molecular target in cancer. *Radiother Oncol.* 2013 Sep;108(3):370–7; doi: 10.1016/j.radonc.2013.06.010 (hereafter referred to as ''*Radiother Oncol.* 2013''). Corrected in: *Radiother Oncol.* 2019 Jan;130:195; doi: 10.1016/j.radonc.2018.10.011.
- Nuclear epidermal growth factor receptor is a functional molecular target in triple-negative breast cancer. *Mol Cancer Ther.* 2014 May;13(5):1356–68; doi: 10.1158/1535–7163.MCT–13–1021 (hereafter referred to as ''*Mol Cancer Ther.* 2014''). Corrected in: *Mol Cancer Ther.* 2019 Apr;18(4):868; doi: 10.1158/1535–7163.MCT–18–1183.
- AXL mediates resistance to cetuximab therapy. *Cancer Res.* 2014 Sep 15;74(18):5152–64; doi: 10.1158/0008–5472.CAN–14–0294 (hereafter referred to as ''*Cancer Res.* 2014'').
- The receptor tyrosine kinase AXL mediates nuclear translocation of the epidermal growth factor receptor. *Sci Signal.* 2017 Jan 3;10(460):eaag1064; doi: 10.1126/scisignal.aag1064 (hereafter referred to as ''*Sci Signal.* 2017''). Retracted in: *Sci Signal.* 2021 Nov 9;14(708):eabn0168; doi: 10.1126/scisignal.abn0168.
- Human Papillomavirus Regulates HER3 Expression in Head and Neck Cancer: Implications for Targeted HER3 Therapy in HPV + Patients. *Clin Cancer Res.* 2017 Jun 15;23(12):3072–3083; doi: 10.1158/1078–0432.CCR–16–2203 (hereafter referred to as ''*Clin Cancer Res.* 2017''). Corrected in: *Clin Cancer Res.* 2021 Jul 15;27(14):4129; doi: 10.1158/1078–0432.CCR–21–2141.
- Cross-talk Signaling between HER3 and HPV16 E6 and E7 Mediates Resistance to PI3K Inhibitors in Head and Neck Cancer. *Cancer Res.* 2018 May 1;78(9):2383–95; doi: 10.1158/0008–5472.CAN–17–1672 (hereafter referred to as ''*Cancer Res.* 2018'').

Specifically, ORI found that Respondent knowingly or recklessly falsified or fabricated data in:

- Figure 6B of Thesis and Figure 6B of *PLoS One* 2013 by reusing a Tubulin western blot panel from cytoplasmic sample to represent Histone H3 panel in nuclear sample
- Figure 6, panel C, of Thesis and Figure 6C of *PLoS One* 2013 by using identical Her3 western blot data to represent samples from different cell lines and using a Tubulin western blot panel from an unrelated experiment.
- Figure 6C, inset 1, of Thesis and Figure 6C, inset 1, of *PLoS One* 2013 by inappropriately cropping the histone H3 nuclear sample to represent equal loading of the samples when the actual data showed an unequal amount.
- Figure 6C, inset 2, of Thesis and Figure 6C, inset 2, of *PLoS One* 2013 by using identical Her3 western panel to represent samples from different cell lines and falsifying loading control by using a Cyclin D western blot panel to represent Tubulin.
- Figure 7A and inset 2 of Thesis and Figure 7A and inset 2 of *PLoS One* 2013 by using identical Her3 western panel to represent samples from different cell lines.
- Figure 2B, SKBr3 inset, of *Radiother Oncol.* 2013 by representing unrelated western panel as Tubulin loading control for the cytoplasmic samples.
- Figure 2B, SUM229 inset, of *Radiother Oncol.* 2013 by representing unrelated western panel as Tubulin loading control in non-nuclear samples.
- Figure 4B of *Mol Cancer Ther.* 2014 by using identical pSFKY419 western blot panels to represent expression in different cell lines.
- Figure 2D of prpS6 western blot panel from HP cell line in *Cancer Res.* 2014 by using a western blot panel from an unrelated experiment.
- Figure 1A of *Sci Signal.* 2017 by using identical western blot panels to represent Histone H3 in non-nuclear samples and Tubulin in nuclear samples.
- Figure 2A of *Sci Signal.* 2017 by using loading control panels from an unrelated experiment in the HC8 experiment.
- Figure 2C of *Sci Signal.* 2017 by using a panel from an unrelated experiment to represent histoneH3 in the nuclear samples.
- Figure 2C inset of *Sci Signal.* 2017 by using a panel from an unrelated experiment to represent tubulin.
- Figure 4A of *Sci Signal.* 2017 by reusing identical panels to represent tubulin (negative) control experiments.
- Figure 5E of *Sci Signal.* 2017 by selective cropping and use of loading control panels from unrelated experiments.
- Tubulin western blot panels in Figure 3A of K99 DE027699–01 by reusing the same data to represent two different cell lines or related data to represent a different cell line.
- Figure 3A of *Clin Cancer Res.* 2017 by using the identical western blot data to represent expression of HER3 and HER3–Y1197 in the SCC47 cell line.
- Supplemental Figure 3A of *Cancer Res.* 2018 by using identical western blot data to represent pAKT–S473 and pAKT–T308 expression in the SCC90 sample.
- Figure 1C of *Clin Cancer Res.* 2017 and Figure 1B of K99 DE027699–01 by representing the same western blot panels to represent E6 and E7 expression in different experiments.

Respondent neither admits nor denies ORI's findings of research misconduct. The parties entered into a Voluntary Settlement Agreement (Agreement) to conclude this matter without further expenditure of time, finances, or other resources. The settlement is not an admission of liability on the part of the Respondent.

Respondent voluntarily agreed to the following:

(1) Respondent will have her research supervised for a period of four (4) years beginning on March 23, 2022 (the ''Supervision Period''). Prior to the submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity in PHS-supported research, Respondent will submit a plan for supervision of Respondent's duties to ORI for approval. The supervision plan must be designed to ensure the integrity of Respondent's research. Respondent will not participate in any PHS-supported research until such a supervision plan is approved by ORI. Respondent will comply with the agreed-upon supervision plan.

(2) The requirements for Respondent's supervision plan are as follows:

i. A committee of 2–3 senior faculty members at the institution who are familiar with Respondent's field of research, but not including Respondent's supervisor or collaborators, will provide oversight and guidance during the Supervision Period. The committee will review primary data from Respondent's laboratory on a quarterly basis and submit a report to ORI at six (6) month intervals setting forth the committee meeting dates and Respondent's compliance with appropriate research standards and confirming the integrity of Respondent's research.

ii. The committee will conduct an advance review of each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved. The review will include a discussion with Respondent of the primary data represented in those documents and will include a certification to ORI that the data presented in the proposed application, report, manuscript, or abstract are supported by the research record.

(3) During the Supervision Period, Respondent will ensure that any institution employing her submits, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract.

(4) If no supervision plan is provided to ORI, Respondent will provide certification to ORI at the conclusion of the Supervision Period that her participation was not proposed on a research project for which an application for PHS support was submitted and that she has not participated in any capacity in PHS-supported research.

(5) During the Supervision Period, Respondent will exclude herself voluntarily from serving in any advisory or consultant capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee.

(6) Respondent will request that the following papers be corrected or retracted:

- *PLoS One* 2013 Aug 8;8(8):e71518
- *Cancer Res.* 2014 Sep 15;74(18):5152–64
- *Cancer Res.* 2018 May 1;78(9):2383–95

Respondent will copy ORI and the Research Integrity Officers at UWM and UCSF on the correspondence with the journals.

Dated: April 5, 2022.

Wanda K. Jones,

Acting Director, Office of Research Integrity, Office of the Assistant Secretary for Health.

[FR Doc. 2022–07632 Filed 4–8–22; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. During the meeting, the Advisory Council will celebrate accomplishments since the release of the National Plan to Address Alzheimer's Disease in May 2012. On May 2, the Advisory Council will hear panel presentations on recent research on biomarkers and therapeutics. On May 3, the Dementia Nomenclature Initiative will present an update to the Advisory Council, and there will be a panel of presentations about dementia risk reduction. Time will be available for public comments at the end of the meeting on May 3.

DATES: The meeting will be held on May 2 and 3, 2022 from 1:00 to 4:00 p.m. EDT each day.

ADDRESSES: The meeting will be virtual, streaming live at *www.hhs.gov/live*.

Comments: Time is allocated on the agenda to hear public comments from 3:30 p.m. to 4 p.m. on Tuesday, May 3. The time for oral comments will be limited to two (2) minutes per individual. In order to provide a public comment, please register by emailing your name to *napa@hhs.gov* by Thursday, April 28. On Friday, April 29, registered commenters will receive both a dial-in number and a link to join the meeting virtually; individuals will have the choice to either join virtually via the link, or to call in only by using the dial-in number. *Note:* There may be a 30–45 second delay in the livestream video presentation of the conference. For this reason, if you have pre-registered to submit a public comment, it is important to connect to the meeting by 3:15 p.m. to ensure that you do not miss your name and allotted time when called. If you miss your name and allotted time to speak, you may not be able to make your public comment. All participant audio lines will be muted for the duration of the meeting and only unmuted by the Host at the time of the participant's public comment. Should you have questions during the session email *napa@hhs.gov* and someone will respond to your message as quickly as possible. In order to ensure accuracy, please submit a written copy of oral comments for the record by emailing *napa@hhs.gov* by Wednesday, May 4. These comments will be shared on the website, reflected in the meeting minutes.

In lieu of oral comments, formal written comments may be submitted for the record by Thursday, April 28 to Helen Lamont, Ph.D., OASPE, 200 Independence Avenue SW, Room 424E, Washington, DC 20201. Comments may also be sent to *napa@hhs.gov.* Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Helen Lamont, 202–260–6075, *helen.lamont@hhs.gov.* Note: The meeting will be available to the public live at *www.hhs.gov/live*.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. app. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: Long-term services and supports workforce, caregiving.

Procedure and Agenda: The meeting will be webcast at *www.hhs.gov/live* and video recordings will be added to the National Alzheimer's Project Act website when available, after the meeting.

Authority: 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel is governed by provisions of Public Law 92–463, as amended (5 U.S.C. appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: April 4, 2022.

Rebecca Haffajee,

Acting Assistant Secretary for Planning and Evaluation.

[FR Doc. 2022–07635 Filed 4–8–22; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Brazil Regional Prospective Observational Research in Tuberculosis (RePORT) (U01 Clinical Trial Not Allowed).

Date: May 6, 2022.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Cynthia L. De La Fuente, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31, Rockville, MD 20852, 240–669–2740, *delafuentecl@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 5, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–07657 Filed 4–8–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2022–0032; FXIA16710900000–223–FF09A30000]

Foreign Endangered Species; Receipt of Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications to conduct certain activities with foreign species that are listed as endangered under the Endangered Species Act (ESA). With some exceptions, the ESA prohibits activities with listed species unless Federal authorization is issued that allows such activities. The ESA also requires that we invite public comment before issuing permits for any activity otherwise prohibited by the ESA with respect to any endangered species.

DATES: We must receive comments by May 11, 2022.

ADDRESSES:

Obtaining Documents: The applications, application supporting materials, and any comments and other materials that we receive will be available for public inspection at *https://www.regulations.gov* in Docket No. FWS–HQ–IA–2022–0032.

Submitting Comments: When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. You may submit comments by one of the following methods:

- *Internet: https://www.regulations.gov.* Search for and submit comments on Docket No. FWS–HQ–IA–2022–0032.
- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2022–0032; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

For more information, see Public Comment Procedures under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, by phone at 703–358–2185, via email at *DMAFR@fws.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I comment on submitted applications?

We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

You may submit your comments and materials by one of the methods in **ADDRESSES**. We will not consider comments sent by email or fax, or to an address not in **ADDRESSES**. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**).

When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. Provide sufficient information to allow us to authenticate any scientific or commercial data you include. The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) those that include citations to, and analyses of, the applicable laws and regulations.

B. May I review comments submitted by others?

You may view and comment on others' public comments at *https://www.regulations.gov,* unless our allowing so would violate the Privacy Act (5 U.S.C. 552a) or Freedom of Information Act (5 U.S.C. 552).

C. Who will see my comments?

If you submit a comment at *https://www.regulations.gov,* your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, such as your address, phone number, or email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(c) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), we invite public comments on permit applications before final action is taken. With some exceptions, the ESA prohibits certain activities with listed species unless Federal authorization is issued that allows such activities. Permits issued under section 10(a)(1)(A) of the ESA allow otherwise prohibited activities for scientific purposes or to enhance the propagation or survival of the affected species. Service regulations regarding prohibited activities with endangered species, captive-bred wildlife registrations, and permits for any activity otherwise prohibited by the ESA with respect to any endangered species are available in title 50 of the Code of Federal Regulations in part 17.

III. Permit Applications

We invite comments on the following applications.

Endangered Species

Applicant: U.S. Fish and Wildlife Service, Mexican Wolf Reintroduction Project, Region 2, Albuquerque, NM; Permit No. PER0031854 (formerly Permit No. 001904)

The applicant requests renewal of a permit to import live Mexican or lobo wolves (*Canis lupus baileyi*) for breeding and reintroduction, as well as the import of biological samples for genetic studies, for the purpose of enhancement of the survival of the species and scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Yerkes National Primate Research Center, Atlanta, GA; Permit No. PER0028203 (formerly Permit No. 837068)

The applicant requests renewal of a permit to take captive-bred sooty mangabeys (*Cercocebus atys*) through limited invasive sampling, including anesthetizing, collecting blood, skin, and bone marrow tissue samples, and MRI scanning, usually but not always, during routine veterinary examinations for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: North Georgia Zoo, Cleveland, GA; Permit No. PER0035138

The applicant requests a permit to purchase in interstate commerce two male and two female captive-bred African penguins (*Spheniscus demersus*) from the Tanganyika Wildlife Trust, Goddard, KS, for the purpose of enhancing the propagation or survival of the species. This notification is for a single interstate commerce activity.

Applicant: Miami-Dade Zoological Park and Gardens, Miami, FL; Permit No. PER0036283

The applicant requests a permit to export one male and two female captive-bred clouded leopards (*Neofelis nebulosi*) to Singapore Zoological Gardens, Singapore, for the purpose of enhancing the propagation or survival of the species. This notification is for a single export.

Applicant: Tanganyika Wildlife Foundation, Goddard, KS; Permit No. 83605D

The applicant requests a permit to import one male, one female and one juvenile captive-bred lar gibbon (*Hylobates lar*) from Nature Resource Network, S.R.O., Czech Republic, for the purpose of enhancing the propagation or

survival of the species. This notification is for a single import.

IV. Next Steps

After the comment period closes, we will make decisions regarding permit issuance. If we issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**. You may locate the notice announcing the permit issuance by searching *https://www.regulations.gov* for the permit number listed above in this document. For example, to find information about the potential issuance of Permit No. 12345A, you would go to *regulations.gov* and search for ''12345A''.

V. Authority

We issue this notice under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and its implementing regulations.

Brenda Tapia,

Supervisory Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2022–07647 Filed 4–8–22; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[OMB Control Number 1010–0106; Docket ID: BOEM–2017–0016]

Agency Information Collection Activities; Oil Spill Financial Responsibility

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Ocean Energy Management (BOEM) is proposing to renew an information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before June 10, 2022.

ADDRESSES: Send your comments on this ICR by mail to the BOEM Information Collection Clearance Officer, Anna Atkinson, Bureau of Ocean Energy Management, 45600 Woodland Road, Sterling, Virginia 20166; or by email to *anna.atkinson@boem.gov.* Please reference Office of Management and Budget (OMB) control number 1010–0106 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Anna Atkinson by email at *anna.atkinson@boem.gov,* or by telephone at 703–787–1025. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, BOEM provides the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps BOEM assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand BOEM's information collection requirements and provide the requested data in the desired format.

BOEM is soliciting comments on the proposed ICR described below. BOEM is especially interested in public comments addressing the following issues: (1) Is the collection necessary to the proper functions of BOEM; (2) what can BOEM do to ensure that this information is processed and used in a timely manner; (3) is the burden estimate accurate; (4) how might BOEM enhance the quality, utility, and clarity of the information to be collected; and (5) how might BOEM minimize the burden of this collection on the respondents, including minimizing the burden through the use of information technology?

Comments submitted in response to this notice are a matter of public record. BOEM will include or summarize each comment in its request to OMB for approval of this ICR. You should be aware that your entire comment—including your address, phone number, email address, or other personally identifiable information included in your comment—may be made publicly available. You may request that BOEM withhold from disclosure your personally identifiable information. Your request must identify any information contained in your comment that, if released, would constitute a clearly unwarranted invasion of your personal privacy. You also must briefly describe any possible harmful consequences of disclosure of that information, such as embarrassment, injury, or other harm. While you can ask in your comment that your personally identifiable information be withheld from public disclosure, BOEM cannot guarantee that it will be able to do so under the law.

BOEM protects proprietary information in accordance with the Freedom of Information Act (5 U.S.C. 552), the Department of the Interior's implementing regulations (43 CFR part 2), and 30 CFR parts 550 and 552 promulgated pursuant to the Outer Continental Shelf (OCS) Lands Act (43 U.S.C. 1352(c)).

Title of Collection: 30 CFR part 553, ''Oil Spill Financial Responsibility for Offshore Facilities.''

Abstract: This ICR concerns the paperwork requirements in 30 CFR part 553, including any supplementary notices to lessees and operators that provide clarification, description, or explanation of these regulations, and forms BOEM–1016 through –1023, and BOEM–1025.

BOEM uses forms to collect information to ensure proper and efficient administration of its oil spill financial responsibility requirements. BOEM collects information to:

- Provide a standard method for establishing whether a party is required to demonstrate oil spill financial responsibility for offshore facilities;
- Identify and maintain a record of those offshore facilities that have a potential oil spill liability requiring the demonstration of oil spill financial responsibility;
- Establish and maintain a continuous record of evidence of oil spill financial responsibility to assure payment of claims for oil spill cleanup and damages resulting from operations conducted on covered offshore facilities and from the transportation of oil from covered offshore facilities;
- Establish and maintain a continuous record of responsible parties, as defined in title I of the Oil Pollution Act of 1990, and their agents or authorized representatives for oil spill financial responsibility for covered offshore facilities; and
- Establish and maintain a continuous record of persons to contact and U.S. agents for service of process for claims associated with oil spills from covered offshore facilities.

OMB Control Number: 1010–0106.

Type of Review: Renewal of a currently approved information collection.

Respondents/Affected Public: Designated applicants and holders of leases, permits, right-of-way grants, and right-of-use and easement grants on the OCS and in State coastal waters who are responsible parties. Other respondents

may be designated applicants' insurance agents and brokers, bonding companies, and guarantors. Some respondents may also be claimants.

Total Estimated Number of Annual Responses: 2,233 responses.

Total Estimated Number of Annual Burden Hours: 34,695 hours.

Respondent's Obligation: Mandatory.

Frequency of Collection: On occasion or annual.

Total Estimated Annual Non-Hour Burden Cost: There is no non-hour cost burden associated with this collection.

Estimated Reporting and Recordkeeping Hour Burden: The current annual burden for this collection is 22,133 hours. BOEM proposes to increase the annual burden to 34,695 hours to account for changes in industry operations due to COVID and remote work. As COVID restrictions ease and continue to be lifted, BOEM expects an increase in the number of respondents annually due to industry practices developed during the pandemic as companies resume production and re-establish oil spill financial responsibility coverage.

Remote work led to changes in how industry reviews and processes required documents. Prior to COVID, in-person meetings with a group of reviewers were held to complete the task quickly and efficiently. Now with many employees working from home, document preparation, review, and editing are taking longer as the documents move through several individual reviewers. Companies have provided this feedback through our outreach efforts. Therefore, BOEM is increasing hour burdens to account for the additional review and editing time. This increase in respondents and burden hours may be temporary and will be revisited by BOEM during future reviews of U.S. OCS supply and demand patterns.

The following table details the individual components and respective hour burden estimates of this ICR. In the table, the term ''oil spill financial responsibility'' has been shortened to ''OSFR.''

BURDEN BREAKDOWN

Citation 30 CFR part 553	Reporting requirement *	Hour burden	Average number of annual reponses	Annual burden hours
Various sections	The burdens for all references to submitting evidence of OSFR, as well as required or supporting information, are covered with the forms below.			0
	Applicability and Amount of OSFR			
11(a)(1); 40; 41	Form BOEM–1016—Designated Applicant Information Certification.	3	250	750
11(a)(1); 40; 41	Form BOEM–1017—Appointment of Designated Applicant	10	750	7,500
11(a)(1); (2)	Form BOEM–1025—Independent Designated Applicant Information Certification.	2	200	400
12, 45	Request for determination of OSFR applicability. Provide required and supporting information.	2	5	10
15	Notify BOEM of change in ability to comply	1	1	1
15(f)	Provide claimant written explanation of denial	1	15	15
Subtotal			1,221	8,676
	Methods for Demonstrating OSFR			
21–28; 40	Form BOEM–1018—Self-Insurance Information, including renewals.	3	50	150
30; 40; 41; 43	Form BOEM–1023—Financial Guarantee	2	50	100
29; 40; 41; 43	Form BOEM–1019—Insurance Certificate	120	150	18,000
31; 40; 41; 43	Form BOEM–1020—Surety Bond	24	4	96
32	Proposal and supporting information for alternative method to evidence OSFR (anticipate no proposals, but regulations provide the opportunity).	120	1	120
Subtotal			255	18,466
	Requirements for Submitting OSFR Information			
14; 40; 41; 43	Form BOEM–1021—Covered Offshore Facilities	10	255	2,550
40–42	Form BOEM–1022—Covered Offshore Facility Changes	10	500	5,000
Subtotal			755	7,550
	Claims for Oil-Spill Removal Costs and Damages			
Subpart F	Claims: BOEM is not involved in the claims process. Assessment of burden for claims against the Oil Spill Liability Trust Fund (33 CFR parts 135, 136, 137) falls under the responsibility of the U.S. Coast Guard.			0
60(d)	Claimant request for BOEM assistance to determine whether a guarantor may be liable for a claim.	2	1	2
62	Within 15-calendar days of claim, designated applicant must notify the guarantor and responsible parties of the claim.	1	1	1
Subtotal			2	3

BURDEN BREAKDOWN—Continued

Citation 30 CFR part 553	Reporting requirement *	Hour burden	Average number of annual reponses	Annual burden hours
Total Burden	.....	.....	2,233	34,695

* In the future, BOEM may require electronic filing of financial and bonding submissions.

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.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Peter Meffert,

Acting Chief, Office of Regulations.

[FR Doc. 2022–07634 Filed 4–8–22; 8:45 am]

BILLING CODE 4310–MR–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1196]

Certain In Vitro Fertilization Products, Components Thereof, and Products Containing the Same; Notice of Commission Final Determination To Issue a Limited Exclusion Order and a Cease and Desist Order; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to issue a limited exclusion order (''LEO'') barring entry of certain in vitro fertilization products, components thereof, and products containing the same, that infringe Complainant's asserted trademarks and that are imported by or on behalf of respondents FastIVF of Scottsdale, Arizona (''FastIVF'') and Hermes Ezcanesi of Istanbul, Turkey (collectively, the ''Defaulting Respondents''). The Commission has further determined to issue a cease and desist order (''CDO'') directed to Defaulting Respondent FastIVF. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Houda Morad, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–4716. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On April 16, 2020, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), based on a complaint filed by complainant EMD Serono, Inc. of Rockland, Massachusetts (''Complainant''). *See* 85 FR 21267–68 (Apr. 16, 2020). The complaint, as amended and supplemented, alleges a violation of section 337 based on the importation into the United States, the sale for importation, and the sale within the United States after importation of certain *in vitro* fertilization products, components thereof, and products containing same (collectively, ''Gray Market IVF Products''), by reason of infringement of U.S. Trademark Registration Nos. 4,689,651; 1,772,761; 3,777,170; 3,389,332; 3,816,320; 1,972,079; 3,604,207; and 3,185,427 (collectively, ''the Asserted Trademarks''); unfair methods of competition and unfair acts in the importation and sale of Gray Market IVF Products by reason of false designation of source; and unfair methods of competition and unfair acts in the importation and sale of the Gray Market IVF Products by reason of false advertising. *See id.* In addition to the Defaulting Respondents, the notice of investigation names General Plastik Drug Stores (''Unserved Respondent'') of Istanbul Suadiye, Turkey as a respondent in this investigation. *See id.* The Office of Unfair Import Investigations (''OUII'') is also a party to the investigation. *See id.*

On September 1, 2020, the Chief ALJ issued an initial determination (''ID'') finding each of the Defaulting Respondents in default. *See* Order No. 6 (Sept. 1, 2020), *unreviewed by* Comm'n Notice (Sept. 24, 2020). On October 13, 2020, the Chief ALJ also issued an ID terminating Unserved Respondent from the investigation based on the withdrawal of the complaint allegations as to that respondent. *See* Order No. 8 (Oct. 13, 2020), *unreviewed by* Comm'n Notice (Oct. 26, 2020).

On April 16, 2021, the Chief ALJ issued an ID (Order No. 10) (''SD'') granting in part Complainant's motion for summary determination of violation of section 337 by the Defaulting Respondents with respect to Complainant's claim under section 337(a)(1)(C) (infringement of the Asserted Trademarks) but denied the motion with respect to Complainant's unfair competition claims under section 337(a)(1)(A). In addition, the Chief ALJ recommended that the Commission issue a general exclusion order (''GEO'') and set a bond at 100 percent during the period of Presidential review.

On May 18, 2021, the Commission determined to review the SD (Order No. 10) in part. *See* Comm'n Notice (May 18, 2021). Specifically, the Commission determined to review the SD's findings with respect to the economic prong of the domestic industry requirement. *See id.* The Commission determined not to review any other findings in the SD.

On October 6, 2021, the Commission determined to vacate the SD in part. Specifically, the Commission vacated the SD's finding that Complainant has satisfied the economic prong of the domestic industry requirement. Consequently, the Commission also vacated the SD's finding of a violation of section 337 and remanded the investigation to the Chief ALJ. Because Complainant requested a GEO, the Commission found that Complainant failed to establish a violation by ''substantial, reliable, and probative evidence'' and that genuine issues of material fact remained as to whether the economic prong of the domestic industry requirement was satisfied. *See* Comm'n Op. at 8 n.9, 25 (Oct. 6, 2021) (citing 19 U.S.C. 1337(g)(2)). Commissioners Karpel and Schmidtlein dissented from the Commission's decision that Complainant had failed to satisfy the economic prong of the domestic industry requirement and would have found a violation of section 337 based on substantial, reliable, and probative evidence.

After the Commission's decision to vacate the SD, Complainant withdrew its request for a GEO and requested an LEO against the Defaulting Respondents and a CDO against FastIVF. On December 15, 2021, the Chief ALJ issued an ID partially terminating the investigation as to Complainant's unfair competition claims under section 337(a)(1)(A). *See* Order No. 13 (Dec. 15, 2021), *unreviewed by* Comm'n Notice (Jan. 10, 2022).

On December 15, 2021, the Chief ALJ issued a remand final initial determination (''FID'') finding a violation of section 337 based on the infringement by the Defaulting Respondents of Complainant's Asserted Trademarks pursuant to section 337(g)(1), 19 U.S.C. 1337(g)(1). In addition, the Chief ALJ issued a Recommended Determination (''RD'') recommending that the Commission issue an LEO against the infringing articles imported by or on behalf of the Defaulting Respondents and a CDO against FastIVF.

On January 4, 2022, Complainant filed a statement on the public interest pursuant to Commission Rule 210.50, 19 CFR 210.50. On the same day, Complainant filed a declaration requesting relief against the Defaulting Respondents, namely, an LEO against the Defaulting Respondents' infringing products and a CDO against FastIVF. No submissions were filed in response to the **Federal Register** notice requesting public interest comments. *See* 86 *FR* 72620–21 (Dec. 22, 2021).

On February 11, 2022, the Commission issued a notice determining not to review the remand FID and therefore affirmed the remand FID's finding of a violation of section 337 pursuant to section 337(g)(1) (19 U.S.C. 1337(g)(1)). *See* 87 FR 9086–88 (Feb. 17, 2022) (''the Remedy Notice''). In default cases governed by section 337(g)(1), the Commission ''presume[s] the facts alleged in the complaint to be true.'' *See* 19 U.S.C. 1337(g)(1). The Remedy Notice also requested briefing on remedy, the public interest, and bonding from the parties and from any interested third party. *See id.*

On February 28, 2022, Complainant and OUII filed responses to the Commission's Remedy Notice. On March 7, OUII filed a reply to Complainant's submission.

Having examined the record of this investigation, including the FID, the RD, and the parties' submissions in response to the Remedy Notice, the Commission has determined that the appropriate remedy in this investigation is: (1) An LEO prohibiting the unlicensed entry of certain in vitro fertilization products, components thereof, and products containing the same, that infringe Complainant's Asserted Trademarks and that are imported by or on behalf of the Defaulting Respondents; and (2) a CDO directed to Defaulting Respondent FastIVF. The Commission has further determined that the bond during the period of Presidential review pursuant to section 337(j) (19 U.S.C. 1337(j)) shall be in the amount of 100 percent of the entered value of the imported articles that are subject to the LEO and/or CDO. Still further, the Commission has determined that the public interest factors enumerated in subsections 337(g)(1) (19 U.S.C. 1337(g)(1)) do not preclude the issuance of the LEO and CDO.

The Commission's vote for this determination took place on April 6, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: April 6, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–07711 Filed 4–8–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–249 and 731–TA–262–263 and 265 (Fifth Review)]

Iron Construction Castings From Brazil, Canada, and China; Scheduling of Expedited Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping and countervailing duty orders on iron construction castings from Brazil, Canada, and China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: March 7, 2022.

FOR FURTHER INFORMATION CONTACT: Nitin Joshi (202–708–1669), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these reviews may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On March 7, 2022, the Commission determined that the domestic interested party group response to its notice of institution (86 FR 68283, December 1, 2021) of the subject five-year reviews was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting full reviews.[1] Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Please note the Secretary's Office will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Staff report.—A staff report containing information concerning the subject matter of the reviews has been placed in the nonpublic record, and will be made available to persons on the Administrative Protective Order service list for these reviews on April 8, 2022. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in section 207.62(d) of the Commission's rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,[2] and any party

[1] A record of the Commissioners' votes is available from the Office of the Secretary and at the Commission's website.

[2] The Commission has found the joint response to its Notice of Institution filed on behalf of D&L

other than an interested party to the reviews may file written comments with the Secretary on what determinations the Commission should reach in the reviews. Comments are due on or before April 15, 2022 and may not contain new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by April 15, 2022. However, should the Department of Commerce (''Commerce'') extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: April 6, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–07714 Filed 4–8–22; 8:45 am]

BILLING CODE 7020–02–P

Foundry, Inc., EJ USA, Inc., Neenah Foundry Company, Tyler Union (a Division of McWane, Inc.), and U.S. Foundry & Manufacturing Corp., domestic producers of heavy iron construction castings and/or light iron construction castings, to be individually adequate for each casting domestic product. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Jennifer Smith, M.D.; Decision and Order

On July 8, 2021, a former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause (hereinafter, OSC) to Jennifer Smith, M.D. (hereinafter, Registrant) of New Hartford, New York. OSC, at 1 and 3. The OSC proposed the revocation of Registrant's Certificate of Registration No. FS0290875. *Id.* at 1. It alleged that Registrant is ''without authority to handle controlled substances in New York, the state in which [she is] registered with DEA'' and alleged that her DEA registration must be revoked based on her lack of state authority. *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that on January 28, 2021, the New York State Board for Professional Medical Conduct (hereinafter, the Board) issued a Determination and Order revoking Registrant's New York medical license, effective February 5, 2021. *Id.* at 1–2. The Board revoked Registrant's New York medical license following its findings, *inter alia,* that Registrant ''failed to comply with the terms of an earlier Consent Order that [she] entered into with the Board on February 15, 2013'' and ''failed to cooperate with an investigation by the New York State Office of Professional Medical Conduct.'' *Id.* at 2.

The OSC notified Registrant of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 2 (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. *Id.* at 3 (citing 21 U.S.C. 824(c)(2)(C)).

Adequacy of Service

In a Declaration dated December 21, 2021, a Diversion Investigator (hereinafter, the DI) assigned to the Syracuse Resident Office of DEA's New York Field Division stated that on or about July 28, 2021, DEA sent a copy of the OSC to Registrant via certified mail, return receipt requested, and on or about July 31, 2021, Registrant herself signed the return receipt for the OSC. Request for Final Agency Action (hereinafter, RFAA) Exhibit (hereinafter, RFAAX) 3 (DI's Declaration), at 1; *see also* RFAAX 3, Appendix (hereinafter, App.) A (Return Receipt Signed by Registrant) and B.

The Government forwarded its RFAA, along with the evidentiary record, to this office on January 26, 2022. In its RFAA, the Government represents that neither Registrant nor any attorney representing Registrant has requested a hearing or submitted a written statement. RFAA, at 2; RFAAX 3, at 2. The Government requests that Registrant's DEA registration be revoked and that any applications for any other DEA registrations by Registrant be denied based on Registrant's lack of authority to handle controlled substances in New York, the state in which she is registered with the DEA. RFAA, at 5.

Based on the DI's Declaration, the Government's written representations, and my review of the record, I find that the Government accomplished service of the OSC on Registrant on or about July 31, 2021. I also find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the DI's Declaration, the Government's written representations, and my review of the record, I find that neither Registrant, nor anyone purporting to represent Registrant, requested a hearing, submitted a written statement while waiving Registrant's right to a hearing, or submitted a corrective action plan. Accordingly, I find that Registrant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

Findings of Fact

Registrant's DEA Registration

Registrant is the holder of DEA Certificate of Registration No. FS0290875 at the registered address of 3985 Oneida Street, Suite 204, New Hartford, New York 13413. RFAAX 1 (Certificate of Registration). Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules IIN, IIIN,[1] IV and V as a practitioner. *Id.*

The Status of Registrant's State License

On October 16, 2020, the New York State Board for Professional Medical Conduct (hereinafter, the Board) issued a Statement of Charges against

[1] Registrant only is authorized to dispense non-narcotic controlled substances in Schedules II and III.

Registrant. RFAAX 3, App. C, at 10 and 12. The Statement of Charges alleged that on or about February 12, 2013, Registrant voluntarily entered into a Consent Order with the Board, in which Registrant ''did not contest pending professional misconduct charges alleging negligence on more than one occasion in violation of N.Y. Educ. Law § 6530(3) and [failure] to maintain records in violation of N.Y. Educ. Law § 6530(32).'' *Id.* at 10. Further, according to the Statement of Charges, the Consent Order stated that Registrant ''stipulated that her failure to comply with any conditions of the [Consent Order] [would] constitute misconduct as defined by N.Y. Educ. Law § 6530(29).'' *Id.* The Statement of Charges stated that the Consent Order was approved on or about February 15, 2013, and became effective on or about February 26, 2013. *Id.* According to the Statement of Charges, the Consent Order required that Registrant remain in continuous compliance with various state laws and regulations and that Registrant cooperate fully with any administration and enforcement, or investigation by the Office of Professional Medical Conduct (hereinafter, OPMC). *Id.* at 10–11. The Statement of Charges stated that the Consent Order also imposed various penalties, including censure, reprimand, license limitation, and probation. *Id.* at 10. According to the Statement of Charges, Registrant violated the terms of the Consent Order when she: Failed to renew her registration with the New York State Education Department after her registration expired at the end of March 2020; failed to update her New York State Physician Profile within the six months prior to the expiration of her registration; failed to fully cooperate with an investigation from OPMC; failed to respond to various correspondences from OPMC; failed to provide records requested from OPMC; and failed to schedule and attend an interview with OPMC.[2] *Id.* at 11. On January 28, 2021, the Board's Order sustained the charge that Registrant committed professional misconduct by violating conditions imposed on her medical license and revoked Registrant's medical license. *Id.* at 3 and 7.

According to New York's online records, of which I take official notice, Registrant's New York medical license is still revoked.[3] Office of the Professions Verification Searches, *www.op.nysed.gov/opsearches.htm* (last visited date of signature of this Order). Accordingly, I find that Registrant is not currently licensed to engage in the practice of medicine in New York, the state in which she is registered with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71,371 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . ., to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton,* 43 FR at 27,617.

According to the New York Controlled Substances Act (hereinafter, the Act), ''[i]t shall be unlawful for any person to manufacture, sell, prescribe, distribute, dispense, administer, possess, have under his control, abandon, or transport a controlled substance except as expressly allowed by this article.'' N.Y. Pub. Health Law § 3304 (McKinney 2022). Further, the Act defines a ''practitioner'' as ''[a] physician . . . or other person licensed, or otherwise permitted to dispense, administer or conduct research with respect to a controlled substance in the course of a licensed professional practice . . . .'' *Id.* at § 3302(27). Finally, New York regulations state that ''[a] prescription for a controlled substance may be issued only by a practitioner who is . . . authorized to prescribe controlled substances pursuant to his licensed professional practice . . .'' N.Y. Comp. Codes R. & Regs. tit. 10, 80.64 (2022).

Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice medicine in New York. As already discussed, a physician must be a licensed practitioner to dispense a controlled substance in New York. Thus, because Registrant lacks authority to practice medicine in New York and, therefore, is not authorized to handle controlled substances in New York, Registrant is not eligible to maintain a DEA registration. Accordingly, I will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. FS0290875 issued to Jennifer Smith, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of

[2] The Board detailed the grounds in which OPMC had begun to investigate Registrant in its Determination and Order (hereinafter, Order) issued January 28, 2021. *Id.* at 3 and 6–7. According to the Order, OPMC had begun to investigate Registrant because ''it had reasonable grounds to believe that [Registrant] was impaired to practice medicine by drugs or a physical and/or psychiatric condition.'' *Id.* at 6.

[3] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration of finding of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.usdoj.gov.*

Jennifer Smith, M.D. to renew or modify this registration, as well as any other pending application of Jennifer Smith, M.D., for additional registration in New York. This Order is effective May 11, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–07700 Filed 4–8–22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 21–17]

Gilbert Y. Kim, D.D.S.; Decision and Order

On May 26, 2021, a former Assistant Administrator, Diversion Control Division, of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Gilbert Y. Kim, D.D.S. (hereinafter, Respondent) of Oakland Gardens, New York. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (OSC), at 1 and 3. The OSC proposed the denial of Respondent's application for DEA Certificate of Registration No. W20055916C (hereinafter, COR or registration) and the denial of any applications for any other DEA registrations pursuant to 21 U.S.C. 824(a)(5) because Respondent has been excluded from participation in Medicare, Medicaid, and all federal health care programs pursuant to 42 U.S.C. 1320a–7(a). *Id.* at 1.

On June 7, 2021, Respondent timely requested a hearing, which commenced (and ended) on August 17, 2021, at the DEA Hearing Facility in Arlington, Virginia with the parties, counsel, and witnesses participating via video teleconference (VTC). On October 12, 2021, Administrative Law Judge Teresa A. Wallbaum (hereinafter, the ALJ) issued her Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, Recommended Decision or RD). By letter dated November 8, 2021, the ALJ certified and transmitted the record to me for final Agency action. In the letter, the ALJ advised that neither party filed exceptions. Having reviewed the entire record, I adopt the ALJ's rulings, findings of fact, as modified, conclusions of law, and recommended sanction with minor modifications, where noted herein.*[A]

*[A] I have made minor modifications to the RD. I have substituted initials or titles for the names of witnesses and patients to protect their privacy and I have made minor, nonsubstantive, grammatical changes and nonsubstantive, conforming edits. Where I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the ALJ's opinion, I have noted the edits with an asterisk, and I have included specific descriptions of the modifications in brackets following the asterisk or in footnotes marked with a letter and an asterisk. Within those brackets and footnotes, the use of the personal pronoun ''I'' refers to myself—the Administrator.

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

Teresa A. Wallbaum, Administrative Law Judge, October 12, 2021

*[B] Respondent proceeded *pro se* throughout the entire case.[1] Respondent timely filed a Request for Hearing. ALJ Ex. 2 at 1. A Prehearing Conference was conducted on July 13, 2021, by video teleconference (VTC). A Merits Hearing of the OSC allegations was conducted on August 17, 2021, via VTC at the DEA Hearing Facility in Arlington, Virginia. The Government filed a Post-Hearing Brief on October 6, 2021.

The ultimate issue in these proceedings is whether Respondent's application should be denied pursuant to 21 U.S.C. 823 and 824(a)(5) based upon his exclusion from participation in Medicare, Medicaid, and all federal health care programs pursuant to 42 U.S.C. 1320a–7(a). After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

I. Findings of Fact

A. Allegations

The Government alleges that the denial of Respondent's application is supported by incontrovertible record evidence that he has been excluded from participation in Medicare, Medicaid, and all federal health care programs. ALJ Ex. 1 at 1. Specifically, the Government alleges that judgment was entered against Respondent in the United States District Court for the Eastern District of New York (the District Court) after pleading guilty to one count of Conspiracy to Commit Health Care Fraud in violation of 18 U.S.C. 1349. *Id.* at 1–2 (citing *United States* v. *Gilbert Kim,* No. 1:11–CR–073 (E.D.N.Y. May 12, 2014)). The Government alleges that, due to this conviction, the U.S. Department of Health and Human Services, Office of Inspector General (HHS/OIG) mandatorily excluded Respondent from participation in Medicare, Medicaid, and all federal health care programs pursuant to 42 U.S.C. 1320a–7(a).[2] ALJ Ex. 1 at 2. According to the Government, this exclusion was effective as of August 29, 2014,[3] and runs for a period of ten years.[4] ALJ Ex. 1 at 2.

B. Stipulations

The parties mutually agreed upon the following stipulations, and they were conclusively accepted as fact in the proceedings:

1. On or about June 9, 2020, Respondent applied to DEA for registration as a practitioner in Schedules II through V with a proposed registered address of 22902 Horace Harding Expressway, Fl. 2, Oakland Gardens, New York 11364.

2. Respondent's Application was assigned Control Number W20055916C.

3. Respondent was previously registered with DEA as a practitioner under DEA Certificate of Registration No. AK2569284.

4. DEA Certificate of Registration No. AK2569284 was surrendered for cause on or about August 15, 2018.

5. On or about May 12, 2014, judgment was entered against Respondent in the United States District Court for the Eastern District of New York based on his conviction on one count of ''Conspiracy to Commit Health Care Fraud,'' in violation of 18 U.S.C. 1349.

6. By letter dated August 29, 2014, the U.S. Department of Health and Human Services, Office of Inspector General (HHS/OIG), mandatorily excluded Respondent from participation in Medicare, Medicaid, and all federal health care programs pursuant to 42 U.S.C. 1320a–7(a).

7. Respondent's exclusion under 42 U.S.C. 1320a–7(a) was effective on September 18, 2014, and runs for a period of ten years.

8. Respondent is currently excluded from participation in a program pursuant to 42 U.S.C. 1320a–7(a).

9. By letter dated March 23, 2020, the Office of Professional Discipline of the New York State Education Department informed Respondent that he may resume the practice of Dentistry in the State of New York no earlier than March 29, 2020.

*[B] I have omitted a section of the RD's discussion of the procedural history to avoid repetition with my introduction.

[1] Respondent was advised during the Prehearing Conference that, under 21 CFR 1316.50, he had the right to seek representation by a qualified attorney at his own expense. Respondent was also advised that, if he continued to represent himself, he would be held to the same standards and procedural requirements of an attorney, including adherence to the procedural orders and rulings of this tribunal and to the procedural rules set forth in 21 CFR 1316.41–1316.68. ALJ Ex. 6 at 1, n.1. During the merits hearing, Respondent acknowledged that he had been so advised and confirmed that he wanted to proceed *pro se.* Tr. 8–9.

[2] Respondent has stipulated to the factual basis underlying this allegation. *See* Stip. 6.

[3] The OSC states that the exclusion was effective on August 29, 2014; however, per the HHS/OIG letter, the exclusion was effective on September 18, 2014. See Gov. Ex. 6.

[4] Respondent has stipulated to the factual basis underlying this allegation. *See* Stip. 7.

C. Government's Case-in-Chief

The Government's case-in-chief consisted of the testimony of a single witness, a DEA Diversion Group Supervisor (hereinafter, the GS). The GS testified that her duty station is the New York Field Division, located in New York City, where she has served in her capacity as a Group Supervisor for approximately one year. Tr. 24–25. Before the GS became a Group Supervisor, she was a Diversion Investigator for approximately six-and-a-half years. *Id.* at 25. As a Diversion Investigator, the GS's responsibilities included preventing and detecting the diversion of controlled substances through administrative, civil, and criminal investigations. *Id.* at 26. Additionally, the GS conducted scheduled investigations of DEA registrants. *Id.*

Respondent came to the GS's attention when a Diversion Investigator under her supervision was assigned his application for DEA registration. *Id.* at 29. Through the GS's testimony, the Government laid the foundation for introducing multiple exhibits in support of its allegations.[5] The parties agree, and the evidence demonstrates, that on April 25, 2014, Respondent pleaded guilty to one count of Conspiracy to Commit Health Care Fraud in violation of 18 U.S.C. 1349. Gov. Ex. 5; Stip. 5; Tr. 68. The HHS/OIG sent Respondent a letter informing him that he had been excluded from Medicare, Medicaid, and all federal health care programs for a period beginning on September 18, 2014 and lasting a minimum of ten years. Gov. Ex. 6; Tr. 31.

The GS testified that, on June 16, 2021, she ran a new search on a web page of the HHS/OIG and confirmed through that search that Respondent was excluded from Medicare, Medicaid, and all federal health care programs. Gov. Ex. 7; Tr. 38–39. The GS again searched the database the morning before her testimony and confirmed that Respondent was still excluded from Medicare, Medicaid, and all federal health care programs. Tr. 39.

The GS presented as an objective investigator, with no discernable motive to mislead, fabricate, or exaggerate. The testimony of this witness was primarily focused on the uncontroversial and unopposed introduction of documentary evidence and her contact with this case.[6] Her testimony was sufficiently detailed, plausible, and internally consistent to be afforded full credibility.

D. Respondent's Case

Respondent, proceeding *pro se,* presented his own testimony and offered eight exhibits in support of his case.[7] According to Respondent, he graduated from the University of Illinois College of Dentistry in 1983. *Id.* at 55. He obtained a license to practice dentistry in Illinois in 1983 and then a license in New York on or around 1986; however, Respondent only ever practiced in New York City. *Id.* at 55–56. Respondent practiced general dentistry and primarily did so in a solo practice. *Id.* at 57. Respondent is not board-certified. *Id.*

Respondent testified that prior to 2014, he had no criminal convictions. *Id.* Additionally, prior to 2014, Respondent had no disciplinary proceedings for his Illinois license, but he was disciplined once in New York. *Id.* Specifically, Respondent was disciplined in or around 1993 for using a dirty cup while doing mobile dentistry for a nonprofit. *Id.* at 57–58. Respondent blamed the incident on a child and explained that the child had taken a dirty cup from the garbage and returned it to the cuspidor. *Id.* Respondent received one year of probation and twenty-five hours of community service as discipline. *Id.* at 58.

Respondent admitted that he pleaded guilty to one count of Conspiracy to Commit Health Care Fraud in violation of 18 U.S.C. 1349. *Kim,* No. 1:11–CR–073; Stip. 5. Respondent was sentenced to one year of home confinement, three years of supervised release, and 300 hours of community service and ordered to pay $5,991,417.13 in restitution. Tr. 71–73; Gov. Ex. 5 at 2–5. Respondent's New York Dentistry license was suspended for three years and was reinstated on March 29, 2020. Stip. 9; Resp't Ex. 1 at 2.

According to Respondent's own exhibits from his criminal case, Respondent was a manager in the conspiracy. Prior to Respondent's sentencing, he was described as ''an active manager at the clinics with deep involvement in the planning and execution of the scheme.'' Resp't Ex. 3 at 4.[8] ''For example, [Respondent] was present at a meeting with other managers at the clinic where they discussed how to bill Medicare for lesion removals, when, in fact, they would only provide cosmetic facial services that would entice beneficiaries to come to the clinic.'' *Id.; see also* Resp't Ex. 4 at 8. Additionally, Respondent's Presentence Report (PSR) stated that he was a manager of the clinics and that he managed employees involved in the conspiracy. Resp't. Ex. 4 at 7. During his criminal proceedings, Respondent did not object to these statements in his PSR. *Id.*

During these administrative proceedings, Respondent's description of the events behind his conviction was unclear and, at times, internally inconsistent and inconsistent with his own exhibits. Respondent stated that he had to help his father with the clinic, so he assisted with signing checks for rent and electrical bills, while also contributing his own money to keep the business solvent. Tr. 60–62; *see also* Resp't Ex. 4 at 10 (''[There] was a shortage of money. I had to give the money to the operating'' expenses) (cleaned up). Despite the record from his criminal trial, however, Respondent maintained that he was not a manager at the clinic. Tr. 60 (denying prosecutor's unopposed claim at sentencing that Kim was a manager—''I had no idea'') and 61–62 (''I was not in payroll on management, so called management''). Respondent explained the discrepancy between his trial documents and his hearing testimony by stating that he ''was not 100 percent truthful on [being a manager],'' when he pleaded guilty. *Id.* at 100. Respondent further stated that he was practicing dentistry outside of the clinic while his wife, E.K., and sister, M.L., were responsible for the management work at the clinic. *Id.* at 61.

While acknowledging his guilty plea, Respondent nonetheless denied any direct role in the conspiracy. Rather, when asked about his culpability, he responded: ''I don't know what conspiracy meant, but I think I was a—you know, I hear it, what's going on. I didn't stop them.'' *Id.* at 70; *see also id.* at 64 (''I was aware what's going on, but I was not actively involved at meetings.''); *but see id.* at 68 (''I'm not an attorney, but I'm assuming that I was a manager, on that indictment, I was a

[5] Specifically, the GS's testimony laid the foundation for Government Exhibits 2 and 4–7. *Id.* at 26–28, 34–36, 36–38, 31–33, 38–40. Prior to the GS's testimony, the Government moved for the admission of Government Exhibits 1 and 3 as self-authenticating documents certifying the accuracy of DEA records regarding Respondent's DEA registration status and history. *Id.* at 17.

[6] Respondent did not object to the admission of any exhibit offered by the Government. Tr. 20–21, 28, 33, 36–37, 40.

[7] Respondent's exhibits 1, 3, and 4–7 were admitted. Tr. 77–93. Respondent's exhibits 2 and 8 were excluded. *Id.* at 82 and 93.

[8] Respondent's Exhibit 3 is the letter submitted by the prosecutor in his criminal case pursuant to § 5K1.1 of the United States Sentencing Guidelines. While Respondent did not sign the letter, he accepted the benefit of the letter, which was a sentence reduction for providing substantial assistance to the government. Moreover, the § 5K1.1 letter is based upon, and repeatedly cites, ¶ 20 of the Presentence Report, to which Respondent did not object during his sentencing proceedings. Resp't. Ex. 4 at 7.

manager.''). He repeatedly denied understanding the Medicare fraud. *Id.* at 53 (''I was not involved in the billing. I don't know what the medical billing was.''); 60 (''And then also the Medicare billing. And that, I have no idea.''); 62–66 (''I don't know completely'' about billing practices of other members at the clinic); 69 (''to this day, I don't know what Medicare, you know, medical billing is about'') (''still I—scratching my head'' about the billing); 101 (''Again, I said, you know, even medical billing, I, to this day I have no idea what, you know, the billing code is, I have no idea.''); 109 (''. . . but Medicare billing, and you know, that part, I have no idea up to this point'').

When asked whether he was ''present during management meetings where the scheme was discussed,'' Respondent answered: ''I have to say no, little bit yes.'' *Id.* at 64. When asked to clarify that answer, Respondent testified that he ''knew what's going on.'' *Id.* at 65. Specifically, he testified that he learned about the fraud from conversations with his wife and sister. *Id.* at 66. Later in his testimony, however, Respondent stated that he had pleaded guilty because at ''the early meeting, I was a participant, fully participant on that.'' *Id.* at 69.

Respondent pleaded guilty to health care fraud involving luring Medicare beneficiaries to the clinics for massages, facials, lunches, dancing classes, and other services, inducing those beneficiaries to provide their Medicare numbers, and billing Medicare for services that were not provided or medically necessary (Gov. Ex. 4 at 5); however, at the hearing, Respondent defined the fraud as narrowly involving a decision to save money by not hiring enough physical therapists to justify the treatment. Tr. 63–67. He testified that he tried to convince his family members to do the billing correctly but they refused. *Id.* at 66–67 (''I said do it correctly, you know . . . That's what I was trying to tell them, but they did not listen. So I did not stop them.''). Because he was ''very concerned,'' Respondent also spoke to his father about the billing practices and suggested the clinic use a third-party billing company. *Id.* at 67–68. According to Respondent, his wife and sister—the managers of the clinic—''never listened to [his] advice.'' *Id.* at 68.

Respondent repeatedly explained that he pleaded guilty because of his family. *Id.* at 19 (''I had to plead guilty to minimize any trauma.'') (cleaned up); 53 (''I should have stopped the business' so-called rehab. However, you know, I have to admit that I'm part of it, because if I had not done that I would have pointed out my wife, my sister, and would traumatize all the family. So I had to plead guilty.''); 54 (''I pled guilty to minimize the financial and emotional, you know, trauma to my family. And I decided that I, you know, needed to avoid a costly and lengthy trial.''). The only wrongdoing to which Respondent admitted throughout his testimony was that he should have stopped his family, not that he was a manager in the clinic, consistent with his guilty plea. *Id.* at 63 (''I was trying to stop them''); 65 (''I knew what's going on. I couldn't stop them''); 71–72 (''I don't know what conspiracy meant, but I think I was a—you know, I hear it, what's going on. I didn't stop them . . . I should have stopped them, but I didn't—I couldn't stop them, you know. That was my involvement'').

On cross-examination, Respondent admitted that he failed to disclose that the New York State Dental Board placed him on probation in 1993 on two of his DEA applications for registration. *Id.* at 106–108. Respondent confirmed that he submitted an application in 2016 and in 2020 for DEA registration and that he did not disclose his probation in 1993 in response to the following question on both applications: ''Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' *Id.;* Gov. Ex. 1 at 1; Gov. Ex. 3 at 2. Respondent acknowledged that he provided false responses on both applications and attempted to excuse his responses by stating that he misunderstood the question. Tr. 107–108.

Additionally, Respondent admitted that he did not object to being classified as a manager in his PSR and during his sentencing hearing. *Id.* at 109–110. Respondent insisted that he was telling the truth now, *i.e.,* that he was not actually a manager at the clinic. *Id.* at 110–111. He explained that he was classified as a manager and given a role enhancement as a part of his sentence because he was ''not 100 percent truthful'' during his sentencing hearing. *Id.;* Resp't Ex. 4 at 9.

According to Respondent, he has been practicing dentistry part-time and seeing many pro-bono patients since his dentistry license was reinstated in March 2020. Tr. 77. While he acknowledged that it is possible to continue practicing without a DEA registration, he compared it to sending a solider to war without any bullets. *Id.* at 104.[9]

As for remedial measures, Respondent testified that his wife and family are not involved in his dental practice since they were ''the biggest issue.'' Tr. 101. He is the sole manager and is ''in total control'' of the finances and billing practices. *Id.* at 101–102. He stated that if it were not for his family at the clinic, he would have done the billing 100 percent correctly,[10] so his sole remedial measure is not working with his family. *Id.*

II. Discussion

The Government opposes Respondent's COR application on the ground that he has been excluded from participating in Medicare, Medicaid, and all federal health care programs. ALJ Ex. 1 at 1. *[C] [In its OSC, the Government relies upon grounds Congress provided to support revocation/suspension, not denial of an application. Prior Agency decisions have addressed whether it is appropriate to consider a provision of 21 U.S.C. 824(a) when determining whether or not to grant a practitioner registration application. For over forty-five years, Agency decisions have concluded that it is. *Robert Wayne Locklear, M.D.,* 86 FR at 33744–45 (collecting cases); *see also, William Ralph Kincaid.* In *Robert Wayne Locklear, M.D.,* the former Acting Administrator stated his agreement with the results of these past decisions and reaffirmed that a provision of section 824 may be the basis for the denial of a practitioner registration application. 86 FR at 33745. He also clarified that allegations related to section 823 remain relevant to the adjudication of a practitioner registration application when a provision of section 824 is involved. *Id.*

Accordingly, when considering an application for a registration, I will

[9] Respondent also suggested that he was being denied a COR because of his race. Respondent's claim was premised on two arguments. First, Respondent offered a motion filed by a co-defendant alleging selective prosecution based on race. Resp't Ex. 8 for identification. That motion—which was not accepted into evidence—did not relate to Respondent and was apparently never ruled upon by the court handling the criminal proceedings. Second, Respondent referenced an unnamed ''Caucasian'' dentist who he claimed was banned for life from participation in Medicare and Medicaid but was able to obtain a new DEA registration number. Tr. 90. This claim had no relationship to Respondent's Exhibit 8 for identification, which did not reference the unnamed dentist, nor was Respondent able to identify the unnamed dentist or provide any documentary evidence to support his claim.

[10] As previously discussed, Respondent testified multiple times that he has no understanding of medical billing. Tr. 60, 69, 101, 109.

*[C] I have substituted the RD's language assessing the application of the revocation grounds to my assessment of an application under 21 U.S.C. 823(f) in accordance with recent decisions.

consider any actionable allegations related to the grounds for denial of an application under 823 and will also consider any allegations that the applicant meets one of the five grounds for revocation or suspension of a registration under section 824. *Id. See also Dinorah Drug Store, Inc.,* 61 FR 15972, 15973–74 (1996).

A. 21 U.S.C. 823(f): The Five Public Interest Factors

Pursuant to section 303(f) of the Controlled Substances Act (hereinafter, CSA), ''[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Section 303(f) further provides that an application for a practitioner's registration may be denied upon a determination that ''the issuance of such registration . . . would be inconsistent with the public interest.'' *Id.* In making the public interest determination, the CSA requires consideration of the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f).

In this case, it is undisputed that Respondent holds a valid state dentistry license and is authorized to dispense controlled substances in the State of New York where he practices.

Because the Government has not alleged that Respondent's registration is inconsistent with the public interest under section 823, and although I have considered 823, I will not analyze Respondent's application under the public interest factors. Therefore, in accordance with prior agency decisions, I will move to assess whether the Government has proven by substantial evidence that a ground for revocation exists under 21 U.S.C. 824(a).

Regarding the revocation/suspension grounds alleged in the OSC, the CSA provides, in pertinent part: ''A registration pursuant to section 824 of this title to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant: . . . (5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of Title 42.'' 21 U.S.C. 824(a)(5).][11]

B. Exclusion From Participation in a Federal Health Care Program

The CSA grants the Agency discretion to [revoke a respondent's registration] if he ''has been excluded (or directed to be excluded) from participation in a program pursuant to [42 U.S.C. 1320a–7(a)].'' 21 U.S.C. 824(a)(5) (2012). *See supra.* Section 1320a–7 comprises the exclusion of individuals or entities by the Secretary of the U.S. Department of Health and Human Services HHS from participating in federal health care programs. 42 U.S.C. 1320a–7 (2012). A federal health care program is (1) a plan or program providing health benefits and which is funded in some way by the U.S. Government (42 U.S.C. 1320a–7b(f)); or (2) a state health care program or plan receiving certain approval or funding from the U.S. Government (42 U.S.C. 1320a–7(h)). Under clear DEA precedent, Medicare and Medicaid programs qualify as ''federal health care programs,'' exclusion from which can constitute a basis for revocation of a registration. *See, e.g., Daniel Ortiz-Vargas, M.D.,* 69 FR 62095, 62095–96 (2004); *Joseph M. Piacentile, M.D.,* 62 FR 35527, 35527–28 (1997); *Anibal P. Herrera, M.D.,* 61 FR 65075, 65077 (1996); *Suresh Gandotra, M.D.,* 58 FR 64781, 64782 (1993); *George D. Osafo, M.D.,* 58 FR 37508, 37509 (1993).

Specifically, subsection (a) of § 1320a–7, the part of the statute referenced by 21 U.S.C. 824(a)(5), dictates when HHS is required to exclude individuals or entities.[12] *Id.* § 1320a–7(a) (''The Secretary *shall* exclude the following individuals and entities from participation in any [f]ederal health care program . . . .'') (emphasis added). There are four instances requiring mandatory exclusion: (1) Conviction of a criminal offense ''related to the delivery of an item or services under [42 U.S.C. 1395 *et seq.*] or under any [s]tate health care program''; (2) conviction, ''under [f]ederal or [s]tate law,'' related to patient ''neglect or abuse'' connected ''with the delivery of a health care item or service[;] (3) [f]elony conviction related to health care fraud''; and ''(4) [f]elony conviction related to . . . the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.'' *Id.* The unambiguous words of the CSA in 21 U.S.C. 824(a)(5) provide that a practitioner's registration ''may be suspended or revoked'' if the practitioner ''has been excluded'' from participating in a program pursuant to 42 U.S.C. 1320a–7(a). 21 U.S.C. 824(a)(5). DEA has strictly interpreted this provision and acknowledged that the Administrator has discretionary power to suspend or revoke a registration only when the practitioner has been mandatorily excluded from a federal health care program under subsection (a) of 42 U.S.C. 1320a–7. *See, e.g., Terese, Inc., d/b/a Peach Orchard Drugs,* 76 FR 46843, 46847 (2011); *Herrera,* 61 FR at 65077; *Gandotra,* 58 FR at 64782; *Nelson Ramirez-Gonzalez, M.D.,* 58 FR 52787, 52788 (1993). [The Agency has consistently found that] the misconduct mandating exclusion need not relate to controlled substances in order to provide the Administrator with the power to suspend or revoke (or in this case deny an application for) a COR. *Ibrahim Al-Qawaqneh, D.D.S.,* 86 FR 10354, 10356 (2021) (registrant excluded due to a conviction for illegal remuneration); *Jeffrey Stein, M.D.,* 84 FR 46968, 46973 (2019) (registrant excluded due to a conviction for tax evasion); *Melvin N. Seglin, M.D.,* 63 FR 70431, 70433 (1998) (registrant excluded due to a conviction for vendor fraud); *Osafo,* 58 FR at 37508 (registrant excluded due to conviction for second degree larceny). Additionally, the Agency is generally unwilling to consider the impact of revocation or suspension on the community when exercising the discretionary authority to grant/deny/revoke/suspend a practitioner COR under the CSA. *Linda Sue Cheek, M.D.,* 76 FR 66972, 66972 (2011); *see also, Gregory D. Owens, D.D.S.,* 74 FR 36751, 36757 (2009).

When DEA alleges that a practitioner has been mandatorily excluded from a federal health care program under 42 U.S.C. 1320a–7a, and thus seeks to impose a COR sanction, the Government bears the burden to prove that such an exclusion occurred. *Jin,* 77 FR at 35023; *see also,* 21 CFR 1301.44(d) (2018) (''At [a] hearing for the denial of a [COR], the [Government] shall have the burden of proving that the requirements for such registration . . . are not satisfied.''). A mandatory exclusion, however, does not mandate revocation/suspension or denial of an application; the Agency

[11] [To avoid repetition, I have omitted the RD's footnote which briefly discussed how, in accordance with prior Agency decisions, analysis of the public interest factors is unnecessary when the Government has not alleged that Respondent's registration is inconsistent with the public interest under section 823.]

[12] In contrast to subsection (a), subsection (b) of 42 U.S.C. 1320a–7 provides sixteen discretionary grounds of exclusion from health care programs. 42 U.S.C. 1320a–7(b) (2012).

retains authority to independently weigh the evidence presented and exercise discretion. *Stein,* 84 FR at 46970 [ ]. Accordingly, DEA is not required to deny Respondent's COR application merely because he is subject to a mandatory exclusion. *Id.*

In the instant case, it is undisputed that Respondent was excluded from participation in Medicare, Medicaid, and all federal health care programs under the mandatory authority of 42 U.S.C. 1320a–7a. Stip. 6; Gov. Ex. 6. Consequently, under § 824(a)(5), it is within the discretion of the Agency to determine, based on the entire record, [the consequence of] his exclusion from federal health care programs [on his registration or application for a registration]. *See Narcisco A. Reyes, M.D.,* 83 FR 61678, 61681 (2018) (holding that where the Government has demonstrated the requisite mandatory federal health care program exclusion(s), it has satisfied its *prima facie* case, shifting the burden to the respondent).

Accordingly, in review of the evidence of record, including the stipulations of the parties, OSC Allegations 1, 2, and 3 are *sustained.*[*D]

III. Sanction

Because the Government has met its *prima facie* burden, the Respondent now has the burden to show that registration should be granted as a matter of discretion, *i.e.,* he must show that he can be entrusted with a registration due to his unequivocal acceptance of responsibility and remedial measures to ensure the misconduct will not recur. *See, e.g., Salvatore Cavaliere, D.O.,* 85 FR 45657, 45666 (2020); *Al-Qawaqneh,* 86 FR at 10356; *George Pursley, M.D.,* 85 FR 80162, 80187 (2020); *Garrett Howard Smith, M.D.,* 83 FR 18882, 18910 (2018); *Heavenly Care Pharmacy,* 85 FR 53402, 53420 (2020); *Suntree Pharmacy and Suntree Medical Equipment, LLC,* 85 FR 73753, 73776 (2020); *Stein,* 84 FR at 49972; *Fred Samimi, M.D.,* 79 FR 18698, 18713 (2014). He must do so by unequivocally acknowledging his misconduct and accepting responsibility. *Al-Qawaqneh,* 86 FR at 10356 (collecting cases); *Stein,* 84 FR at 49972–73; *Mohammed Asgar, M.D.,* 83 FR 29569, 29572 (2018); *Lon F. Alexander, M.D.,* 82 FR 49704, 49728 (2017) (collecting cases); *Jeffery M. Freesemann, M.D.,* 76 FR 60873, 60888 (2011) (collecting cases); *Ronald Lynch, M.D.,* 75 FR 78745, 78749 (2010); *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008).

''The degree of acceptance of responsibility that is required does not hinge on the respondent uttering 'magic words' of repentance, but rather on whether the respondent has credibly and candidly demonstrated that he will not repeat the same behavior and endanger the public in a manner that instills confidence in the Administrator.'' *Stein,* 84 FR at 49973. Mere stipulation to facts without admitting to misconduct does not amount to an acceptance of responsibility. *Ajay S. Ahuja, M.D.,* 84 FR 5479, 5498 n.32 (2019); *see also Kaniz F. Khan-Jaffery, M.D.,* FR 45667, 45690 (2020) (holding that it was not enough for the respondent to simply acknowledge that she ''should have written more''). Minimization of misconduct undermines any acceptance of responsibility. *See Pursley,* 85 FR at 80188 (registrant acknowledged his unfamiliarity with governing regulations, but stated ''I don't think I left a lot of dead bodies laying around.''); *Arvinder Singh, M.D.,* 81 FR 8247, 8249–51 (2016) (registrant minimized conduct when he claimed he overbilled patients only 15 to 20 times, but District Court ordered him to pay more than $227,000 in restitution to approximately 250 payees); *Stein,* 84 FR at 46972–73 (respondent's assertion that his misdeeds had no effect on his patients held to indicate a minimization of his acceptance of responsibility rendering it less than unequivocal); *Lynch,* 75 FR at 78749 (Respondent's attempts to minimize misconduct held to undermine acceptance of responsibility); *Rose Mary Jacinta Lewis, M.D.,* 72 FR 4035, 4042 (2007) (registrant's dishonesty under oath undermined registrant's acceptance of responsibility). Blaming others for misconduct does not constitute acceptance of responsibility. *The Pharmacy Place,* 86 FR 21008, 21016 (2021) (no acceptance when registrant blamed computer software for her inability to have ''readily retrievable documents'' and failed to correct her conduct ''by providing DEA with accurate and complete log within a reasonable time following the inspection''); *Michael W. Carlton, M.D.,* 86 FR 10337, 10353 (2021) (no acceptance of responsibility when registrant blamed another member of the practice); *Hamada Makarita, D.D.S.,* 85 FR 45691, 45699 (2020) (no acceptance of responsibility when registrant blamed his conviction on false testimony of his former office manager and denied he ever wrote a prescription without a valid dental purpose). *But see Michele L. Martinho, M.D.,* 86 FR 24012, 24014, 24019–20 (2021) (Respondent met burden when she testified she accepted responsibility 100%, always referred to herself as a felon, repaid the bribes, amended her tax returns, paid the taxes on the money she took, and embarked upon an effort of ''restorative justice'' by engaging in 69 speaking engagements focused on real-world ethical decisions).

A. Acceptance of Responsibility

In the instant case, Respondent's testimony was not candid on the key issue of culpability.[13] His testimony was, at times, non-responsive, internally inconsistent, and inconsistent with his own exhibits. Importantly, this tribunal cannot ignore that Respondent pleaded guilty to conspiracy to commit health fraud that included a scheme to submit false and fraudulent claims to Medicare. In his criminal proceedings, Respondent did not object to his PSR's description of the fraudulent scheme, which was broader than merely hiring insufficient physical therapists. Resp't Ex. 3 at 3–4 (no physical therapy provided at the clinic; rather, patients were ''lured'' to the clinic and would ''receive medically unnecessary chiropractic services,'' facial treatments, free lunches, and classes). In these proceedings, however, he cast the scheme as merely a desire to save money by not hiring physical therapists. *See* Tr. 63 (''they were not doing all the fraud, but I think for the rehab, I think it was some of them were doing—bypassing—you know, trying to save money.''); *id.* (''I said to do it correctly, . . . you have to hire more physical therapists to justify the treatment.''). I may treat Respondent's failure to dispute these facts at a sentencing hearing as an admission of those specific facts. *See Uvienome Linda Sakor, N.P.,* 86 FR 50173, 50176 (2021).

Nor, in his criminal proceedings, did Respondent object to the assertion in the PSR that he was a manager who *actively* participated in the scheme, which resulted in the application of a

[*D] Moved conclusion and added headings.

[13] During his testimony, Respondent also acknowledged that he had twice failed to disclose a 1993 disciplinary action in New York that resulted in his license being placed on probation. Specifically, Respondent failed to answer the question on the application form which asks: ''Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' Tr. 106; Gov. Ex. 2 at 1. Respondent claimed that he did not understand the question (Tr. 106), although he did correctly answer that same question on his 2020 application. Gov. Ex. 2 at 1. While Respondent's false answers are not the focus of this inquiry, his failure to disclose the 1993 disciplinary proceeding [by his own admission] certainly gives this tribunal pause when evaluating whether he can be entrusted with a DEA registration.

sentencing enhancement based on that managerial role. *See* Resp't Ex. 3 at 4; Resp't Ex. 4 at 7–8; *see also* Tr. 96 (stating this assertion was inaccurate). According to the PSR, that active participation included a meeting with other managers ''where they discussed how to bill Medicare for lesion removals, when, in fact, they would only provide cosmetic facial services that would entice beneficiaries to come to the clinic.'' Resp't Ex. 3 at 4 (citing PSR ¶ 20); *see also* Resp't Ex. 4 at 7 (sentencing transcript, noting Respondent had not objected to nor did he object to PSR ¶ 20). But in these proceedings, Respondent repeatedly denied being in any meetings (Tr. 64–66; 98–99), although he subsequently admitted, at least obliquely, that he had participated in the ''early meeting.'' Tr. 69. On this point, Respondent testified that he was ''not 100 percent truthful'' in his criminal proceedings about his managerial role. *Id.* at 100 and 110–111. That admission alone—that he lied under oath in his criminal proceedings—strongly supports the conclusion that the Agency cannot entrust Respondent with a DEA COR.

More generally, it is worth noting that, by pleading guilty, Respondent obtained a benefit of acceptance of responsibility and, ultimately, a sentence of one year of home confinement despite facing a Guideline Sentence of 63 to 78 months. Tr. 71; Resp't Ex. 4 at 9. His guilty plea in federal court saved him from significant prison time. In these proceedings, however, Respondent has attempted to distance himself from some of his admissions in the criminal proceedings—in particular, his failure to object to the PSR's description of him as a manager and active participant in the scheme. Tr. 110. Respondent's approach is inconsistent with acceptance of responsibility.

Indeed, throughout his testimony, Respondent had ample opportunity to take full and unequivocal responsibility for his misconduct. Yet repeatedly, when pressed on the details of his conviction, Respondent failed to do so and, instead, made excuses and blamed others. He portrayed himself as simply a good son who was only trying to help his family run the clinic and so he began signing checks. Tr. 52. He claimed that he tried to stop his family when he realized they were defrauding federal health care programs, but did little more than have a few conversations with his family members and then gave up when they failed to listen. *Id.* at 67. Finally, he pleaded guilty to spare his family the emotional and financial trauma of a trial. *Id.* at 108–109. Overall, Respondent has seriously minimized his role in the conspiracy, portrayed himself as an innocent party who was protecting his family, and blamed others, including his wife. Thus, Respondent's statements fall far short of unequivocal acceptance of responsibility. *See Pursley,* 85 FR at 80188; *Singh,* 81 FR at 8249–51; *Stein,* 84 FR at 46972–73; *Lynch,* 75 FR at 78749; *Jacinta Lewis,* 72 FR at 4042.[14]

Thus, based on the evidence as detailed *supra,* I find that, in the face of the Government's *prima facie* case, Respondent has failed to unequivocally accept responsibility for his past misconduct; therefore, he cannot be trusted with a DEA COR. *See Singh,* 81 FR at 8250.

Having concluded that Respondent has failed to prove an unequivocal acceptance of responsibility, I need not address remedial measures. *Ahuja,* 84 FR at 5498 n.33; *Daniel A. Glick, D.D.S.,* 80 FR 74800, 74801 (2015); *Perry County Food & Drug,* 80 FR 70084, 70090–91 (2015); *Jones Total Health Care Pharmacy, LLC* v. *DEA,* 881 F.3d 823, 833 (2018). Nevertheless, even if remedial measures were considered, they would not change the result.

The burden is on Respondent to present sufficient evidence of his remedial measures. *See Scott D. Fedosky, M.D.,* 76 FR 71375, 71378 (2011) (declining to give weight to remedial measures where the respondent testified about them but did not present any corroborating evidence to support his claim). And even if Respondent does introduce specific evidence of remedial measures, registration will not be granted unless such measures demonstrate that he can be entrusted with a COR. *Jeri Hassman. M.D.,* 75 FR 8194, 8237 (2010) (denying a COR where the Agency found that the respondent had learned nothing from the remedial steps she had taken).

Here, Respondent's only claimed remedial measure is that he no longer works with his family and he will handle his own billing as he practices dentistry. But this is not a remedial measure; it is a promise that Respondent will not work with his family. It is not a particularly persuasive promise given Respondent's emphasis that his wife and sister never listened to him and his past history—by his own admission—that he simply acquiesces to them. *See, e.g.,* Tr. 67. Notably absent is any true remedial measure, such as hiring a third-party billing company or taking courses to improve his understanding of Medicare billing, to ensure he does not defraud federal health care programs again. Tr. 101–103. Thus, his promise to not work with his family again is unpersuasive and insufficient. Simply put, Respondent has not made an adequate showing that he can be trusted with a COR.

B. Specific and General Deterrence

*[E] In determining whether and to what extent imposing a sanction is appropriate, the Agency considers specific and general deterrence as well as the egregiousness of the offenses established by the Government's evidence. *David A. Ruben,* 78 FR 38363, 38384, 38385 (2013). The Agency has previously found [based on specific circumstances] that criminal convictions and sanctions by state licensing authorities can sufficiently deter physicians from engaging in misconduct, making the denial or of an application for, or revocation of, a COR unnecessary to achieve the goal of general deterrence. *Kansky J. Delisma, M.D.,* 85 FR 23845, 23854 (2020). Likewise, such punitive measures can suffice to deter the registrant or applicant from future misconduct, making revocation or denial of an application unnecessary to achieve specific deterrence. *Id.*

With respect to specific deterrence, Respondent failed in these proceedings to accept responsibility for his role in a four-year health care fraud conspiracy. He has minimized his responsibility,

[14] At the hearing, Respondent—for the first time and with no prior notice—suggested that DEA had an improper racial motive for denying his application for a COR. Tr. 90–92. Notably, Respondent provided no evidence to support his accusation. Respondent's Exhibit 8 for Identification (which was not admitted), was simply a motion filed by a co-defendant in Respondent's criminal case, alleging that non-Asian clinic practitioners were not prosecuted while Asian clinic practitioners were prosecuted. There is no court order granting this motion. Thus, this exhibit, at best, is an unproven allegation about the criminal case. Respondent's second claim—unrelated to Respondent's Exhibit 8 for Identification—alleged that there was a ''Caucasian'' registrant—whose name and specific circumstances are unknown—who received a COR. This is not admissible evidence. In any event, even if Respondent had presented evidence that he was selectively prosecuted by the Government, which he has not done, selective prosecution is not a defense on the merits. *See, e.g., United States* v. *Armstrong,* 517 U.S. 456, 463 (1996) (''Our cases delineating the necessary elements to prove a claim of selective prosecution have taken great pains to explain that the standard is a demanding one.''); *Wayte* v. *United States,* 470 U.S. 598, 607 (1985) (''In our criminal justice system, the Government retains 'broad discretion' as to whom to prosecute.''); *Martex Farms, SE* v. *EPA,* 559 F.3d 29, 32–33 (1st Cir. 2009) (applying criminal law principles to reject selective prosecution arguments in EPA enforcement action). Because I find that the Agency met its *prima facie* case, and because Respondent has failed to unequivocally accept responsibility, his unsupported claim cannot alter the outcome here.

*[E] Language omitted.

blamed others, and has no concrete remedial plan. Given these facts, the tribunal can only conclude that granting Respondent a COR would put the public at risk of Respondent's previous fraudulent behavior. Moreover, with respect to general deterrence, the Agency bears the responsibility to deter conduct similar to Respondent's past misconduct. *Ruben,* 78 FR at 38385. Granting a COR to an applicant who has neither unequivocally taken responsibility for his misconduct, nor demonstrated sufficient remedial measures to ensure such conduct will not happen again, would send a message to all that there will be few consequences to defrauding federal health care programs.

C. Egregiousness

Finally, this tribunal finds that Respondent's behavior was egregious. While Respondent did not divert controlled substances, defrauding federal health care programs is egregious. *See Stein,* 84 FR at 46973 (finding that the respondent's actions were egregious because he defrauded the government of taxes and misused his position of trust); *Ramirez-Gonzalez,* 58 FR at 52788 (''fraud perpetrated by the respondent casts doubt upon his integrity, and as such supports an action against his registration''); *Osafo,* 58 FR at 37509 (''Respondent's submission of fraudulent medical claims and subsequent convictions of larceny indicated that Respondent placed monetary gain above the welfare of his patients, and in so doing, endangered the public health and safety.''). Respondent engaged in a four-year conspiracy to defraud federal health care programs and the cost of that fraud, as reflected in the restitution amount imposed at his sentencing, was $5,991,417.13. Tr. 71–73; Gov. Ex. 5 at 2–5.

Moreover, the Agency ''relies heavily on a registrant's honesty and integrity 'to complete its mission of preventing diversion within such a large regulated population.' '' *Michael Jones, M.D.,* 86 FR 20728, 20731 (2021) (quoting *Stein,* 84 FR at 46974). ''Because DEA depends on the integrity of those it entrusts with controlled substance privileges, it takes a close look at a registrant's fraudulent activity.'' *Jones,* 86 FR at 20731 (citing *Ramirez-Gonzalez,* 58 FR at 52788). Even if the fraud does not involve controlled substances, ''fraudulent activity indicates that a registrant places monetary gain above the welfare of his patients, and in so doing, endangers the public health and safety.'' *Jones,* 86 FR at 20731–32 (internal quotations omitted); *see also Osafo,* 58 FR at 37509. Respondent's behavior demonstrates that he lacks integrity and cannot be trusted. In particular, his admission that he ''was not 100 percent truthful on [being a manager]'' when he pleaded guilty under oath (Tr. 100) is stark proof that the Agency cannot rely on Respondent's honesty as a registrant. His lack of remorse and acceptance of responsibility further shows that he does not recognize the seriousness of his actions, so he should not be entrusted with a COR.

Accordingly, it is herein respectfully recommended that Respondent's application for a DEA registration be *denied.*

Dated: October 12, 2021.

Teresa A. Wallbaum,
Administrative Law Judge.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824 and 823(f), I hereby deny the pending application for a Certificate of Registration, Control Number W20055916C, submitted by Gilbert Y. Kim, D.D.S. as well as any other pending application of Gilbert Y. Kim, D.D.S. for additional registration in New York. This Order is effective May 9, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–07717 Filed 4–8–22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

George Pharmacy, Inc.; Decision and Order

On August 1, 2019, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter, OSC) to George Pharmacy, Inc. (hereinafter, Registrant) of Dayton Beach, Florida. Government's Request for Final Agency Action (hereinafter, RFAA) Exhibit 1 (OSC). The OSC informed Registrant of the immediate suspension of its DEA Certificate of Registration Number FG5612127 (hereinafter, registration or COR) and proposed its revocation, the denial of any pending applications for renewal or modification of such registration, and the denial of any pending applications for additional DEA registrations pursuant to 21 U.S.C. 824(a)(4) and 823(f), because Registrant's ''continued registration is inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 824(a)(4) and 823(f)).

The OSC notified Registrant of its right to request a hearing on the allegations or to submit a written statement while waiving its right to a hearing, the procedures for electing either option, and the consequence of failing to elect either option. *Id.* at 10–11 (citing 21 CFR 1301.43).

In response to the OSC, Registrant filed a timely request for an administrative hearing. RFAAX 3 (Request for Hearing). After both parties filed prehearing statements, and Registrant moved to continue the hearing, the Chief Administrative Law Judge (hereinafter, Chief ALJ), set a hearing date of December 17, 2019, in Arlington, Virginia. RFAAX 4. On December 12, 2019, Registrant filed a motion to terminate proceedings, stating that Registrant ''respectfully withdraws its prior request for hearing and desires that the administrative hearing presently scheduled be cancelled, and the proceedings terminated.'' RFAAX 5. On the same day, the Chief ALJ granted Registrant's motion and cancelled the hearing. RFAAX 6.

On March 12, 2020, the Government forwarded an RFAA, along with the evidentiary record for this matter, to my office. Having considered the record in its entirety, I find that the record establishes, by substantial evidence, that Registrant committed acts rendering its continued registration inconsistent with the public interest. I further find that Registrant's conduct was egregious, and that Registrant's failure to respond to the Government's allegations weighs strongly against continuation of its registration. Accordingly, I conclude that the appropriate sanction is the revocation of Registrant's DEA registration.

I. Findings of Fact

A. Registrant's DEA Registration

Registrant was registered with DEA as a retail pharmacy in Schedules II through V under DEA registration number FG5612127, at the registered address of 948 Orange Avenue, Dayton Beach, Florida 32114–0000. RFAAX 8 (DEA Certificate of Registration). According to Agency records, this registration expired on February 28, 2019. *Id.*[1]

[1] Although Registrant's COR has expired, the Agency has discretion to adjudicate this Order to Show Cause to finality. *See Jeffrey D. Olsen, M.D.,* 84 FR 68474, 68479 (2019) (declining to dismiss an immediate suspension order as moot when the registrant allowed the subject registration to expire before final adjudication). As my predecessor identified in *Olsen,* ''[b]ecause nothing in the CSA

Continued

B. Government's Allegation That Registrant Dispensed Controlled Substances Unlawfully

In its RFAA, the Government alleged that Registrant violated federal and state law by ''fill[ing] prescriptions outside the usual course of professional practice and in violation of the minimum standard of care that governs the practice of pharmacy in the State of Florida.'' RFAAX 1, at 3. Specifically, the Government alleged that for a three-year period from December 12, 2016, to March 26, 2019, Registrant repeatedly filled controlled substance prescriptions for numerous patients without addressing or resolving red flags of drug abuse or diversion. *Id.*

To support this allegation, the Government submitted declarations of the DEA Diversion Investigator (hereinafter, DI) [2] and Group Supervisor (hereinafter, GS),[3] who were assigned to the investigation of Registrant, as well as a declaration of Dr. Thomas Hamilton, who was retained by the Government to opine on Registrant's dispensing patterns. *See* RFAAX 9 (Declaration of DI); RFAAX 10 (Declaration of GS); RFAAX 11 (Declaration of Dr. Thomas Hamilton). The Government also submitted copies of administrative subpoenas, prescription data, patient profiles, and google maps printouts showing the distances traveled by Registrant's customers. RFAAX 9, at App'x A–AY.

1. The Investigation

DI's and GS's declarations summarize DEA's investigation, including DEA's onsite inspections, subpoena requests, and meetings with Registrant.

i. October 31, 2018 Onsite Inspection

On October 31, 2018, GS, DI, and two additional DIs performed an onsite inspection of Registrant. RFAAX 9, at 1–3; RFAAX 10, at 1–2.[4] They spoke to Vivian Khalil, Registrant's owner, and Maher Hanna, Registrant's pharmacist-in-charge. *Id.* According to GS and DI, DEA asked Mr. Hanna to explain how Registrant resolves red flags. *Id.* Mr. Hanna stated that before filling a prescription, someone will obtain a copy of the patient's identification, contact the doctor's office to verify the prescription, check the patient's information on Florida's Prescription Data Monitoring Program (E–FORSCE), and check that the prescribing doctor's license is valid on the Florida Department of Health (hereinafter, DOH) website. *Id.* He stated that someone would make notes on the back of the prescription (including indicating who verified the prescription) and attach a printed copy of the patient's E–FORSCE report to the prescription. *Id.* All of the due diligence that Registrant's pharmacists perform is noted on the back of the prescriptions. *Id.* As long as the physician's license is legitimate, Registrant would fill the prescription. *Id.* Mr. Hanna asked the DEA what other red flags would have to be addressed ''if the doctor is legitimate and the script is legitimate.'' *Id.* Mr. Hanna stated that checking E–FORSCE and DOH was enough due diligence. *Id.*

According to GS and DI, DEA warned Mr. Hanna that Registrant had been filling prescriptions for controlled substances in the face of obvious red flags of abuse and diversion. *Id.* DEA also questioned Mr. Hanna and Mrs. Khalil about the high cash payments made by Registrant's patients, as well as the long distances traveled by Registrant's customers to obtain and fill their prescriptions. *Id.* DEA also warned Mr. Hanna and Mrs. Khalil about the large quantities of hydromorphone prescriptions that Registrant purchased. *Id.* In response, Mr. Hanna and Mrs. Khalil asked for one more chance and the opportunity to take continuing education classes. *Id.*

ii. November 2018 Administrative Subpoena

On November 7, 2018, DEA served an administrative subpoena on Registrant for pharmacy records and patient profiles, including but not limited to due diligence documentation, prescriptions, electronic dispensing logs, and other files related to the dispensing of controlled substances for certain patients between November 1, 2015, and October 31, 2018. RFAAX 9, App'x B (November 2018 Administrative Subpoena). In approximately February 2019, DEA hired Dr. Thomas E. Hamilton as a pharmacy expert in this case. *Id.* at 3. DEA provided Dr. Hamilton with Registrant's dispensing log, prescriptions, patient profiles, and E–FORSCE reports for the patients listed in the November 7, 2018 subpoena. *Id.*

iii. March 12, 2019 Meeting With Registrant

On March 12, 2019, GS, DI, and another DI visited Registrant again and spoke with both Mrs. Khalil and Mr. Hanna. RFAAX 9, at 3–4; RFAAX 10, at 3. At this meeting, DI told Mrs. Khalil and Mr. Hanna that DEA had hired a Florida pharmacy expert to review prescriptions and patient profiles of some of Registrant's customers. *Id.* DI explained Dr. Hamilton's expert opinion about Registrant's dispensing behavior. *Id.* In particular, DI stated that Dr. Hamilton had identified numerous red flags with many of the prescriptions that Registrant had filled, and found no documentation supporting adequate resolution of these red flags. *Id.* In response, Mr. Hanna informed DI that Registrant had stopped filling prescriptions for those patients whose prescriptions were the subject of Dr. Hamilton's opinion (including Patients J.Y., J.S., C.A., L.K., A.O., M.S., M.J., A.M., K.S., and L.S.). *Id.*

DI told Mr. Hanna and Mrs. Khalil that DEA was pursuing administrative action for the revocation of Registrant's COR and asked them to surrender Registrant's COR. *Id.* Mr. Hanna and Mrs. Khalil refused to surrender. *Id.*

iv. Further Investigation in April and July 2019

Upon reviewing Registrant's E–FORSCE report, DEA identified several additional customers whose prescriptions presented red flags of abuse and diversion, such as large cash payments and long distances traveled. *See* RFAAX 9, at 4–5. DEA served additional administrative subpoenas and performed additional onsite inspections in order to obtain documents related to Registrant's dispensing to those additional patients. *Id.* at App'x C (April 22, 2019 Notice of Inspection Form); App'x D (July 15, 2019 Administrative Subpoena); App'x E (July 23, 2019 Notice of Inspection Form). DEA provided these additional materials to Dr. Hamilton. *Id.* at 5.

prohibits an individual or an entity from applying for a registration even when there is . . . a history of having a registration suspended or revoked[,]. . . . having a final, official record of allegations, evidence, and the Administrator's decisions regarding those allegations and evidence, assists and supports future interactions between the Agency and the registrant or applicant.'' *Id.* Here, absent a final adjudication, there would be no final record of the allegations and evidence from this matter. Adjudicating this matter to finality will create an official record the Agency can use in any future interactions with Registrant's owners, employees, or other persons who were associated with Registrant. Moreover, ''a final adjudication is a public record of the Agency's expectations for current and prospective members of that community,'' which ''helps current and prospective registrants comply with the CSA and avoid ISOs/OSCs.'' *Id.*

[2] DI has been a DI for approximately two years. RFAAX 10, at 1. She was originally assigned to the Orlando District Office, but is currently assigned to the Jacksonville District Office. *Id.*

[3] GS has worked for DEA for approximately 30 years and has been a GS for approximately two years. RFAAX 10, at 1. He is currently assigned to the Orlando District Office of the Miami Field Division. *Id.*

[4] DEA presented Registrant with a Notice of Inspection Form, which Registrant signed. RFAAX 9, App'x A.

2. Dr. Hamilton's Unrebutted Expert Opinion

Dr. Hamilton is a doctor of pharmacy with 19 years of experience as a pharmacist. RFAAX 11, at 2, App'x A. He received his Doctor of Pharmacy from Nova Southeastern University in May 1999 and was licensed by the Florida Board of Pharmacy in August 1999. *Id.* He is also a member of the Broward County Pharmacy Association. *Id.*

Dr. Hamilton currently works as a full-time pharmacy manager with Publix Supermarkets and has worked for Publix for most of his career. RFAAX 11, at 1. His responsibilities include ensuring that the pharmacy follows all federal, state, and local regulations; overseeing the ordering and quality of inventory; reviewing patient records; reviewing prescriptions to ensure accuracy and identify possible interactions; and dispensing prescribed medications for patient care. *Id.* He also provides information to pharmacy customers regarding drug interactions, side effects, and proper dosage, and monitors patient profiles. *Id.*

From February 2006 until April 2014, Dr. Hamilton was a pharmacy supervisor with Publix Supermarkets, where he was responsible for the operation of 40 pharmacies. *Id.* During this time, his responsibilities consisted of opening new stores and ensuring that staff was properly trained and operating within the rules and standards set forth by the Florida Board of Pharmacy. *Id.* He was also involved in the analysis, evaluation, and purchase of other retail pharmacies from Key West to West Palm Beach. *Id.* While evaluating pharmacies, he inspected several key areas including their inventory, invoices, sales, and purchasing habits. *Id.*

i. Corresponding Responsibility and Course of Professional Practice in Florida

Dr. Hamilton opined that pharmacists have a corresponding responsibility to ensure that a prescription for a controlled substance is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. *Id.* at 2 (referencing 21 CFR 1306.04 (2022). Dr. Hamilton also opined that Florida pharmacists must ''exercise[e] sound professional judgment'' and ''attempt to work with the patient and the prescriber to assist in determining the validity of the prescription.'' *Id.* (referencing Fla. Admin. Code r. 64B16–27.831) (2022).[5] Additionally, Florida pharmacists must review every new and refill prescription to identify red flags of abuse and diversion, such as (a) Over-utilization or under-utilization; (b) Therapeutic duplication; (c) Drug-disease contraindications; (d) Drug-drug interactions; (e) Incorrect drug dosage or duration of drug treatment; (f) Drug-allergy interactions; (g) Clinical abuse/misuse. *Id.* (referencing Fla. Admin. Code r. 64B16–27.810 (2022)).[6]

Dr. Hamilton identified additional red flags that pharmacists must ''address or resolve'' prior to filling a prescription, including long distances traveled, cocktail medications, cash payments at inflated prices, inappropriate drug dosages and durations of treatment, and pattern prescribing. *Id.* at 3–5.

Long Distances Traveled

Dr. Hamilton opined that patients traveling extremely long distances to obtain or fill their controlled substances prescriptions is a well-known red flag of abuse or diversion that Florida pharmacists must ''address or resolve.'' *Id.* at 3.

Cocktail Medications

Dr. Hamilton opined that another common red flag of abuse that Florida pharmacists must ''address or resolve'' is when a physician prescribes ''cocktail medications.'' *Id.* He explained that cocktail medications are potent combinations of controlled substances that are widely known to be abused or diverted. *Id.* He further explained that one well-known cocktail medication is the ''Trinity'' cocktail, which is a combination of opioids (Schedule II controlled substances), benzodiazepines (Schedule IV controlled substances, such as alprazolam and clonazepam), and muscle relaxants (Schedule IV controlled substances, such as carisoprodol, or non-controlled drugs such as cyclobenzaprine). *Id.* Dr. Hamilton opined that these drugs are widely known to be abused, because when taken together, their pharmacological impact is similar to heroin. *Id.*

Cash Payments at Inflated Prices

Dr. Hamilton opined that another red flag of abuse or diversion that Florida pharmacists must ''address or resolve'' is when patients are willing to pay inflated prices for their prescriptions with cash. *Id.* He explained that when a patient is willing to pay for their prescriptions at prices that exceed what other pharmacies would charge, a Florida pharmacist must be concerned that it is dispensing controlled substances to someone who is abusing or diverting the drugs. *Id.* Dr. Hamilton opined that a reasonable Florida pharmacist must also be suspicious for the same reasons when patients are paying cash for a large quantity of controlled substances. *Id.* He explained that between 2017 and 2019, other pharmacies in Florida sold hydromorphone for approximately $1.60 per pill and oxycodone for approximately $1.40[7] per pill. *Id.* Therefore, he opined that patients willing to pay in cash well above those prices is a red flag of abuse or diversion that Florida pharmacists must address or resolve. *Id.* For example, as discussed in more detail below, Registrant's customers often paid more than five times the prices charged at other Florida pharmacies, which Dr. Hamilton determined to be a red flag. *See supra,* I.B.2.ii. Dr. Hamilton opined that customers taking prescriptions for legitimate medical needs would not pay such extreme prices for medication that could have been purchased elsewhere for a fraction of the amount. *Id.* at 3–4.

Inappropriate Drug Dosages and Durations of Treatment

Dr. Hamilton opined that Florida pharmacists must review patient records and prescriptions for inappropriate drug dosages and durations of treatment before dispensing controlled substances. *Id.* at 4 (referencing Fla. Admin. Code r. 64B16–27.810). He explained that this is based upon the pharmacist's obligation to promote the therapeutic appropriateness of prescribed medication. *Id.*

Dr. Hamilton opined that Patients receiving prescriptions for immediate-release opioids, such as hydromorphone and oxycodone, for several months at a time is a red flag of abuse or diversion.

[5] This rule was amended in 2018, during the timeframe that relevant misconduct in this case took place; however, there were no relevant, substantive modifications to this regulation in 2018.

[6] There were no substantive changes to the relevant portions of Fla. Admin. Code r. 64B16–27.810 (2022) during the time period of the allegations in this case.

[7] Dr. Hamilton's Declaration does not identify supporting sources for his findings as to the average prices of these controlled substances; however, Dr. Hamilton's opinions in this matter were based on his 19 years of training and experience as a Florida pharmacist. RFAAX 11, at 1. As a pharmacy supervisor with Publix Supermarkets for eight years, Dr. Hamilton operated 40 Publix pharmacies and opened new Publix pharmacies. *Id.* He was also involved in evaluating other Florida retail pharmacies for potential purchase, which included ''inspect[ing] key areas including their inventory, invoices, sales, and purchasing habits.'' *Id.* There is no evidence to rebut Dr. Hamilton's opinions regarding average prices. Additionally, as explained further below, the differences in the prices charged by Registrant are so vastly in excess of the average prices identified by Dr. Hamilton that I find that the evidence weighs in favor of a finding that Registrant was charging excessive prices.

Id. He explained that this is because immediate-release medication should only be used to treat short-term, acute pain, and patients with legitimate chronic pain would eventually be switched to safer, long-term pain medication. *Id.* Moreover, Dr. Hamilton opined that Florida pharmacists should also address and resolve the red flag of patients receiving large quantities of opioids at their highest available strengths. *Id.* He explained that the Centers for Disease Control and Prevention (CDC) recommends avoiding or carefully adjusting Morphine Milligram Equivalent (MME) dosages prescribed beyond 90 mg a day. *Id.*

Dr. Hamilton opined that opiate-naive patients receiving more than 24 mg per day of hydromorphone (96 MME) or more than 80 mg per day of oxycodone (120 MME) is a red flag of abuse or diversion. *Id.* He explained that starting dosages this high are potentially lethal for opiate-naive patients. *Id.*

Pattern Prescribing

Dr. Hamilton opined that another common red flag of abuse or diversion that Florida pharmacists must address before filling is ''pattern prescribing,'' which refers to a physician who regularly prescribes common drugs of abuse or diversion in the same dosages and quantities to many patients sharing the same surnames and/or addresses, and uses the same diagnosis codes to justify these prescriptions. *Id.* at 5. He explained that ''pattern prescribing'' is a red flag of abuse or diversion because it indicates that the physician is focused on distributing drugs with high street value rather than on examining his patients and developing individualized treatment plans. *Id.*

Dr. Hamilton opined that the manner in which a Florida pharmacist addresses and resolves red flags of abuse or diversion must be documented on the prescription and/or in the patient's profile. *Id.* He explained that Florida pharmacists must maintain a patient record system, or patient profile, that documents how the pharmacists resolved the red flags of abuse or diversion. *Id.* (referencing Fla. Admin. Code r. 64B16–27.800 (2022)).[8]

ii. Dr. Hamilton's Opinion That Registrant Repeatedly Dispensed Controlled Substances Outside the Usual Course of Professional Practice

Dr. Hamilton reviewed prescriptions, patient profiles, and E–FORSCE reports for Registrant's customers J.Y., J.S., C.A., L.K., A.O., M.S., B.B., E.R., S.R., M.J., C.K., K.L., A.M., K.S., and L.S. *Id.* (referencing RFAAX 9, at App'x F–AX). Dr. Hamilton opined that each prescription that he reviewed presented red flags of abuse and diversion, and that Registrant failed to address these red flags on the customers' prescriptions or in their patient profiles. *Id.* Dr. Hamilton concluded that Registrant failed to follow the minimum requirements for Florida pharmacists, and therefore acted outside the usual course of professional practice in filling each prescription. *Id.*

J.Y.

Registrant filled the following three prescriptions for J.Y. on six separate occasions from January 13, 2017, to June 30, 2017: (1) 112 tablets of hydromorphone 8 mg, (2) 28 tablets of morphine sulfate extended release (ER) 30 mg, and (3) 28 tablets of clonazepam 2 mg. RFAAX 9, at App'x H (Prescriptions for J.Y.); *see also id.* at App'x G (J.Y.'s E–FORSCE report), App'x F (J.Y.'s Patient Profile).[9] On each occasion, Registrant also dispensed cyclobenzaprine, which is a non-controlled muscle relaxant. *Id.* at App'x H. Dr. Hamilton opined that J.Y.'s prescriptions presented the red flags of cocktail medications and long distances traveled. RFAAX 11, at 6–7.

Dr. Hamilton opined that it was a red flag that Registrant dispensed the widely-abused ''Trinity'' cocktail on each occasion specified above. *Id.* at 6. In this case, the ''Trinity'' cocktail consisted of two opioids (hydromorphone and morphine sulfate ER), a benzodiazepine (clonazepam), and a muscle relaxant (cyclobenzaprine),[10] all of which were prescribed by the same prescriber. *Id.* Additionally, Dr. Hamilton opined that it was a red flag that J.Y. traveled at least 106 miles roundtrip to obtain and fill her prescriptions. *Id.* J.Y.'s residence was at least 53 miles from her doctor's office and 37 miles from Registrant, and her doctor's office was approximately 16 miles from Registrant. RFAAX 9, at 11, App'x AY; *see also* RFAAX 11, at 6.

Dr. Hamilton did not see any evidence that Registrant addressed these red flags of abuse or diversion on J.Y.'s prescriptions or patient profile. RFAAX 11, at 7. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

J.S.

On 12 separate occasions between February 23, 2017, and June 1, 2018, Registrant filled prescriptions for J.S. for 90 tablets of oxycodone 30 mg. RFAAX 9, at App'x K (Prescriptions for J.S.); *see also id.* at App'x I (J.S.'s patient profile), App'x J (J.S.'s E–FORSCE report).[11] Additionally, on at least nine occasions between November 30, 2017, and August 30, 2018, Registrant filled prescriptions for J.S. for 150 tablets of oxycodone-acetaminophen 10/325 mg and a range of 30 to 60 tablets of carisoprodol 350 mg within the same month. *Id.*[12] On at least six of these occasions, Registrant dispensed both of the prescriptions within two or fewer days of each other. *Id.*

Dr. Hamilton opined that J.S.'s prescriptions presented the red flags of cocktail medications and cash payments at inflated prices. RFAAX 11, at 7–8. Dr. Hamilton opined that it was a red flag that Registrant repeatedly filled prescriptions for J.S. for oxycodone-acetaminophen (an opioid) and carisoprodol (a muscle relaxant), even though J.S. was filling prescriptions for benzodiazepines at another pharmacy during the same timeframe. *Id.* at 7. Thus, J.S. was receiving the ''Trinity'' cocktail, and on several occasions, all three prescriptions were written by the same prescriber. *Id.* Additionally, Dr. Hamilton opined that it was also a red flag that J.S. paid approximately $903 in cash for 90 tablets of oxycodone 30 mg on at least 12 occasions, which amounted to approximately $10.03 per tablet. *Id.* Dr. Hamilton opined that

[8] There were no substantive changes to the relevant portions of Fla. Admin. Code r. 64B16–27.800 (2022) during the time period of the allegations in this case.

[9] These prescriptions were filled on January 13, February 10, March 10, April 7, May 5, and June 30, 2017. *Id.*

[10] Cyclobenzaprine is not a controlled substance. Therefore, it is only relevant to my Decision to the extent that Dr. Hamilton opined that is potentially dangerous to prescribe cyclobenzaprine concurrently with opioids and benzodiazepines, and that Registrant should have addressed and resolved this red flag before filling the controlled substance prescriptions.

[11] These prescriptions were filled on February 23, March 27, April 26, May 23, June 20, July 18, August 15, September 7, October 6, and November 2, 2017; and February 23, and June 1, 2018. *Id.*

[12] These prescriptions were filled on November 30, 2017 (150 tablets of oxycodone-acetaminophen 10-325 mg and 30 tablets of carisoprodol 350 mg); December 22, 2017 (150 tablets of oxycodone-acetaminophen 10-325 mg and 60 tablets of carisoprodol 350 mg); January 12, 2018 (150 tablets of oxycodone-acetaminophen 10-325 mg); January 19, 2018 (60 tablets of carisoprodol 350 mg); February 2, 2018 (150 tablets of oxycodone-acetaminophen 10-325 mg); February 16, 2018 (60 tablets of carisoprodol 350 mg); March 22, 2018 (150 tablets of oxycodone-acetaminophen 10-325 mg and 60 tablets of carisoprodol 350 mg); May 8, 2018 (150 tablets of oxycodone-acetaminophen 10-325 mg); May 10, 2018 (60 tablets of carisoprodol 350 mg); June 27, 2018 (150 tablets of oxycodone-acetaminophen 10-325 mg and 60 tablets of carisoprodol 350 mg); July 23, 2018 (150 tablets of oxycodone-acetaminophen 10-325 mg); July 24, 2018 (30 tablets of carisoprodol 350 mg); August 17, 2018 (150 tablets of oxycodone-acetaminophen 10-325 mg); and August 30, 2018 (60 tablets of carisoprodol 350 mg). *Id.*

other pharmacies charge approximately $1.40 per tablet, which is approximately seven times less than what J.S. paid. *Id.* at 8.

Finally, on at least 11 occasions between November 30, 2017, and October 1, 2018, Registrant filled a range of 120 to 150 tablets of oxycodone-acetaminophen 10–325 mg for two patients with the same address and same surname, J.S. and L.S., within 14 days of each other. RFAAX 9, at App'x I, J, K, AV, AW, AX.[13] On at least seven occasions, the prescriptions were issued on the same day. *Id.*[14] Dr. Hamilton opined that these prescriptions were indicative of pattern prescribing. RFAAX 11, at 8.

Dr. Hamilton did not find any evidence that Registrant addressed the red flags of abuse or diversion on J.S.'s prescriptions or patient profile. *Id.* Dr. Hamilton also opined that there was no justification for Registrant to have repeatedly filled prescriptions written by a pattern-prescribing physician. *Id.* Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

C.A.

Between April 3, 2017, and February 26, 2018, Registrant filled 11 prescriptions for C.A. for a range of 84 to 112 tablets of hydromorphone 8 mg. RFAAX 9, at App'x N (C.A.'s Prescriptions); *see also id.* at App'x M (C.A.'s E–FORSCE report), App'x L (C.A.'s patient profile).[15] Dr. Hamilton opined that C.A.'s prescriptions presented the red flags of long distances traveled and long duration of treatment with high-dose, immediate-release opioids. RFAAX 11, at 9.

Dr. Hamilton opined that it was a red flag that C.A. traveled at least 107 miles roundtrip to obtain and fill her prescriptions. *Id.* C.A.'s residence was at least 37 miles from her doctor's office and 20 miles from Registrant, and her doctor's office was approximately 50 miles from Registrant. RFAAX 9, at 11–12, App'x AY; *see also* RFAAX 11, at 9. Dr. Hamilton also opined that it was a red flag that C.A. received a large quantity of an immediate-release opioid at the highest available strength for nearly 11 months, in a dosage that amounted to approximately 96 to 158.12 MME per day. RFAAX 11, at 9. Dr. Hamilton did not see any evidence that Registrant addressed these red flags of abuse or diversion on C.A.'s prescriptions or patient profile. *Id.* at 9–10. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

L.K.

Registrant filled 18 prescriptions for L.K. for a range of 112 to 126 tablets of hydromorphone 8 mg from January 9, 2017, to May 2, 2018. RFAAX 9, at App'x Q (L.K.'s Prescriptions); *see also id.* at App'x P (L.K.'s E–FORSCE Report), App'x O (L.K.'s Patient Profile).[16] Dr. Hamilton opined that L.K.'s prescriptions presented the red flags of long distances traveled, cash payments at inflated prices, and long duration of treatment with high-dose, immediate-release opioids. RFAAX 11, at 10–11.

Dr. Hamilton opined that it was a red flag that L.K. traveled at least 120 miles roundtrip to obtain and fill his prescriptions. *Id.* L.K.'s residence was at least 27 miles from his doctor's office and 57 miles from Registrant, and his doctor's office was approximately 36 miles from Registrant. RFAAX 9, at 12, App'x AY; *see also* RFAAX 11, at 10. Dr. Hamilton also opined that it was a red flag that L.K. received the highest available strength of hydromorphone for approximately 16 months, which amounted to approximately 128 to 161.28 MME per day. RFAAX 11, at 11. Finally, Dr. Hamilton opined that it was a red flag that J.S. paid between $1,150 and $1,294 in cash for each prescription, or $10.27 per tablet. *Id.* at 10. Dr. Hamilton opined that other pharmacies charge approximately $1.60 per tablet for hydromorphone, which is approximately six times less than what L.K. paid. *Id.*

Dr. Hamilton did not see any evidence that Registrant addressed these red flags of abuse or diversion on L.K.'s prescriptions or patients profile. *Id.* at 11. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

A.O.

On November 13, 2017, Registrant filled a prescription for A.O. for 112 tablets of oxycodone 30 mg. RFAAX 9, at App'x T (A.O.'s Prescriptions); *see also id.* at App'x S (A.O.'s E–FORSCE Report), App'x R (A.O.'s Patient Profile). On December 18, 2017, Registrant filled a prescription for A.O. for 140 tablets of oxycodone 30 mg. *Id.* Dr. Hamilton opined that it was a red flag that A.O. traveled at least 380 miles roundtrip to obtain and fill her prescriptions. *Id.* A.O.'s residence was at least 67 miles from her doctor's office and 194 miles from Registrant, and her doctor's office was approximately 128 miles from Registrant. RFAAX 9, at 12, App'x AY; *see also* RFAAX 11, at 11–12. Dr. Hamilton did not see any evidence that Registrant addressed this red flag of abuse or diversion on A.O.'s prescriptions or patient profile. RFAAX 11, at 12. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

M.S.

Between April 7, 2017, and December 15, 2017, Registrant filled 11 prescriptions for M.S. for a range of 60 to 112 tablets of hydromorphone 8 mg. RFAAX 9, at App'x W (M.S.'s Prescriptions); *see also id.* at App'x V (M.S.'s E–FORSCE Report), App'x U (M.S.'s Patient Profile).[17] Dr. Hamilton opined that M.S.'s prescriptions presented the red flags of long distances traveled and cash payments at inflated prices. RFAAX 11, at 12–13.

Dr. Hamilton opined that it was a red flag that M.S. traveled at least 548 miles roundtrip to obtain and fill his prescriptions. *Id.* M.S.'s residence was at least 242 miles from his doctor's office and 258 miles from Registrant, and his doctor's office was approximately 50 miles from Registrant. RFAAX 9, at 12, App'x AY; *see also* RFAAX 11, at 12. Additionally, Dr. Hamilton opined that it was a red flag that M.S. paid between $509 and $969 in cash for each prescription, or between $8.48 and $8.68 per tablet. RFAAX 11, at 12–13. Dr. Hamilton opined that other pharmacies charge approximately $1.60 per pill tablet for hydromorphone, which is approximately five times less than what M.S. paid. *Id.*

[13] These prescriptions were filled on November 30, 2017 (J.S. and L.S.); December 22, 2017 (J.S. and L.S.); January 12, 2018 (J.S.), and January 19, 2018 (L.S.); February 16, 2018 (L.S.), February 23, 2018 (J.S.); March 15, 2018 (L.S.), and March 22, 2018 (J.S.); April 13, 2018 (L.S.), and April 14, 2018 (J.S.); May 8, 2018 (J.S.), May 10, 2018 (L.S.); June 27, 2018 (J.S.), and July 6 (L.S.); July 23, 2018 (J.S.), and August 2, 2018 (L.S.); August 17, 2018 (J.S.), and August 30, 2018 (L.S.); September 21, 2018 (J.S.), and October 1, 2018 (L.S.). *Id.*

[14] The prescriptions were issued on the same day on November 30, 2017; December 22, 2017; February 2, 2018; February 22, 2018; April 16, 2018; June 26, 2018; and August 16, 2018. *Id.*

[15] These prescriptions were filled on April 3, May 4, June 2, June 30, July 28, August 25, September 22, October 19, November 15, 2017; and January 29 and February 26, 2018. *Id.*

[16] These prescriptions were filled on January 9, February 6, March 6, April 3, May 1, May 30, June 27, July 25, August 22, September 19, October 17, November 14, and December 12, 2017; and January 9, February 6, March 6, April 3, and May 2, 2018. *Id.*

[17] These prescriptions were filled on April 7, May 5, June 2, July 7, August 1, August 25, September 26, October 23, November 20, and December 15, 2017. *Id.*

Dr. Hamilton did not see any evidence that Registrant addressed these red flags of abuse or diversion on M.S.'s prescriptions or patient profile. *Id.* at 12. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

B.B.

Between November 7, 2018, and March 26, 2019, Registrant filled six prescriptions for B.B. for a range of 84 to 100 tablets of oxycodone 30 mg. RFAAX 9, at App'x Z (B.B.'s Prescriptions); *see also id.* at App'x Y (B.B.'s E–FORSCE Report), App'x X (B.B.'s Patient Profile).[18] Dr. Hamilton opined that B.B.'s prescriptions presented the red flags of long distances traveled, cash payments at inflated prices, and long duration of treatment with high-dose, immediate-release opioids. RFAAX 11, at 13–14.

Dr. Hamilton opined that it was a red flag that B.B. traveled at least 101 miles roundtrip to obtain and fill his prescriptions. *Id.* B.B.'s residence was at least 34 miles from his doctor's office and 23 miles from Registrant, and his doctor's office was approximately 50 miles from Registrant. RFAAX 9, at 12, App'x AY; RFAAX 11, at 13. Dr. Hamilton also opined that it was a red flag that B.B. received the highest available strength of oxycodone for nearly five months, which amounted to approximately 135 to 184.09 MME per day. RFAAX 11, at 13. Finally, Dr. Hamilton opined that it was a red flag that B.B. paid between $637 and $726 in cash for each prescription, or between $7.26 and $7.59 per tablet. *Id.* at 13–14. Dr. Hamilton opined that other pharmacies charge approximately $1.40 per tablet for oxycodone, which is approximately five times less than what B.B. paid. *Id.*

Dr. Hamilton did not see any evidence that Registrant addressed these red flags of abuse or diversion on B.B.'s prescriptions or patient's profile. *Id.* at 14. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

E.R.

Between November 20, 2018, and March 18, 2019, Registrant filled five prescriptions for E.R. for 70 tablets of oxycodone 30 mg. RFAAX 9, at App'x AC (E.R.'s Prescriptions); *see also id.* at App'x AB (E.R.'s E–FORSCE Report), App'x AA (E.R.'s Patient Profile).[19] Dr. Hamilton opined that it was a red flag that M.S. traveled at least 158 miles roundtrip to obtain and fill his prescriptions. RFAAX 11, at 14–15. E.R.'s residence was at least 51 miles from her doctor's office and 24 miles from Registrant, and her doctor's office was approximately 73 miles from Registrant. RFAAX 9, at 13, App'x AY; *see also* RFAAX 11, at 14–15. Dr. Hamilton did not see any evidence that Registrant addressed this red flag of abuse or diversion on E.R's prescriptions or in E.R.'s patient's profile. RFAAX 11, at 15. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

S.R.

Between November 2, 2018 and March 20, 2019, Registrant filled six prescriptions for S.R. for 100 tablets of hydromorphone 8 mg. RFAAX 9, at App'x AF (S.R.'s Prescriptions); *see also id.* at App'x AE (S.R.'s E–FORSCE Report), App'x AD (S.R.'s Patient Profile).[20] Dr. Hamilton opined that it was a red flag that S.R. traveled at least 108 miles roundtrip to obtain and fill her prescriptions. RFAAX 11, at 15–16. S.R.'s residence was at least 35 miles from her doctor's office and 23 miles from Registrant, and her doctor's office was approximately 50 miles from Registrant. RFAAX 9, at 13, App'x AY; RFAAX 11, at 15. Dr. Hamilton did not see any evidence that Registrant addressed this red flag of abuse or diversion on S.R.'s prescriptions or patient profile. RFAAX 11, at 16. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

M.J.

Between January 31, 2017, and December 6, 2017, Registrant filled 12 prescriptions for M.J. for 112 tablets of hydromorphone 8 mg. RFAAX 9, at App'x AI (M.J.'s Prescriptions); *see also id.* at App'x AH (M.J.'s E–FORSCE Report), App'x AG (M.J.'s Patient Profile).[21] Dr. Hamilton opined that M.J.'s prescriptions presented the red flags of cash payments at inflated prices and long duration of treatment with high-dose, immediate-release opioids. RFAAX 11, at 16–17.

Dr. Hamilton opined that it was a red flag that M.J. received a large quantity of the highest available strength of hydromorphone for at least ten months, which amounted to approximately 128 MME per day. *Id.* at 16. Additionally, Dr. Hamilton opined that it was a red flag that M.J. paid between $919 and $967 in cash for each prescription, or between $8.20 and $8.63 per tablet. *Id.* Dr. Hamilton opined that other pharmacies charge approximately $1.60 per tablet for hydromorphone, which is approximately five times less than what M.J. paid. *Id.*

Dr. Hamilton did not see any evidence that Registrant addressed these red flags of abuse or diversion on M.J.'s prescriptions or patient's profile. *Id.* at 17. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

C.K.

Between November 6, 2018, and March 1, 2019, Registrant filled five prescriptions for C.K. for 84 tablets of oxycodone 30 mg. RFAAX 9, at App'x AL (C.K.'s Prescriptions); *see also id.* at App'x AK (C.K.'s E–FORSCE Report), App'x AJ (C.K.'s Patient Profile).[22] Dr. Hamilton opined that it was a red flag that C.K. paid $684 in cash for each prescription, or $8.14 per tablet. RFAAX 11, at 17. Dr. Hamilton opined that other pharmacies charge approximately $1.40 per tablet for oxycodone, which is approximately five times less than what C.K. paid. *Id.* Dr. Hamilton did not see any evidence that Registrant addressed this red flag of abuse or diversion on C.K.'s prescriptions or patient profile. *Id.* Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

K.L.

Between November 5, 2018, and March 25, 2019, Registrant filled six prescriptions for K.L. for 112 tablets of oxycodone 30 mg. RFAAX 9, at App'x AO (K.L.'s Prescriptions); *see also id.* at App'x AN (K.L.'s E–FORSCE Report), App'x AM (K.L.'s Patient Profile).[23] Dr. Hamilton opined that it was a red flag that K.L. received a large quantity of the highest available strength of oxycodone for nearly five months, which amounted to approximately 180 MME per day.

[18] These prescriptions were filled on November 7, December 4, 2018, January 4, January 29, February 26, and March 26, 2019. *Id.*

[19] These prescriptions were filled on November 20 and December 19, 2018, and January 16, February 19, and March 18, 2019. *Id.*

[20] These prescriptions were filled on November 2, November 29, and December 26, 2018; and January 24, February 20, and March 20, 2019.

[21] These prescriptions were filled on January 31, February 27, March 24, April 21, May 22, June 16, July 14, August 11, September 8, October 5, November 6, and December 6, 2017. *Id.*

[22] These prescriptions were filled on November 6 and December 4, 2018, and January 2, January 30, and March 1, 2019. *Id.*

[23] These prescriptions were filled on November 5, December 3, and December 31, 2018; and January 28, February 25, and March 25, 2019. *Id.*

RFAAX 11, at 18. Dr. Hamilton did not see any evidence that Registrant addressed this red flag of abuse or diversion on K.L.'s prescriptions or patient profile. *Id.* Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

A.M.

On November 1, 2017, Registrant filled a prescription for A.M. for 112 tablets of hydromorphone 8 mg, at a starting dosage of 32 mg of hydromorphone per day (128 MME). RFAAX 11, at 18; RFAAX 9, at App'x AR (A.M.'s Prescriptions); *see also id.* at App'x AQ (A.M.'s E–FORSCE Report), App'x AP (A.M.'s Patient Profile). In the two years prior to filling this prescription, A.M. had not filled any opioid prescriptions in Florida. *See* RFAAX 9, at App'x AQ. Dr. Hamilton opined that this meant that A.M. was opiate naïve. RFAAX 11, at 18. Dr. Hamilton opined that it is a red flag for an opiate-naïve patient to receive more than 24 mg per day of hydromorphone (96 MME), because these doses could be potentially lethal. RFAAX 11, at 4. A.M.'s starting dose of 128 MME was well above 96 MME. RFAAX 11, at 18–19.

Dr. Hamilton did not see any evidence that Registrant addressed this red flag of abuse or diversion on A.M.'s prescriptions or in A.M's patient's profile. *Id.* at 19. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

K.S.

On September 21, 2017, Registrant filled a prescription for K.S. for 84 tablets of hydromorphone 8 mg, at a starting dosage of 32 mg of hydromorphone per day (128 MME). RFAAX 11, at 19; RFAAX 9, at App'x AU (K.S.'s Prescriptions); *see also id.* at App'x AT (K.S.'s E–FORSCE Report), App'x AS (K.S.'s Patient Profile). In the two years prior to filling this prescription, K.S. had only filled one opioid prescription in Florida, approximately six months before the September 21 prescription. *See* RFAAX 9, at App'x AT. Dr. Hamilton opined that this meant that K.S. was opiate naïve. RFAAX 11, at 19. Dr. Hamilton opined that it is a red flag for an opiate-naïve patient to receive more than 24 mg per day of hydromorphone (96 MME), because these doses could be potentially lethal. RFAAX 11, at 4. K.S.'s starting dose of 128 MME was well above 96 MME. *Id.* at 19. Dr. Hamilton did not see any evidence that Registrant addressed this red flag of abuse or diversion on K.S.'s prescriptions or patient profile. *Id.* at 19–20. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

L.S.

As discussed in more detail above, on at least 11 occasions between November 30, 2017, and October 1, 2018, Registrant filled a range of 120 to 150 tablets of oxycodone-acetaminophen 10–325 mg for two patients with the same address and same last name, J.S. and L.S., within 14 days of each other. RFAAX 9, at App'x AX (L.S.'s Prescriptions), App'x AW (L.S.'s E–FORSCE Report), App'x AV (L.S.'s Patient Profile). On at least seven occasions, the prescriptions were issued on the same day. *Id.* Dr. Hamilton opined that these prescriptions were written by a pattern-prescribing physician. RFAAX 11, at 8, 20.

Dr. Hamilton did not find any evidence that Registrant addressed this red flag on L.S.'s prescriptions or patient profile. *Id.* at 20. Dr. Hamilton also opined that there was no justification for Registrant to have repeatedly dispensed these prescriptions written by a pattern-prescribing physician. *Id.* at 8. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.* at 20.

II. Discussion

A. Registrant's Registration Is Inconsistent With the Public Interest

The Government alleged that Registrant's DEA registration should be revoked because Registrant committed acts that would render its registration inconsistent with the public interest as provided in 21 U.S.C. 823(f). The Government's case centers on Registrant's unlawful dispensing of controlled substances to 15 customers.

Under the Controlled Substances Act (hereinafter, the CSA), ''[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). In the case of a ''practitioner,'' which is defined in 21 U.S.C. 802(21) to include a pharmacy, Congress directed the Attorney General to consider the following factors in making the public interest determination:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The [registrant]'s experience in dispensing . . . controlled substances.

(3) The [registrant]'s conviction record under Federal or State laws relating to the . . . distribution[ ] or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f). These factors are considered in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003).

According to Agency decisions, I ''may rely on any one or a combination of factors and may give each factor the weight [I] deem[ ] appropriate in determining whether'' to revoke a registration. *Id.; see also Jones Total Health Care Pharm., LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018) (citing *Akhtar-Zaidi* v. *Drug Enf't Admin.,* 841 F.3d 707, 711 (6th Cir. 2016); *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482. ''In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009). Accordingly, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

The Government has the burden of proving that the requirements for revocation of a DEA registration in 21 U.S.C. 824(a) are satisfied. 21 CFR 1301.44(e). When the Government has met its *prima facie* case, the burden then shifts to the registrant to show that revoking its registration would not be appropriate, given the totality of the facts and circumstances on the record. *Med. Shoppe-Jonesborough,* 73 FR 364, 387 (2008).

In this matter, while I have considered all of the factors, the Government's evidence in support of its *prima facie* case is most appropriately considered under Factors Two and

Four.[24] I find that the Government has satisfied its *prima facie* burden of showing that Registrant's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4).

1. Factors Two and Four—The Registrant's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

In determining the public interest under Factors Two and Four, I consider evidence of Registrant's compliance (or non-compliance) with laws related to controlled substances and Registrant's experience dispensing controlled substances. The Government's case relies primarily on the actions of Registrant's dispensing pharmacists. Furthermore, the Agency ''has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist, or other key employee.'' *Perry Cty. Food & Drug,* 80 FR 70084, 70109 (2015) (citing *EZRX, LLC,* 69 FR 63178, 63181 (1988); *Plaza Pharmacy,* 53 FR 36910, 36911 (1988)).

The Government alleged that Registrant violated federal and state laws related to controlled substances by repeatedly dispensing controlled substances to 15 customers without addressing or resolving red flags of drug abuse and diversion. OSC, at 2–3 (citing violations of 21 CFR 1306.06 and 1306.04(a); and Fla. Admin. Code. r. 64B16–27.800, 64B16–27.810, and 64B16–27.831).

i. Violations of Federal Law

According to the CSA's implementing regulations, a lawful controlled substance order or prescription is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). While the ''responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, . . . a corresponding responsibility rests with the pharmacist who fills the prescription.'' *Id.* The regulations establish the parameters of the pharmacy's corresponding responsibility:

> An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of . . . 21 U.S.C. 829 . . . and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Id. ''The language in 21 CFR [§] 1306.04 and relevant caselaw could not be more explicit. A pharmacist has his own responsibility to ensure that controlled substances are not dispensed for non-medical reasons.'' *Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy,* 55 FR 4729, 4730 (1990) (citing *United States* v. *Hayes,* 595 F.2d 258 (5th Cir. 1979), cert. denied, 444 U.S. 866 (1979); *United States* v. *Henry,* 727 F.2d 1373 (5th Cir. 1984) (reversed on other grounds)). As the Supreme Court explained in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006).

To prove that a pharmacist violated his corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter. *See* 21 CFR 1306.04(a) (''[T]he person *knowingly* filling [a prescription issued not in the usual course of professional treatment] . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'') (emphasis added). DEA has also consistently interpreted the corresponding responsibility regulation such that ''[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.'' *Bertolino,* 55 FR at 4730 (citations omitted); *see also JM Pharmacy Group, Inc. d/b/a Pharmacia Nueva and Best Pharmacy Corp.,* 80 FR 28667, 28670–72 (2015) (applying the standard of willful blindness in assessing whether a pharmacist acted with the requisite scienter). Pursuant to their corresponding responsibility, pharmacists must exercise ''common sense and professional judgment'' when filling a prescription issued by a physician. *Bertolino,* 55 FR at 4730. When a pharmacist's suspicions are aroused by a red flag, the pharmacist must question the prescription and, if unable to resolve the red flag, refuse to fill the prescription. *Id.; Med. Shoppe-Jonesborough,* 300 F. App'x 409, 412 (6th Cir. 2008) (''When pharmacists' suspicions are aroused as reasonable professionals, they must at least verify the prescription's propriety, and if not satisfied by the answer they must refuse to dispense.'').

In this case, I find that the Government has proven through Dr. Hamilton's unrebutted expert opinion that Registrant repeatedly filled prescriptions for controlled substances that presented obvious red flags of abuse or diversion, in violation of its corresponding responsibility under 21 CFR 1306.04(a), and outside the usual course of the professional practice of pharmacy in Florida, in violation of 21 CFR 1306.06. Registrant's customers traveled round-trip distances of up to 580 miles, paid enormous cash sums of up to $1,294, and presented prescriptions for high dosages and dangerous combinations of controlled substances, such as the ''Trinity'' cocktail, whose pharmacological effect is similar to heroin. *See supra* B.2.ii. Additionally, several of Registrant's customers presented prescriptions written by physicians who were pattern prescribing. *Id.* As discussed above, there is no evidence that Registrant made any attempt to address or resolve these red flags. *Id.* Agency decisions have consistently found based on credible expert testimony that prescriptions with similar red flags were so suspicious as to support a finding that the pharmacists who filled them violated the Agency's corresponding responsibility rule due to actual knowledge of, or willful blindness to, the prescriptions' illegitimacy.[25]

[24] In this case, I find that Factors One and Three weigh neither for nor against revocation. The record does not contain a ''recommendation of the appropriate State licensing board or professional disciplinary authority.'' 21 § U.S.C. 823(f)(1) Prior Agency decisions have found that where the record contains no evidence of a recommendation by a state licensing board, that absence does not weigh for or against revocation. *See, e.g., Ajay S. Ahuja, M.D.,* 84 FR 5479, 5490 (2019) (finding that ''where the record contains no evidence of a recommendation by a state licensing board that absence does not weigh for or against revocation.''); *Holiday CVS LLC dba CVS Pharmacy Nos 219 and 5195,* 77 FR 62316, 62340 (2012); *Roni Dreszer, M.D.,* 76 FR 19434, 19444 (2011). Additionally, there is no evidence related to any convictions ''relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 § U.S.C. 823(f)(3). However, as Agency cases have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.,* 75 FR 49956, 49973 (2010). Agency cases have therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

[25] *See, e.g., Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy,* 83 FR 10876, 10898, *pet. for*

Registrant's flagrant violations of federal law weigh strongly against a finding that Registrant's continued registration is consistent with the public interest.

ii. Violations of State Law

In addition to alleging that Registrant violated 21 CFR 1306.04(a) and 1306.06, the Government alleges that Registrant violated Florida State law by: (1) Failing to ''exercis[e] sound professional judgment'' and ''work with the patient and the prescriber to assist in determining the validity of the prescription''; [26] and by (2) failing to review each prescription for potential problems, such as ''[o]ver utilization or under-utilization'' and ''[c]linical abuse/misuse,'' and failing to ''take appropriate steps to avoid or resolve the potential problems.'' [27]

I find that the Government has provided substantial evidence that Registrant violated these state laws by dispensing controlled substances to the 15 customers outlined above without documenting any attempt to address or resolve the numerous red flags with these prescriptions. The records clearly do not support a finding that Registrant ''exercise[d] sound professional judgment'' or ''work[ed] with the patient and the prescriber to assist in determining the validity of the prescription,'' as required by Fla. Admin. Code. r. 64B16–27.831. Instead, Registrant repeatedly dispensed controlled substances to 15 customers without documenting any attempt to address or resolve the blatant red flags with these prescriptions, such as patients traveling extreme distances and paying enormous cash sums. *See supra* B.2.ii. Additionally, Registrant failed to identify and respond to factors that indicated a lack of ''therapeutic appropriateness'' of the drugs dispensed, as outlined in Fla. Admin. Code. r. 64B16–27.810. For example, on numerous occasions, Registrant dispensed dangerous and potentially-lethal combinations and dosages of controlled substances without documenting any attempt to address or resolve the red flags with these prescriptions. *See, e.g., supra* B.2.ii (J.Y., J.S., A.M., K.S.).

In light of Registrant's repeated failure to address or resolve blatant red flags of abuse or diversion, I conclude that Factors Two and Four overwhelmingly demonstrate that Registrant ''has committed such acts as would render [its] registration . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). I further conclude that Registrant has not rebutted the Government's *prima facie* case.

III. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Registrant's continued registration is inconsistent with the public interest, the burden shifts to the Registrant to show why it can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18882, 18910 (2018) (collecting cases).

The CSA authorizes the Attorney General to ''promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.'' 21 U.S.C. 871(b). This authority specifically relates ''to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute.'' *Gonzales,* 546 U.S. at 259. ''Because 'past performance is the best predictor of future performance, *ALRA Labs, Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.' '' *Jayam Krishna-Iyer,* 74 FR at 463 (quoting *Med. Shoppe,* 73 FR at 387 (2008)); *see also Samuel S. Jackson,* 72 FR 23848, 23853 (2007); *John H. Kennnedy, M.D.,* 71 FR 35705, 35709 (2006); *Prince George Daniels, D.D.S.,* 60 FR 62884, 62887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant; therefore, the Agency looks at factors, such as the acceptance of responsibility, and the credibility of that acceptance as it relates to the probability of repeat violations or behavior, and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).

Here the Registrant did not avail itself of the opportunity to refute the Government's case. In light of Registrant's egregious violations, which go to the heart of the CSA's purpose of ''prevent[ing] addiction and recreational abuse'' of controlled substances,[28] Registrant's silence weighs against the Registrant's continued registration. *Zvi H. Perper, M.D.,* 77 FR at 64142 (citing *Med. Shoppe,* 73 FR at 387); *see also Jackson,* 72 FR at 23853.

Accordingly, I find that the factors weigh in favor of revocation, and I shall order the sanctions that the Government requested, as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I hereby revoke DEA Certificate of Registration No. FG5612127 issued to George Pharmacy, Inc. Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I further hereby deny any pending applications for renewal or modification of this registration, as well as any other pending application of George Pharmacy for additional registration in Florida. Pursuant to the authority vested in me by 21 U.S.C. 824(f), as well as 28 CFR 0.100(b), I further order that any controlled substances seized pursuant to the Order of Immediate Suspension of Registration are forfeited to the United States. This Order is effective May 11, 2022.

Anne Milgram,

Administrator.

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rev. denied, 789 F. App'x 724 (11th Cir. 2019) (long distances; pattern prescribing; customers with the same street address presenting the same prescriptions on the same day; drug cocktails; cash payments; early refills); *Hills Pharmacy,* 81 FR 49816, 49836–39 (2016) (multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting similar prescriptions on the same day; long distances; drug cocktails); *The Medicine Shoppe,* 79 FR 59504, 59507, 59512–13 (2014) (unusually large quantity of a controlled substance; pattern prescribing; irregular dosing instructions; drug cocktails); *Holiday CVS,* 77 FR 62316, 62317–22 (2012) (long distances; multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting virtually the same prescriptions within a short time span; payment by cash); *East Main Street Pharmacy,* 75 FR 66149, 66163–65 (2010) (long distances; lack of individualized therapy or dosing; drug cocktails; early fills/refills; other pharmacies' refusals to fill the prescriptions).

[26] *See* Fla. Admin. Code. r. 64B16–27.831 (2022).

[27] *See* Fla. Admin. Code. r. 64B16–27.810 (2022). I am not including a finding based on Fla. Admin. Code. r. 64B16–27.800 because there is more than enough evidence on the record to revoke Registrant's registration based on consideration of the other found violations under Factors Two and Four.

[28] *Gonzales* v. *Oregon,* 546 U.S. at 274.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Kirk A. Hopkins, M.D.; Decision and Order

On December 2, 2021, a former Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause (hereinafter, OSC) to Kirk A. Hopkins, M.D. (hereinafter, Registrant) of Chicago, Illinois. Request for Final Agency Action (hereinafter, RFAA), Exhibit (hereinafter RFAAX) 2 (OSC), at 1 and 3. The OSC proposed the revocation of Registrant's Certificate of Registration No. BH9069205. *Id.* at 1. It alleged that Registrant is ''without authority to handle controlled substances in Illinois, the state in which [he is] registered with DEA.'' *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that on December 10, 2020, the Illinois Department of Financial and Professional Regulation entered an Order, effective December 24, 2020, indefinitely suspending Registrant's state medical license after finding that Registrant ''had been convicted of wire fraud, in violation of 18 U.S.C. 1343, as a result of a scheme [he] conducted to defraud Medicare and Medicaid.'' *Id.* According to the OSC, the Order also required Registrant to immediately surrender his state medical license. *Id.* Further, according to the OSC, because Registrant's state medical license was suspended, his Illinois controlled substance license was placed on ''inoperative'' status. *Id.*

The OSC notified Registrant of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 2–3 (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. *Id.* at 3 (citing 21 U.S.C. 824(c)(2)(C)).

Adequacy of Service

In a Declaration dated March 8, 2022, a Diversion Investigator (hereinafter, the DI) assigned to the Chicago Field Division stated that on December 9, 2021, she sent a copy of the OSC via certified mail to Registrant at the address where he is presently incarcerated. RFAAX 3, at 1–2. The DI stated that on December 15, 2021, DEA received a signed return receipt indicating that the OSC had been delivered. *Id.* at 2; *see also id.* at Appendix (hereinafter, App.) B. Further, the DI stated that on December 16, 2021, she spoke with the mail room receptionist at Registrant's place of incarceration and confirmed that Registrant had received the copy of the OSC. *Id.* at 2.

The Government forwarded its RFAA, along with the evidentiary record, to this office on March 15, 2022. In its RFAA, the Government represents that neither Registrant nor any attorney representing Registrant has requested a hearing or submitted a written statement. RFAA, at 2; *see also* RFAAX 3 (DI's Declaration), at 2. The Government requests that Registrant's DEA registration be revoked and that any applications for renewal of Registrant's DEA registration be denied because Registrant does not have state authority to handle controlled substances. RFAA, at 5.

Based on the DI's Declaration, the Government's written representations, and my review of the record, I find that the Government accomplished service of the OSC on Registrant on or before December 16, 2021. I also find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the DI's Declaration, the Government's written representations, and my review of the record, I find that neither Registrant, nor anyone purporting to represent the Registrant, requested a hearing, submitted a written statement while waiving Registrant's right to a hearing, or submitted a corrective action plan. Accordingly, I find that Registrant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

Findings of Fact

Registrant's DEA Registration

Registrant is the holder of DEA Certificate of Registration No. BH9069205 at the registered address of 4426 S King Drive, Chicago, Illinois 60653. RFAAX 1 (DEA Certificate of Registration). Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules II through V as a practitioner. *Id.* Registrant's registration expires on October 31, 2022. *Id.*

The Status of Registrant's State License

On June 17, 2020, Registrant entered into a Plea Agreement in the United States District Court for the Northern District of Illinois, Eastern Division, in which Registrant agreed to enter a voluntary plea of guilty to two counts of wire fraud. RFAAX 3, App. A, at 7–8 and 24. By entering into the Plea Agreement, Registrant admitted that ''[b]eginning in or around 2008, and continuing through in or around May 2014 . . . [he] knowingly devised, intended to devise, and participated in a scheme to defraud and to obtain money from Medicare and Medicaid by means of materially false and fraudulent pretenses, representations[,] and promises.'' *Id.* at 8. Registrant also admitted that as a result of the false claims that he submitted and caused to be submitted to Medicare and Medicaid, he received approximately $3,365,616. *Id.* at 11.

As the Plea Agreement details, Registrant owned and controlled a facility that ''purported to provide psychotherapy services to Medicaid and Medicare beneficiaries [who] were bused from group and nursing homes to the clinic to participate in a day program.'' *Id.* at 8. However, Registrant ''submitted, and caused to be submitted, false claims to Medicare and Medicaid for psychiatric services purportedly provided to the participants in the day program, when such services were not provided . . . .'' *Id.* at 8–9. Specifically, ''[Registrant] purportedly provided individual psychotherapy sessions when, in fact, the services were not provided'' and ''purportedly provided, or [purportedly] supervised another therapist providing, group psychotherapy sessions when, in fact, the services were not provided either by [Registrant] or under his supervision.'' *Id.* at 9. Notably, ''[n]umerous dates of services on the false claims included dates on which [Registrant] was traveling [outside of Illinois] and dates on which the beneficiaries were themselves unavailable to have received the purported services because they were admitted into a hospital facility or deceased.'' *Id.*

Moreover, Registrant ''also paid, and caused his employees to pay, cash to certain beneficiaries in order to entice them to attend the day program'' when ''[i]n reality, rather than receive psychotherapy services[,] the participants of the day program were placed in a large holding room to watch television and, on occasion, received group therapy from unsupervised and often-unlicensed counselors.'' *Id.* As for the submission of the false claims, Registrant ''directed his employees to delay submission of the false claims until after beneficiaries' deductibles had been exhausted[ ] in order to insure [sic]

that [Registrant's facility] received payment because [Registrant] did not collect deductibles.'' *Id.*

In addition, Registrant ''also purportedly provided psychotherapy services to Medicare and Medicaid beneficiaries residing at nursing home facilities'' and ''submitted, and caused to be submitted, false claims to Medicaid or Medicare for payment for services purportedly rendered to such nursing home residents when, in fact, [Registrant] had not provided the services because [he] was traveling [outside of Illinois] or the beneficiaries were themselves unavailable to have received the purported services because they were admitted into a hospital facility or deceased.'' *Id.* at 9–10.

Finally, Registrant ''also offered and paid renumeration, including kickbacks and bribes'' to induce individuals, including employees of ''Healthcare Facility A,'' to refer residents who were insured by Medicare or Medicaid to Registrant for psychotherapy treatment at either Registrant's facility or at Healthcare Facility A. *Id.* at 10. Further, Registrant ''submitted, and caused to be submitted, false claims to Medicare and Medicaid for psychiatric services purportedly provided to patients at Healthcare Facility A[ ] when such services were not provided.'' *Id.* Again, Registrant ''purportedly provided individual psychotherapy sessions when, in fact, the services were not provided'' and ''purportedly provided, or [purportedly] supervised another therapist providing, group psychotherapy sessions when, in fact, the services were not provided either by [Registrant] or under his supervision.'' *Id.* Additionally, ''dates of services on the false claims for services purportedly provided or supervised by [Registrant] at Healthcare Facility A included dates on which [Registrant] was traveling [outside of Illinois] and dates on which the beneficiaries were themselves unavailable to have received the purported services because they were admitted into a hospital facility or deceased.'' *Id.*

On October 7, 2020, a Judgment was entered by the United States District Court for the Northern District of Illinois, Eastern District, after Registrant pleaded guilty to two counts of ''Fraud By Wire, Radio, Or Television.'' *Id.* at 25. Registrant was sentenced to 36 months imprisonment followed by a one-year period of supervised release. *Id.* at 26–27. Registrant was also required to pay restitution of $3,189,007.88. *Id.* at 31–32.

On October 9, 2020, the Illinois Department of Financial and Professional Regulation (hereinafter, the Department) issued to Registrant a Notice of Intent to Issue Indefinite Suspension Order in which the Department stated its intent to ''issue an order indefinitely suspending [Registrant's] license as an Illinois Physician and Surgeon'' following Registrant's guilty plea and conviction. *Id.* at 3. On December 10, 2020, the Department issued its Indefinite Suspension Order, effective December 24, 2020, in which Registrant's Illinois Physician and Surgeon License was indefinitely suspended and Registrant was ordered to surrender his license to the Department. *Id.* at 1–2.

According to Illinois online records, of which I take official notice, Registrant's state medical license is still suspended.[1] Illinois Department of Financial and Professional Regulation License Lookup, *https://online-dfpr.micropact.com/lookup/licenselookup.aspx* (last visited date of signature of this Order). Further, Illinois online records list the status of Registrant's state controlled substance license as ''inoperative.'' *Id.*

Accordingly, I find that Registrant is not currently licensed to engage in the practice of medicine nor registered to dispense controlled substances in Illinois, the state in which he is registered with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71371 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27616, 27617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51104, 51105 (1993); *Bobby Watts, M.D.,* 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton,* 43 FR at 27617.

Pursuant to the Illinois Controlled Substances Act, a ''practitioner'' means ''a physician licensed to practice medicine in all its branches . . . or other person licensed, registered, or otherwise lawfully permitted by the United States or this State to distribute, dispense, conduct research with respect to, administer or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.'' 720 Ill. Comp. Stat. Ann. 570/102(kk) (West 2022). Further, the Illinois Controlled Substances Act requires that ''[e]very person who manufactures, distributes, or dispenses any controlled substances . . . must obtain a registration issued by the Department of Financial and Professional Regulation in accordance with its rules.'' *Id.* at 570/302(a). The Illinois Controlled Substances Act also authorizes the Department of Financial and Professional Regulation to discipline a practitioner holding a

[1] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration of finding of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.usdoj.gov*.

controlled substance license, stating that ''[a] registration under Section 303 to manufacture, distribute, or dispense a controlled substance . . . may be denied, refused renewal, suspended, or revoked by the Department of Financial and Professional Regulation.'' *Id.* at 570/304(a).

Here, the undisputed evidence in the record is that Registrant currently lacks authority to handle controlled substances in Illinois as his Illinois medical license is suspended and his Illinois controlled substance license is inoperative. As already discussed, a practitioner must hold a valid controlled substance license to dispense a controlled substance in Illinois. Thus, because Registrant lacks authority to handle controlled substances in Illinois, Registrant is not eligible to maintain a DEA registration. Accordingly, I order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BH9069205 issued to Kirk A. Hopkins, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Kirk A. Hopkins, M.D. to renew or modify this registration, as well as any other pending application of Kirk A. Hopkins, M.D. for additional registration in Illinois. This Order is effective May 11, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–07696 Filed 4–8–22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Kareem Hubbard, M.D.; Decision and Order

On June 4, 2020, the former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Kareem Hubbard, M.D. (hereinafter, Applicant) of San Leandro, California. Request for Final Agency Action (hereinafter, RFAA) Exhibit (hereinafter RFAAX) 2 (OSC), at 1 and 12. The OSC proposed to deny Applicant's application for a DEA Certificate of Registration, as well as to deny any applications for any other registrations, pursuant to 21 U.S.C. 824(a)(1) and (4) because Applicant ''materially falsified [his] application'' and because ''[Applicant's] registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).'' *Id.* at 1.

The OSC alleged that Applicant's application contained a materially false statement in which Applicant failed to disclose his previous surrender for cause of his DEA registration. *Id.* at 3. According to the OSC, Applicant had surrendered for cause his previous DEA registration ''less than two months before submitting [his] application.'' *Id.* Further, the OSC alleged that Applicant ''violated federal and California law by issuing prescriptions for controlled substances to four patients outside the usual course of professional practice and not for a legitimate medical purpose.'' *Id.* at 4.

The OSC notified Applicant of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 11 (citing 21 CFR 1301.43). The OSC also notified Applicant of the opportunity to submit a corrective action plan. *Id.* at 11–12 (citing 21 U.S.C. 824(c)(2)(C)).

By letter dated July 23, 2020, Applicant requested a hearing through counsel. RFAAX 3 (Request for Hearing), at 1. In his Request for Hearing, Applicant requested that his application for DEA registration be granted, because ''he applied for it in good faith and did not believe his surrender of [his] previous certificate was 'for cause.' '' *Id.* Additionally, Applicant's Request for Hearing included an attachment addressing the Government's allegations in detail. *Id.* at 3–5. On July 23, 2020, Applicant also submitted a Corrective Action Plan in which he offered a ''historical perspective, in addition to [his] interim practice activities and corrective action plan.'' RFAAX 4, at 5. On August 14, 2020, Applicant submitted a Withdrawal of Hearing Request in which he ''with[drew] his request for a hearing in [the] matter'' and ''with[drew] his pending application for a new DEA Certificate of Registration'' [1] without ''waiv[ing] his future right to reapply for [the] same.'' RFAAX 5, at 1; RFAAX 6 (Order Terminating Proceedings). On August 17, 2020, the Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, the Chief ALJ) terminated the proceedings. RFAAX 6.

On September 23, 2020, the Government forwarded its RFAA, along with the evidentiary record for this matter, to my office. The Government seeks a final order of denial of Applicant's application for DEA registration because Applicant ''materially falsified his application under 21 U.S.C. 824(a)(1), and committed acts which render his continued registration inconsistent with the public interest'' under 21 U.S.C. 824(a)(4) and 823(f). RFAA, at 1. I issue this Decision and Order after considering the entire record before me, 21 CFR 1301.43(e); and I make the following findings of fact.

I. Findings of Fact

A. Application for DEA Registration

On or about April 8, 2019, Applicant applied for a DEA Certificate of Registration as a practitioner in Schedules II through V with a proposed registered address of 15035 E 14th St., San Leandro, CA 94578. RFAAX 1 (Certification of Non Registration), at 1. Applicant's application was assigned Control No. W19032408C and is in a ''new pending'' status. *Id.* On Applicant's application, when presented with the question, ''Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?'' Applicant answered, ''No.'' *Id.* Applicant previously held DEA Certificate of Registration Control No. FH4372859, which expired on October 31, 2016, and DEA Certificate of Registration Control No. FH4334037, which expired on October 31, 2019. *Id.* at 2. Both of Applicant's previous DEA

[1] After an applicant has received an OSC regarding his or her application for DEA registration, the application may not be withdrawn without the permission of the Administrator. 21 CFR 1309.36(a). Here, Applicant had already received the OSC before attempting to withdraw his application, and he has not demonstrated good cause why his application should be withdrawn, nor do I find that withdrawal would be in the public interest due to the nature and extent of the allegations in front of me and the Applicant's stated intention that he will reapply for a registration. Adjudicating this matter to finality will create an official record the Agency can use in any future interactions with Applicant. As additionally noted in *Olsen,* ''a final adjudication is a public record of the Agency's expectations for current and prospective members of that community,'' and adjudications inform stakeholders, such as legislators and the public, about the Agency's work and allow them to provide feedback to the Agency, thereby helping shape how the Agency carries out its responsibilities under the CSA. *Id.* Adjudicating this matter to finality will create a public record to educate current and prospective registrants about the Agency's expectations regarding the responsibilities of registrants under the CSA and allow stakeholders to provide feedback regarding the Agency's enforcement priorities and practices. I have not permitted Applicant's application to be withdrawn. Accordingly, Applicant's withdrawal is not effective.

registrations are currently in a ''retired'' status. *Id.*

B. Investigation of Applicant

1. Declaration of Group Supervisor

According to a DEA Group Supervisor (hereinafter, the GS 1) in the San Jose Resident Office of the San Francisco Field Division assigned to investigate Applicant, ''DEA began investigating [Applicant] in 2018 after receiving information that he had prescribed large quantities of controlled substances.'' RFAAX 8 (GS's Declaration), at 1. GS stated that in early 2019, ''DEA reviewed [Applicant's] report from CURES, California's Prescription Data Monitoring Program'' and ''identified several red flags of abuse or diversion in [Applicant's] controlled substance prescribing, such as patients traveling long distances and receiving drug cocktails, among other red flags.'' *Id.* On February 21, 2019, DEA served an administrative subpoena on Applicant's practice for Applicant's patient files. *Id.* at 2*; see also id.* at Appendix (hereinafter, App.) A (administrative subpoena). On the same day, DEA also ''interviewed [Applicant] regarding his care of some of the patients whose files were the subject of the administrative subpoena'' and ''informed [Applicant] about several red flags of abuse or diversion (such as long distances traveled by patients, high dosages, and opioid cocktails) that DEA identified in his controlled substance prescribing.'' *Id.* at 2. Accordingly, DEA asked Applicant to voluntarily surrender his DEA Certificate of Registration Control No. FH4334037, and he did. *Id.; see also id.* at App B (Applicant's signed surrender for cause).

2. Declaration of Diversion Investigator T.B.

A DEA Diversion Investigator (hereinafter, the DI) assigned to investigate Applicant's application found that Applicant voluntarily surrendered for cause his previous DEA Certificate of Registration Control No. FH4334037 on February 21, 2019. RFAAX 7 (DI's Declaration), at 2. The DI also found that Applicant ''did not previously possess a DATA (Drug Addiction Treatment Act)[ ] Waiver number, which authorizes registrants to prescribe controlled substances for maintenance or detoxification treatment.'' *Id.*

Additionally, the DI obtained Applicant's 2017–2019 report from the CURES database to review Applicant's controlled substance prescribing from 2017–2019. *Id.* at 3; *see also id.* at App. B (CURES Report for Applicant dated from May 1, 2017 to June 30, 2019). In response to administrative subpoenas served to various pharmacies, the DI obtained copies of the controlled substance prescriptions issued by Applicant to Patients L.C., P.B., S.N., and J.H. *Id.* at 3; *see also id.* at Apps. C–F (copies of patient prescription records). Further, the DI determined the respective distances between Applicant's previous registered address and the home addresses for Patients L.C., P.B., and S.N. by entering the addresses online into Bing Maps. *Id.* at 3; *see also id.* at App. G (printouts from Bing Maps). The DI found that the distance between Patient L.C.'s home address and Applicant's previous registered location was at least 30 miles; the distance between Patient P.B.'s home address and Applicant's previous registered location was nearly 80 miles; and the distance between Patient S.N.'s home and Applicant's previous registered location was at least 35 miles. *Id.* at 4; *see also id.* at App. G (printouts from Bing Maps). Finally, in response to administrative subpoenas served to Applicant's practice, the DI obtained copies of the patient files for Patients L.C., P.B., S.N., and J.H. *Id.; see also id.* at Apps. H(i)–K (copies of patient files).

C. The Government Expert's Review of Applicant's Prescriptions

The DEA hired Dr. Timothy Munzing, M.D. to opine on Applicant's controlled substance prescribing based on the CURES report and the patient files described above. *Id.* at 4. Dr. Munzing is a physician licensed in California who has been the Family Medicine Residency Program Director at Kaiser Permanente Orange County for three decades. RFAAX 9 (Dr. Munzing's Declaration), at 1; *see also id.* at App. A (Dr. Munzing's CV). Dr. Munzing has also held an appointment as a full Clinical Professor at the University of California, Irvine School of Medicine since 2005 and has served on the Board of Directors of the Orange Academy of Family Physicians for over twenty years as well as on the Board of Directors for the California Academy of Family Physicians for five years. *Id.* Dr. Munzing currently serves on several other national and state boards and committees overseeing quality of care and residency and medical student training and in his three decades of practice has formally taught and/or lectured to thousands of physicians and students the core principles and guidelines of appropriate opioid and controlled substance medication prescribing. *Id.* at 1–2; *see also id.* at App. A. I find that Dr. Munzing is an expert in the standard of care for prescribing controlled substances in California, and I give his report full credit.

Dr. Munzing was retained as an expert to determine whether or not Applicant's prescribing was ''consistent with the usual course of professional practice, as required under 21 CFR 1306.04(a), and with California law.'' *Id.* at 2. Accordingly, Dr. Munzing's Declaration ''explain[ed] [his] expert opinion on the standard of care in California for medical practice, particularly with respect to the prescribing of controlled substances, and [his] conclusions as to [Applicant's] prescribing outside of that standard of care with regard to specific prescriptions that [Applicant] issued to [the] four different patients'' described above. *Id.*

1. The Standard of Care in California

Dr. Munzing attested that various state laws and regulations, as well as two guidelines published by the Medical Board of California, informed his opinion as to California's standard of care for the practice of medicine, particularly with respect to the prescribing of controlled substances for pain. *Id.* at 3–7. Dr. Munzing noted that California Health and Safety Code § 11153(a) requires that '' '[a] prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.' '' *Id.* at 3. Further, California Health and Safety Code § 11154(a) states that '' 'no person shall knowingly prescribe, administer, dispense, or furnish a controlled substance to or for any person . . . not under his or her treatment for a pathology or condition.' '' *Id.* Dr. Munzing also cited California Business and Professions Code §§§ 2242(a), 2234, and 725(a), noting that unprofessional conduct subject to sanction includes '' '[p]rescribing, dispensing, or furnishing [controlled substances] without an appropriate prior examination and a medical indication' . . . '[g]ross negligence'; '[r]epeated negligent acts'; '[i]ncompetence'; or '[t]he commission of any act involving dishonesty or corruption that is substantially related to the qualifications, functions, or duties of a physician and surgeon' . . . and '[r]epeated acts of clearly excessive prescribing, furnishing, dispensing, or administering of drugs . . .' '' *Id.* at 3–4. Finally, the two Medical Board of California guidelines referenced by Dr. Munzing included the Guide to the Laws Governing the Practice of

Medicine by Physicians and Surgeons [2] and the Guidelines for Prescribing Controlled Substances for Pain.[3] *Id.* at 3.

Dr. Munzing opined that, as informed by the above statutes and guidelines, the California standard of care requires that before prescribing controlled substances, at minimum, a practitioner must:

(1) ''obtain a medical history and perform an appropriate physical examination'';

(2) ''assess the patients' pain, physical and psychological functions, substance abuse history, and history of prior pain treatment (such as reviewing past medical records, laboratory studies, and imaging studies to establish a diagnosis and medical necessity)'';

(3) ''assess any underlying or coexisting diseases or conditions and order and perform diagnostic testing if necessary'';

(4) ''discuss the risks and benefits of using controlled substances and any other treatment modalities (such as non-opioid therapeutic options)'';

(5) ''periodically review the course of pain treatment or gather any new information, if any, about the etiology of a patient's state of health'';

(6) ''give special attention to patients who, by their own words and actions, pose a risk for medication misuse and/or diversion'';

(7) ''maintain accurate and complete records''; and

(8) ''document the presence of a recognized medical indication for the use of a controlled substance.''

Id. at 4. Additionally, Dr. Munzing opined that, as informed by guidelines from the Centers for Disease Control and Prevention (hereinafter, CDC) [4] and from the Food and Drug Administration (hereinafter, FDA),[5] the California standard of care imposes additional requirements and considerations for prescribing opioids as well as for prescribing benzodiazepines in combination with opioids. RFAAX 9, at 5–6. These additional requirements and considerations include that:

(1) ''[o]pioids prescribed at Morphine Milligram Equivalent ('MME') dosages above 90 mg per day significantly increase a patient's risk of overdose and death'';

(2) practitioners must ''carefully adjust, as well as closely monitor, patients who are prescribed MME dosages above 90 MME a day—a dangerously high dosage of opioids'';

(3) ''required monitoring when high-dosage opioids are prescribed include[s]: Periodic and close evaluations or examinations to determine the appropriateness of high-dosage opioids or [the consideration of] non-opioid alternatives; frequent and periodic review of a patient's report from [CURES]; and periodic urine drug screens'';

(4) MME dosages above 90 mg per day should be avoided or carefully justified;

(5) ''[t]he FDA requires 'Black Box' warnings about combining benzodiazepines with opioids'' because ''taking benzodiazepines with opioids can cause profound sedation, respiratory depression, coma, and death'';

(6) ''the combination of opioids and benzodiazepines should be avoided except in limited circumstances given the heightened risk of overdose and death when opioids and benzodiazepines are taken in combination'';

(7) ''[t]he combination of oxycodone, a benzodiazepine, and the muscle relaxant carisoprodol, is a dangerous drug cocktail known as the 'Holy Trinity' '';

(8) ''[t]he 'Holy Trinity' cocktail, as well as the combination of an opioid and a benzodiazepine, are both red flags of abuse or diversion''; and

(9) ''[t]he 'Holy Trinity' cocktail, in particular, is a combination of drugs that is popular among the drug-abusing community.''

Id. Finally, Dr. Munzing opined that the California standard of care requires ''practitioners prescribing controlled substances to monitor and address red flags of abuse or diversion, such as long distances traveled, inconsistent urine drug screen results, early refills, and drug cocktails'' and to ''document how they addressed or resolved red flags of abuse or diversion.'' *Id.* at 6. Specifically, Dr. Munzing noted that, per the California standard of care:

(1) ''[p]atients willing to travel long distances to see a physician to obtain controlled substances is a red flag of abuse or diversion'' and physicians must address or resolve this red flag;

(2) ''[p]eriodic urine drug screening is part of a physician's duty to perform ongoing monitoring of patients prescribed controlled substances'' and physicians prescribing controlled substances must ''address or resolve inconsistent urine drug screen results, which are red flags of abuse or diversion'';

(3) ''[i]nconsistent urine drug screen results that must be addressed or resolved are: (1) Positive results for non-prescribed controlled substances; and (2) negative results for prescribed controlled substances'';

(4) ''[e]ven should a physician address or resolve an inconsistent urine drug screen result,'' the physician must ''proceed to closely monitor the patient, which may include additional and more frequent urine drug screens''; and

(5) ''[p]atients with a history or pattern of obtaining or requesting early refills is a red flag of abuse or diversion'' and physicians must address or resolve this red flag.

Id. at 6–7.

Having read and analyzed all of the record evidence and law, I find that Dr. Munzing's declaration concerning a California physician's standard of care when prescribing controlled substances is supported by substantial evidence and is consistent with the explicit text of California law as well as state and federal guidelines. As such, I apply the standard of care of the state of California as described by Dr. Munzing.

2. The Subject Patients

i. Patient L.C.

From May 1, 2017, to February 21, 2019, and on an approximately monthly basis, Applicant prescribed Patient L.C. various opioids including oxycodone, hydrocodone-acetaminophen, Nucynta, Belbuca (buprenorphine), and hydromorphone, which Dr. Munzing calculated to amount to at least 420 mg MME per day. RFAAX 9, at 8; *see also* RFAAX 7, App. B (Applicant's CURES Report), App. C (prescription records for Patient L.C.), and Apps. H(i)–(ii) (patient file for Patient L.C.). Based upon his review of Patient L.C.'s file, Dr. Munzing concluded that Applicant ''prescribed such high-dosage opioids without consistently performing detailed examinations or evaluations, dependably considering non-opioid alternatives, or reliably weaning Patient L.C. off such high dosages.'' RFAAX 9, at 8. In particular, ''[Applicant's] frequent concurrent prescribing for Patient L.C. of oxycodone and hydrocodone-acetaminophen (both short-acting opioids) was therapeutically duplicative and therefore medically unnecessary.'' *Id.* Dr. Munzing also stated that, ''[t]here was no medical justification for [Applicant's] Belbuca (buprenorphine) prescriptions for Patient L.C.'' and noted that ''[Applicant] could not have prescribed Belbuca (a Schedule III opioid) for maintenance or detoxification treatment (for which Belbuca is usually prescribed) because [Applicant] did not possess a DATA-waiver at the time he issued these prescriptions.'' *Id.* Moreover, according to Dr. Munzing, ''given all the other high-dosage opioids Patient L.C. was prescribed, there was no legitimate medical purpose for additionally prescribing buprenorphine for pain management.'' *Id.*

Additionally, Dr. Munzing concluded, based upon his review of Patient L.C.'s file, that ''[Applicant] frequently prescribed to Patient L.C. either (1) a combination of opioids and the

[2] Available at: *http://web.archive.org/web/20210921192242/http://www.mbc.ca.gov/Download/Documents/laws-guide.pdf.*

[3] Available at: *https://www.mbc.ca.gov/Download/Publications/pain-guidelines.pdf.*

[4] The CDC guidelines referenced by Dr. Munzing included the CDC publication, ''Calculating Total Daily Dose of Opioids for Safer Dosage'' and the CDC's ''Guideline for Prescribing Opioids for Chronic Pain'' published in 2016. *Id.* at 5; *see https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf* and *https://www.cdc.gov/drugoverdose/prescribing/guideline.html.*

[5] Dr. Munzing referenced the FDA publication, ''New Safety Measures Announced for Opioid Analgesics, Prescription Opioid Cough Products, and Benzodiazepines'' published in 2016. RFAAX 9, at 5–6; *see https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm518110.htm.*

benzodiazepine, clonazepam . . . or (2) the 'Holy Trinity' cocktail, which consists of an opioid; a benzodiazepine, such as clonazepam; and carisoprodol . . . without performing adequate evaluation or monitoring to medically justify these combinations.'' *Id.* at 8–9. Specifically, Dr. Munzing noted that by February 6, 2018, Patient L.C. reported experiencing ''side effects attributable to [Applicant's] controlled substance prescriptions and which [Applicant] did not adequately examine or evaluate.'' *Id.* at 9. Further, ''[Applicant] improperly continued to prescribe these dangerous drug cocktails after February 6, 2018[,] without further examining or evaluating Patient L.C.'s reported side effects.'' *Id.*

Finally, Dr. Munzing concluded, based upon his review of Patient L.C.'s file, that Applicant failed to address several red flags of abuse or diversion. *Id.* First, Dr. Munzing noted that there was no documentation that Applicant adequately addressed or resolved Patient L.C.'s inconsistent urine drug screen results, which included positive results for controlled substances that Applicant had not prescribed to Patient L.C. and that Patient L.C. had not filled the prescriptions anywhere in California according to CURES reports, some of which were dangerous in combination with the high-dosage opioids that Applicant had prescribed to Patient L.C. *Id.* at 9–10. Patient L.C.'s urine drug screen results also included negative results for controlled substances for which Applicant had issued prescriptions to Patient L.C. and which Patient L.C. had filled. *Id.* at 10. Second, Dr. Munzing noted that there was no documentation that Applicant adequately addressed or resolved evidence of Patient L.C.'s early refills of controlled substances on at least 34 occasions between 2017 and 2019.[6] *Id.* at 10–11. Finally, Dr. Munzing noted that there was no documentation that Applicant addressed or resolved evidence that Patient L.C. traveled a long distance (at least 60 miles roundtrip from Martinez, CA to Applicant's office in San Leandro, CA) to obtain controlled substances from Applicant on a nearly monthly basis. *Id.; see also* RFAAX 7, App. G (printouts from Bing Maps), at 3.

[6] Dr. Munzing noted that ''[e]ven though [Applicant] documented on several occasions about providing early refills due to Patient L.C. claiming to have lost her tablets from vomiting, there was no legitimate medical purpose for consistently continuing to provide early refills for this reason without first treating Patient L.C.'s issues with vomiting.'' *Id.* at 11.

ii. Patient P.B.

On an approximately monthly basis, Applicant prescribed Patient P.B. various opioids including OxyContin, oxycodone, Nucynta, and levorphanol tartrate, which Dr. Munzing calculated to amount to at least 840 mg MME per day. RFAAX 9, at 11; *see also* RFAAX 7, App. B (Applicant's CURES Report), App. D (prescription records for Patient P.B.), and App. I (patient file for Patient P.B.). Based upon his review of Patient P.B.'s file, Dr. Munzing concluded that Applicant ''prescribed such high-dosage opioids without consistently performing detailed examinations or evaluations, dependably considering non-opioid alternatives, or reliably weaning Patient P.B. off such high dosages.'' RFAAX 9, at 11–12. In particular, Dr. Munzing stated that, ''[Applicant's] concurrent prescribing for Patient P.B. of oxycodone and Nucynta (both short-acting opioids) on at least one occasion was therapeutically duplicative and therefore medically unnecessary.'' *Id.* at 12. Additionally, Dr. Munzing concluded, based upon his review of Patient P.B.'s file, that ''[Applicant] frequently prescribed to Patient P.B. either (1) a combination of opioids and the benzodiazepine, clonazepam . . . or (2) the ''Holy Trinity'' cocktail, which consists of an opioid; a benzodiazepine, such as clonazepam; and carisoprodol . . . without performing adequate evaluation or monitoring to medically justify these combinations.'' *Id.*

Finally, Dr. Munzing concluded, based upon his review of Patient P.B.'s file, that Applicant failed to address several red flags of abuse or diversion. *Id.* Specifically, Dr. Munzing noted that there was no documentation that Applicant adequately addressed or resolved Patient P.B.'s inconsistent urine drug screen results, which included positive results for controlled substances that Applicant had not prescribed to Patient P.B. and for which Patient P.B. had not filled the prescriptions anywhere in California according to CURES reports. *Id.* at 12–13. Patient P.B.'s inconsistent urine drug screen results also included a negative result for a controlled substance for which Applicant had issued prescriptions to Patient P.B. and which Patient P.B. had filled. *Id.* at 13. Dr. Munzing also noted that there was no documentation that Applicant addressed or resolved evidence that Patient P.B. traveled a long distance (at least 160 miles roundtrip from Newman, CA to Applicant's office in San Leandro, CA) to obtain controlled substances from Applicant on a nearly monthly basis. *Id.* at 14; *see also* RFAAX 7, App. G (printouts from Bing Maps), at 4.

iii. Patient S.N.

On an approximately monthly basis, Applicant prescribed Patient S.N. various opioids including OxyContin, oxycodone, and Xtampza, which Dr. Munzing calculated to amount to at least 405 mg and 885 mg MME per day. RFAAX 9, at 14; *see also* RFAAX 7, App. B (Applicant's CURES Report), App. E (prescription records for Patient S.N.), and App. J (patient file for Patient S.N.). Based upon his review of Patient S.N.'s file, Dr. Munzing concluded that Applicant ''prescribed such high-dosage opioids without consistently performing detailed examinations or evaluations, dependably considering non-opioid alternatives, or reliably weaning Patient S.N. off such high dosages.'' RFAAX 9, at 14.

Additionally, Dr. Munzing concluded, based upon his review of Patient S.N.'s file, that Applicant failed to address several red flags of abuse or diversion. *Id.* First, Dr. Munzing noted that there was no documentation that Applicant adequately addressed or resolved Patient S.N.'s inconsistent urine drug screen results, which included a positive result for controlled substances that Applicant had not prescribed to Patient S.N. and for which Patient S.N. had not filled the prescriptions anywhere in California according to CURES reports. *Id.* Dr. Munzing also noted that ''[Applicant] failed to document any test results for Patient S.N.'s three subsequent urine drug screens performed in 2018.'' *Id.* at 14–15. Second, Dr. Munzing noted that there was no documentation that Applicant adequately addressed or resolved evidence of Patient S.N.'s early refills of controlled substances on at least three occasions between 2017 and 2019. *Id.* at 15. Finally, Dr. Munzing noted that there was no documentation that Applicant addressed or resolved evidence that Patient S.N. traveled a long distance (at least 70 miles roundtrip from Pittsburg, CA to Applicant's office in San Leandro, CA) to obtain controlled substances from Applicant on a nearly monthly basis. *Id.; see also* RFAAX 7, App. G (printouts from Bing Maps), at 1–2.

iv. Patient J.H.

On an approximately monthly basis, Applicant prescribed Patient J.H. various opioids including oxycodone, oxycodone-acetaminophen, OxyContin, and fentanyl, which Dr. Munzing calculated to amount to at least 1,350 mg MME per day. RFAAX 9, at 15; *see also* RFAAX 7, App. B (Applicant's

CURES Report), App. F (prescription records for Patient J.H.), and App. K (patient file for Patient J.H.). Based upon his review of Patient J.H.'s file, Dr. Munzing concluded that Applicant ''prescribed such high-dosage opioids without consistently performing detailed examinations or evaluations, dependably considering non-opioid alternatives, or reliably weaning Patient J.H. off such high dosages.'' RFAAX 9, at 15. In particular, ''[Applicant's] frequent concurrent prescribing for Patient J.H. of oxycodone and oxycodone-acetaminophen (both short-acting opioids) was therapeutically duplicative and therefore medically unnecessary.'' *Id.*

Dr. Munzing also concluded, based upon his review of Patient J.H.'s file, that ''[Applicant] frequently prescribed Patient J.H. the 'Holy Trinity' cocktail, which consists of an opioid; a benzodiazepine, such as alprazolam . . . and carisoprodol . . . without performing adequate evaluation or monitoring to medically justify this combination.'' *Id.* at 15–16. Specifically, Dr. Munzing noted that by January 29, 2018, Patient J.H. reported having experienced ''side effects attributable to [Applicant's] controlled substance prescriptions and which [Applicant] did not adequately examine or evaluate.'' *Id.* at 16. Further, ''[Applicant] improperly continued to prescribe the 'Holy Trinity' after January 29, 2018[,] without further examining or evaluating Patient J.H.'s reported side effects.'' *Id.* Dr. Munzing also concluded, based upon his review of Patient J.H.'s file, that, ''[Applicant] frequently prescribed stimulants, either amphetamine salts . . . or modafinil . . . without any legitimate medical purpose.'' *Id.* Dr. Munzing noted that he did not find any apparent medical diagnosis or evaluation in Patient J.H.'s file for Attention-Deficit Hyperactivity Disorder (ADHD), ''for which amphetamine salts are normally used to treat.'' *Id.* Additionally, Dr. Munzing noted that ''while amphetamine salts and modafinil can be used to treat drowsiness or extreme sleepiness, the use of such stimulants for Patient J.H. was not medically appropriate as the patient's drowsiness or sleepiness were likely side effects of his prescribed high-dosage opioids.'' *Id.*

Finally, Dr. Munzing concluded, based upon his review of Patient J.H.'s file, that Applicant failed to address or resolve several red flags of abuse or diversion. *Id.* Specifically, Dr. Munzing noted that there was no documentation that Applicant adequately addressed or resolved Patient J.H.'s inconsistent urine drug screen results, which included positive results for controlled substances that Applicant had not prescribed to Patient J.H. and for which Patient J.H. had not filled the prescriptions anywhere in California according to CURES reports, some of which were dangerous in combination with the high-dosage opioids that Applicant had prescribed to Patient J.H. *Id.* at 16–17. Applicant's inconsistent urine drug screen results also included positive results for alcohol, which Dr. Munzing noted can ''amplify the risk of overdose and death associated with the 'Holy Trinity' cocktail [Applicant] prescribed Patient J.H.'' *Id.* at 17. Moreover, Applicant's inconsistent urine drug screen results included negative results for controlled substances for which Applicant had issued prescriptions to Patient J.H. and which Patient J.H. had filled. *Id.* at 17–18.

Based on his expert medical opinion, Dr. Munzing concluded, and I agree, that ''the controlled substance[ ] prescriptions issued by [Applicant] for Patients L.C., P.B., S.N., and J.H. between May 1, 2017, and February 21, 2019[,] were issued without a legitimate medical purpose and were issued beneath the standard of care for the practice of medicine in the State of California, and therefore outside of the usual course of professional practice.'' *Id.* at 7.

II. Discussion

A. Government's Position

In its RFAA, the Government sought denial of Applicant's application for DEA registration because Applicant ''materially falsified his application under 21 U.S.C. 824(a)(1), and committed acts which render [granting his] registration inconsistent with the public interest.'' RFAA, at 1 (citing 21 U.S.C. 824(a)(1), (a)(4) and 823(f). Specifically, the Government argued that Applicant had materially falsified his application when he falsely provided a ''No'' response to the liability question asking him whether he had ever surrendered for cause a federal controlled substance registration and when he knew or should have known that his ''No'' response was false. *Id.* at 19. The Government also argued that Applicant had repeatedly violated state and federal law by issuing prescriptions for controlled substances to four patients outside of the standard of care in the State of California and outside of the usual course of professional practice. *Id.* at 21. The Government concluded its RFAA by requesting that Applicant's application for DEA registration be denied and that any applications by Applicant for any other registrations be denied. *Id.* at 25.

B. Applicant's Position

Within his Request for Hearing and his Corrective Action Plan, both submitted in response to the OSC, Applicant offered explanation as to his misconduct, however, Applicant did not offer supporting evidence nor any ability for me to assess the credibility of his unsworn statements.[7] *See* RFAAX 3 (Request for Hearing) and RFAAX 4 (Corrective Action Plan). In his Request for Hearing, Applicant addressed the allegations of material falsification and stated that when, on February 21, 2019, DEA investigators visited Applicant's registered location to serve an administrative subpoena for patient files from his practice, the investigators ''explained that the DEA was concerned about certain red flags associated with [his] controlled substance prescribing, including but not limited to, long distances traveled by patients, high dosages, and drug cocktails.'' RFAAX 3, at 3. Applicant stated that he ''believed that if [he] surrendered [his] DEA certificate that [he] would be demonstrating good faith that [he] had done nothing wrong.'' *Id.* Applicant also stated that he ''was unaware and did not understand that [he] was being asked to surrender [his] DEA certificate 'for cause.' '' *Id.*

In both his Request for Hearing and his Corrective Action Plan, Applicant offered a ''historical perspective'' regarding the improper prescribing allegations. RFAAX 3, at 3–5; RFAAX 4, at 5. According to Applicant, in 2018, he ''acquired a medical practice from anesthesiologist/pain medicine specialist [M. J.], a frequent prescriber of schedule II and III medications.'' RFAAX 4, at 5. Applicant stated that prior to considering the purchase of M. J.'s practice, and before working with him, Applicant ''discussed with him his patient population'' and '' [a] contract was drawn up ensuring that all [M. J.] was doing was within state and deferral [sic] laws.'' RFAAX 3, at 3. Applicant stated that he and M. J. agreed that M. J. would continue to work with Applicant for the first year and then turn the practice over to Applicant. *Id.* The contract was signed by both

[7] Applicant specifically did not opt to submit a written statement in lieu of a hearing under 21 CFR 1316.49. In this case, I have considered these unsworn submissions minimally to represent Applicant's position because they address the underlying allegations. Even if I afforded these unsupported and unsworn statements the weight of a written statement, they would be insufficient to rebut the Government's case for denial of Applicant's application for the reasons stated herein.

Applicant and M. J. and witnessed by a third party. *Id.* According to Applicant, CDC guidelines were also discussed, and M.J. ''informed [Applicant] that [they] were recommendations, not mandates.'' *Id.* M.J. said that patients had been established with him for 20–30 years. *Id.* Further, M.J. discussed the ''tolerance displayed by long term chronic pain patients,'' their ''functionality'' (that patients could ''go to work, address activities of daily life, [and] enjoy the benefits of being sociable'') and ''an overall high level of productivity of patients.'' *Id.* M.J. further stated that ''if there had been any problems, he would not [have been] allowed to operate for all this time, incident free.'' *Id.*

According to Applicant, upon his evaluation of the patients, he realized that ''many patients were not getting the proper workups, diagnostic studies[,] and referrals needed to improve their pain.'' *Id.* Further, ''[m]any of them were exhibiting chronic pain due to lack of early appropriate treatment'' and ''patients had been pushed toward interventional procedures that either were not indicated or ended up hurting them.'' *Id.* Applicant stated that ''[t]his was all done under the guise of performing a 'trial' '' and that ''[m]edications had been escalated due to failed 'trials' and recommended due to inability to control pain with interventions.'' *Id.* Applicant stated that ''[a]s medications were elevated and encouraged by [M.J.], patients had become dependent on their current regimens, and had been educated that their pain was so severe that high medication dosages were indicated.'' *Id.*

According to Applicant, in April 2019, he was the victim of a cyber crime when ransomware was placed onto his servers and corrupted all of his electronic medical records. *Id.* at 4. Applicant stated that ''[although] no HIPPA violation occurred and the charts were retrieved on an external hard drive, upon attempting to upload the data, the external hard drive became corrupted leading to loss of all charting information.'' *Id.* As a result of the data loss, Applicant was only able to provide management details for the four patients referenced in the OSC by memory and not by specific references to their patient records. *Id.* Applicant stated that ''[a]ll four patients cited in the [OSC] were patients managed or at one time managed by [M.J.].'' *Id.* Further, ''[n]one of them were naïve to opioids and were elevated to the regimens in question by [M.J.].'' *Id.* Applicant concluded that ''[a]ll of these patients, from the moment [he] inherited them, were already and for years [had been] above the current state, federal[,] and CDC guidelines.'' *Id.*

Regarding Patient L.C., Applicant stated that her medications had been escalated prior to her becoming Applicant's patient. *Id.* According to Applicant, Patient L.C. had indicated that ''she had tried many procedures for her condition including [ ] a trial of a Spinal Cord Stimulator (SCS).'' *Id.* However, Patient L.C. said that during the SCS trial she had been hurt and she ''frequently had her mother [with her] at appointments to advocate that she would never have [an] SCS [again] due to the adverse experience during the trial.'' *Id.* Applicant stated that he and other physicians believed that Patient L.C. was getting too much medication and Applicant ''used [other] opinions to further bolster [his own],'' but Patient L.C. disagreed and ''cit[ed] [M.J.].'' *Id.* Applicant then started Patient L.C. on a ''slow wean'' of her medications. *Id.* According to Applicant, Patient L.C. was also undergoing a trial of Belbuca for her pain, and as he was weaning down her medications, Belbuca was used ''to continue to cover her chronic pain.'' *Id.* Applicant stated that Belbuca ''is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.'' *Id.* For Patient L.C., Belbuca was ''not being used for maintenance or detoxification treatment.'' *Id.*

Regarding Patient P.B., Applicant stated that her medications had been escalated prior to her becoming Applicant's patient. *Id.* According to Applicant, there had been no diagnostic studies on file for Patient P.B. and weaning down of her medications occurred once diagnostic studies were performed. *Id.*

Regarding Patient S.N., Applicant stated that his medications had also been escalated prior to him becoming Applicant's patient. *Id.* at 5. According to Applicant, Patient S.N. ''cited tailbone pain that made sitting for long periods difficult'' and ''had a job where he often traveled by plane and was not able to stop and take breaks from sitting.'' *Id.* ''Refills made early usually represented a documented trip he had on behalf of his profession.'' *Id.* According to Applicant, Patient S.N. ''had never been worked up for his pain'' and ''[m]ultiple diagnostic studies were conducted in attempts to find a solution.'' *Id.* Applicant stated that he started Patient S.N. on a weaning down of his medication and ''[a]fter S.N. transferred care to obtain medication from another provider, he continued to work with [Applicant] in an attempt to solve his pain.'' *Id.* Applicant also stated that Patient S.N. ''attempted a nerve block to further investigate a solution to his pain, though no opioids were being prescribed by [Applicant] at the time.'' *Id.*

Finally, regarding Patient J.H., Applicant stated that his medications too had been escalated prior to him becoming Applicant's patient. *Id.* According to Applicant, Patient J.H. had sustained an occupational injury and was being managed under a workers' compensation insurer. *Id.* Patient J.H. previously had a failed surgical procedure and was a candidate for a revision procedure. *Id.* Applicant stated that he had agreed with the revision procedure as an option, but that the procedure was denied by the insurer. *Id.* According to Applicant, ''[o]ther non-opioid options were recommended to help decrease [Patient J.H.'s use of] opioids and [to] manage his pain.'' *Id.*

Applicant concluded his Request for Hearing by asserting that his patients ''had been taught that issues that could have normally been mitigated by appropriate treatment were instead only able to be addressed with high levels of medication'' and that ''[t]he belief had been ingrained that medications were the only option.'' *Id.* Applicant asserted that his patients in turn became dependent on their medications and that ''[a]s a competent, caring doctor, [he] could not abandon them.'' *Id.* Applicant stated that he ''was working diligently to reduce their medication use, but found a number of patients who had been on long term opiate use'' and thus ''[had] to very slowly wean them.'' *Id.*

In his Corrective Action Plan, Applicant stated, ''Given my training in physical medicine and rehabilitation, my focus was to taper his patients from high dose opioids and offer them an array of alternative treatment options.'' RFAAX 4, at 5. According to Applicant, ''[o]n February 23, 2019, in the midst of this process, DEA officers presented to the clinic and requested that [he] surrender [his] DEA license'' to which Applicant ''voluntarily complied.'' *Id.* Applicant further stated that ''[a]t that time, patients who were on scheduled medications were provided the option of tapering off their medications or provided a list of alternative physicians for transfer of care, including an addiction medicine specialist.'' *Id.* Applicant asserted that ''[f]or those patients who decided to taper/discontinue their medications, [he] continued to provide them care in the framework of holistic treatment options such as physical and behavioral therapies, procedures, durable medical

equipment, self-directed exercise, and other non-medical pain management strategies.'' *Id.*

Applicant stated that he ''proceeded to close the practice, and after full disclosure, [he has] been evaluating and treating patients at RehabOne Medical Group, Inc.'' *Id.* Applicant chose to work at RehabOne ''because of their positive reputation in the community [and] their focus on functional restoration.'' *Id.* Applicant also chose RehabOne for ''their attentiveness to documentation, record keeping, and compliance [as well as] medical provider supervision[,] oversight, and collaboration.'' Finally, Applicant chose RehabOne for their ''adherence with evidence-based guideline recommendations for prescribing controlled substances.'' *Id.* Applicant stated that ''[a]lthough [he has] not personally prescribed any scheduled medications, RehabOne has a strong risk management policy that utilizes opioid and addiction risk screening tools, long-term controlled substance agreements, routine CURES analysis, initial and random urine toxicology, and '5 As' monitoring.'' *Id.* Further, ''[w]hen opioid or non-opioid medications are considered appropriate as part of a treatment plan, all efforts are made to utilize the lowest dose and frequency possible to achieve optimal outcomes.'' *Id.* According to Applicant, ''[a]t RehabOne, medications are very carefully considered as part of an overall, comprehensive treatment strategy with the primary goal of functional restoration and quality of living.'' *Id.*

Applicant concluded his Corrective Action Plan by stating that ''[m]oving forward, [he plans] to strictly adhere to these practices and principles as [he strives] to help [his] patients lead full and meaningful lives.'' *Id.* Applicant stated that he ''will continue to review and implement the most current evidence-based guidelines for the treatment of chronic pain'' and requested that ''[DEA] reinstate [his] DEA license so that [he] can utilize appropriate medications as one tool in the toolbox to achieve these outcomes.'' *Id.*

C. Analysis

1. 21 U.S.C. 823(f): The Five Public Interest Factors

Pursuant to section 303(f) of the Controlled Substances Act (hereinafter, CSA), ''[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Section 303(f) further provides that an application for a practitioner's registration may be denied upon a determination that ''the issuance of such registration . . . would be inconsistent with the public interest.'' *Id.* In making the public interest determination, the CSA requires consideration of the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f).

The DEA considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993). Thus, there is no need to enter findings on each of the factors. *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Furthermore, there is no requirement to consider a factor in any given level of detail. *Trawick* v. *Drug Enf't Admin.,* 861 F.2d 72, 76–77 (4th Cir. 1988). The balancing of the public interest factors ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest . . . .'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009). When deciding whether registration is in the public interest, the DEA must consider the totality of the circumstances. *See generally Joseph Gaudio, M.D.,* 74 FR 10083, 10094–95 (2009) (basing sanction on all evidence on record).

The Government does not dispute that Applicant holds a valid state medical license and is authorized to dispense controlled substances in the State of California where he practices. *See* RFAAX 2 (OSC), at 2. While I have considered all of the public interest factors[8] in 21 U.S.C. 823(f), the Government's evidence in support of its *prima facie* case for denial of Applicant's application is confined to Factors Two and Four. *See* RFAA, at 19–25. Moreover, the Government has the burden of proof in this proceeding. 21 CFR 1301.44. I find that the Government's evidence satisfies its *prima facie* burden of showing that Applicant's registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(f). I further find that Applicant failed to provide sufficient evidence to rebut the Government's *prima facie* case.

i. Factors Two and Four

Evidence is considered under Public Interest Factors Two and Four when it reflects compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. Established violations of the CSA, DEA regulations, or other laws regulating controlled substances at the state or local level are cognizable when considering whether granting a registration is consistent with the public interest.

Here, the Government has alleged that from at least May 1, 2017, through at least February 21, 2019, Applicant unlawfully issued prescriptions for controlled substances in violation of the CSA. RFAAX 2 (OSC), at 2 and 4–10. Specifically, the Government alleges that Applicant repeatedly violated 21 CFR 1306.4(a) by issuing prescriptions for controlled substances to Patients L.C., P.B., S.N., and J.H. beneath the standard of care and outside the usual course of professional practice in California—the state in which Applicant is applying for DEA registration. *Id.*

[8] As to Factor One, there is no record evidence of disciplinary action against Applicant's state medical license. 21 U.S.C. 823(f)(1). State authority to practice medicine is ''a necessary, but not a sufficient condition for registration . . . .'' *Robert A. Leslie, M.D.,* 68 FR at 15230. Therefore, ''[t]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of [or granting of a] DEA certification is consistent with the public interest.'' *Roni Dreszer, M.D.,* 76 FR 19434, 19444 (2011).

As to Factor Three, there is no evidence in the record that Applicant has been convicted of an offense under either federal or state law ''relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, as Agency cases have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.,* 75 FR 49956, 49973 (2010). Agency cases have therefore found that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

As to Factor Five, the Government's evidence fits squarely within the parameters of Factors Two and Four and does not raise ''other conduct which may threaten the public health and safety.'' 21 U.S.C. 823(f)(5). Accordingly, Factor Five does not weigh for or against Applicant.

According to the CSA's implementing regulations, a lawful controlled substance order or prescription is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). The Supreme Court has stated, in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription, that ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006).

I found above that the Government's expert credibly declared, as supported by California law and federal and state guidelines, that the standard of care in California requires physicians to, among other things, perform a sufficient physical exam and take a medical history, counsel patients on the risks and benefits of the use of particular controlled substances, periodically review the course of treatment and adjust as needed, give special attention to patients who pose a risk for medication misuse and diversion, and monitor and address any red flags of abuse or diversion. Further, the standard of care in California requires additional care and consideration for the prescribing of opioids, as well as for the prescribing of benzodiazepines in combination with opioids.

Based on the credible and unrebutted opinion of the Government's expert, I found above that Applicant issued a high number of controlled substance prescriptions to at least four different patients, often for extremely high doses of opioids and in dangerous combinations of opioids and benzodiazepines, without performing detailed examinations or evaluations, dependably considering non-opioid alternatives, reliably weaning patients off such high dosages, or resolving or documenting resolution of red flags of abuse and/or diversion as required by the standard of care. *See supra* I.C.2.i–iv. My findings demonstrate that Applicant repeatedly violated the applicable standard of care when prescribing controlled substances and that his conduct was not an isolated occurrence, but occurred with multiple patients. *See Kaniz Khan Jaffery,* 85 FR 45667, 45685 (2020); *Wesley Pope, M.D.,* 82 FR 42961, 42986 (2017). As such, I find that the Government has presented substantial evidence that from May 1, 2017, to February 21, 2019, Applicant issued controlled substance prescriptions to the four subject patients beneath the applicable standard of care in California and outside the usual course of professional practice. Accordingly, I am sustaining the Government's allegation that Applicant violated 21 CFR 1306.04(a).

The Government has also alleged that Applicant's prescribing practices in regard to the subject patients violated California State law. RFAAX 2, at 2–3 and 4–10. Echoing the federal regulations, California law requires that a ''prescription for a controlled substance shall only be issued for a medical purpose by an individual practitioner acting in the usual course of his or her professional practice.'' Cal. Health & Safety Code § 11153(a).[9] Further, California Business and Professions Code § 2242(a) states, ''Prescribing, dispensing, or furnishing [controlled substances] without an appropriate prior examination and a medical indication[ ] constitutes unprofessional conduct.'' [10] Accordingly, I find that, similarly to 21 CFR 1306.04(a), the record contains substantial evidence that Applicant violated these provisions with respect to the controlled substance prescriptions for Patients L.C., P.B., S.N., and J.H.

In sum, I find that the record contains substantial evidence that Applicant issued a multitude of prescriptions for controlled substances, including high dosages of opioids, to multiple patients beneath the applicable standard of care, outside the usual course of professional practice, and in violation of federal and state law. I, therefore, find that Factors Two and Four weigh in favor of denial of Applicant's application and thus find Applicant's registration to be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(f).

2. 21 U.S.C. 824(a)(1): Material Falsification

In addition to the public interest allegations, as previously mentioned, the OSC in this matter also alleges that Applicant's application for registration should be denied, because Applicant's application contains a materially false response to a liability question. RFAAX 2, at 1 and 3–4; *see supra* I.A–B.1. The CSA, however, places the provision addressing the ramification of a material falsification with the bases for revocation or suspension of a registration. 21 U.S.C. 824(a). Prior Agency decisions have addressed whether it is appropriate to consider a material falsification and other provisions of 21 U.S.C. 824(a) when determining whether or not to grant a practitioner registration application. For over forty-five years, Agency decisions have concluded that it is. *See, e.g., Lisa M. Jones, N.P.,* 86 FR 52196 (2021), *Robert Wayne Locklear,* 86 FR 33738 (2021) (collecting Agency decisions). These decisions offer multiple bases and analyses for that conclusion. 86 FR at 33744–45.

Having read and analyzed all of the record evidence, I find from clear, unequivocal, convincing, and unrebutted record evidence that Applicant surrendered (for cause) his previous DEA registration on February 21, 2019. *See supra* I.A–B.1. Having read and analyzed all of the record evidence, I find from clear, unequivocal, convincing, and unrebutted record evidence that when presented with the liability question, ''Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?''—Applicant answered, ''No.'' *Id.* Applicant's false answer to this liability question in his application implicates two of the public interest factors that the CSA requires me to consider (*see supra* II.C.1): Applicant's experience in dispensing controlled substances and Applicant's compliance with applicable federal laws relating to controlled substances. 21 U.S.C. 823(f)(2) and (4); *Frank Joseph Stirlacci, M.D.,* 85 FR 45229, 45234 (2020). As such, Applicant's false response to this liability question in his application was ''predictably capable of affecting, *i.e.,* had a natural tendency to affect'' my official decision on Applicant's application. *Frank Joseph Stirlacci,*

[9] The Government also alleged that Applicant violated California Health and Safety Code § 11154(a), which states that ''no person shall knowingly prescribe, administer, dispense, or furnish a controlled substance to or for any person . . . not under his or her treatment for a pathology or condition.'' Dr. Munzing's expert report did not address whether Applicant knowingly prescribed controlled substances to or for any person not under his treatment for a pathology or condition. Accordingly, I find that the Government has not met its burden to prove by substantial evidence that Applicant violated California Health and Safety Code § 11154(a).

[10] The Government also alleged that Applicant violated California Business and Professions Code §§ 2234 and 725(a), which state that unprofessional conduct includes ''[g]ross negligence''; ''[r]epeated negligent acts''; ''[i]ncompetence''; or ''[t]he commission of any act involving dishonesty or corruption that is substantially related to the qualifications, functions, or duties of a physician and surgeon'' as well as ''[r]epeated acts of clearly excessive prescribing, furnishing, dispensing, or administering of drugs.'' Dr. Munzing's expert report did not address whether Applicant engaged in these particular forms of unprofessional conduct. Accordingly, I find that the Government has not met its burden to prove by substantial evidence that Applicant violated California Business and Professions Code §§ 2234 and 725(a).

M.D., 85 FR at 45238. Accordingly, I find from clear, unequivocal, convincing, and unrebutted record evidence that Applicant's application for DEA registration contains a material falsification, which is an independent basis for the denial of Applicant's application.

III. Sanction

The Government has established grounds to deny a registration; therefore, I will review any evidence and argument that Applicant submitted to determine whether or not Applicant has presented ''sufficient mitigating evidence to assure the Administrator that [he] can be trusted with the responsibility carried by such a registration.'' *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller, M.D.,* 53 FR 21931, 21932 (1988)). '' 'Moreover, because ''past performance is the best predictor of future performance,'' *ALRA Labs, Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.' '' *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009) (quoting *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Samuel S. Jackson, D.D.S.,* 72 FR at 23853; *John H. Kennnedy,* M.D., 71 FR 35705, 35709 (2006); *Prince George Daniels, D.D.S.,* 60 FR 62884, 62887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).

A. Acceptance of Responsibility

As previously discussed, although Applicant initially requested a hearing and submitted a Corrective Action Plan on July 23, 2020, Applicant later withdrew his hearing request on August 14, 2020, and the proceedings were terminated. *See* RFAAX 3 (Request for Hearing); RFAAX 4 (Corrective Action Plan); RFAAX 5 (Withdrawal of Hearing Request); RFAAX 6 (Order Terminating Proceedings). As such, there is no credible, sworn evidence on the record regarding acceptance of responsibility for me to consider. Further, even if I could consider the explanations that Applicant offered in his initial Request for Hearing and Corrective Action Plan, they do not demonstrate sufficient acceptance of responsibility or evidence of remedial measures that would aid me in entrusting Applicant with registration. *See* RFAAX 3 and RFAAX 4.

As to the allegations of material falsification, Applicant claimed that, at the time he surrendered his DEA certificate for cause, he misunderstood that he was doing so and believed instead that he was ''demonstrating good faith that [he] had done nothing wrong.'' [11] RFAAX 3, at 3. Whether or not Applicant's claims are truthful, they do not demonstrate acceptance of responsibility for his (intentional or not) materially false response to a liability question. Rather, Applicant's claims demonstrate an attempt to either shift the blame to DEA investigators for failing to properly explain the situation to him or to simply use his ignorance as an excuse, neither of which inspire confidence that Applicant fully appreciates an applicant's obligation to provide truthful and accurate responses on an application for DEA registration.

As to the allegations of improper prescribing, Applicant claimed that he had inherited the subject patients from his purchase of another physician's practice and that the physician he had purchased the practice from had assured him that all was proper regarding the practice and his patients. RFAAX 3, at 3; RFAAX 4, at 5. However, Applicant claimed that he only later realized that all was *not* proper regarding the practice and the patients that he had inherited and that he had done the best that he could to wean the four subject patients off of their high dosages of controlled substances. RFAAX 3, at 3–5; RFAAX 4, at 5. Again, Applicant's statements do not demonstrate acceptance of responsibility for his improper prescribing, but instead demonstrate an attempt to shift the blame to the physician whom he had inherited the subject patients from or, at the very least, a failure to acknowledge that, regardless of his intentions, his prescribing was beneath the applicable standard of care and outside the usual course of professional practice.

As for remedial measures, I do not consider them when an Applicant has not unequivocally accepted responsibility, however, even if I were to consider Applicant's remedial measures here, I do not find them to be sufficient. Applicant discussed how since surrendering his DEA registration, he has closed his practice and has begun treating patients at another practice, one which he lauds for its adherence to best practices for prescribing controlled substances. RFAAX 4, at 5. Applicant also stated his own commitment to adhering to these best practices moving forward, however, Applicant did not specify in what ways he would ensure this adherence. *Id.* As such, Applicant has not sufficiently demonstrated that he is ready to be entrusted with the responsibility of registration.

B. Specific and General Deterrence

In addition to acceptance of responsibility, the Agency considers both specific and general deterrence when determining an appropriate sanction. *Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,810 (2015). Specific deterrence is the DEA's interest in ensuring that a registrant complies with the laws and regulations governing controlled substances in the future. *Id.* General deterrence concerns the DEA's responsibility to deter conduct similar to the proven allegations against the registrant for the protection of the public at large. *Id.* In this case, I believe that denial of Applicant's application for DEA registration would deter Applicant and the general registrant community from the improper prescribing of controlled substances as well as from ignoring their obligation to provide accurate and truthful responses on an application for DEA registration.

C. Egregiousness

The Agency also looks to the egregiousness and the extent of the misconduct as significant factors in determining the appropriate sanction. *Garrett Howard Smith, M.D.,* 83 FR at 18,910 (collecting cases). Here, the record contains substantial evidence that Applicant issued a high number of prescriptions for controlled substances, including high dosages of opioids and dangerous combinations of opioids and benzodiazepines, to at least four different patients beneath the applicable standard of care and outside the usual course of professional practice. Further, Applicant gave a materially false response to a liability question on his application for DEA registration that directly concerned his improper prescribing practices and his negative history with DEA registration.

As discussed above, to be granted a registration when grounds for denial

[11] It is noted that in spite of Applicant's claims that he did not know that he was surrendering his previous registration ''for cause,'' RFAAX 3, at 3, the DEA Form 104 that Applicant signed was clearly entitled, ''Surrender *for Cause* of DEA Certificate of Registration,'' RFAAX 8, App. B (emphasis added).

exist, an Applicant must convince the Administrator that his acceptance of responsibility is sufficiently credible to ensure that his misconduct will not reoccur and that he can be entrusted with registration. I find that Applicant has not met this burden. In sum, Applicant has not offered any credible evidence on the record to rebut the Government's case for denial of his application and Applicant has not demonstrated that he can be entrusted with the responsibility of registration. Accordingly, I will order the denial of Applicant's application below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f) and 21 U.S.C. 824(a), I hereby deny the pending application for a Certificate of Registration, Control Number W19032408C, submitted by Kareem Hubbard, M.D., as well as any other pending application of Kareem Hubbard, M.D. for additional registration in California. This Order is effective May 11, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–07702 Filed 4–8–22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 20–17]

Noah David, P.A.; Decision and Order

On March 9, 2020, a former Assistant Administrator, Diversion Control Division, of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Noah David, P.A. (hereinafter, Respondent) of Richmond, Virginia. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (OSC), at 1. The OSC proposed the revocation of Respondent's DEA Certificate of Registration No. MD3130717 (hereinafter, COR or registration) and the denial of ''any pending application for renewal or modification of such registration and any applications for any other DEA registrations, pursuant to 21 U.S.C. 824(a)(4), because [Respondent's] registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).'' *Id.*

On April 7, 2020, the Respondent timely requested a hearing, which commenced (and ended) on September 22, 2020, at the DEA Hearing Facility in Arlington, Virginia with the parties, counsel, and witnesses participating via video teleconference (VTC). On December 8, 2020, Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, the Chief ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge (hereinafter, Recommended Decision or RD). By letter dated January 5, 2021, the ALJ certified and transmitted the record to me for final Agency action. In that letter, the ALJ advised that neither party filed exceptions. Having reviewed the entire record, I adopt the ALJ's rulings, findings of fact, as modified, conclusions of law and recommended sanction with minor modifications, where noted herein.*[A]

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

John J. Mulrooney, II

Chief Administrative Law Judge

December 8, 2020

*[B] After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

I. Findings of Fact

A. Allegations

The Government alleges that the Respondent's COR should be revoked because he has committed acts which render his continued registration against the public interest. ALJX 1, at 1. Specifically, the Government contends that on numerous occasions between April 2014 and November 2018, the Respondent unlawfully prescribed controlled substances to his wife without establishing a *bona fide* practitioner-patient relationship and without properly documenting treatment. *Id.* at 3–4. The Government additionally alleges that the Respondent conspired with colleagues to unlawfully receive controlled substances. *Id.* at 4.

B. Stipulations

The parties entered into a robust set of factual stipulations which were accepted by the tribunal. Accordingly, the following factual matters are deemed conclusively established in this case:

1. The Respondent is registered with the DEA as a practitioner to handle controlled substances in Schedules II–V under DEA COR No. MD3130717 at 5211 West Broad Street, Suite 101, Richmond, Virginia 23230–3000.

2. DEA COR No. MD3130717 was issued on May 15, 2019 and expires by its own terms on June 30, 2022.

3. The Respondent is presently licensed as a physician assistant in Virginia under License No. 0110004505, which expires April 30, 2021.

4. Respondent Exhibit 1 is a true and correct copy of the Respondent's COR.

5. The Respondent prescribed the following controlled substances on the following dates to his wife, B.D.:

(1) 11/28/2018: Oxycodone-Acetaminophen 5–325, 36 tablets
(2) 11/20/2018: Oxycodone-Acetaminophen 5–325, 36 tablets
(3) 11/08/2018: Oxycodone-Acetaminophen 5–325, 36 tablets
(4) [10/30/2018: Oxycodone-Acetaminophen 5–325, 36 tablets]
(5) 10/01/2018: Oxycodone-Acetaminophen 10–325, 18 tablets
(6) 9/21/2018: Oxycodone-Acetaminophen 10–325, 18 tablets
(7) 9/13/2018: Oxycodone-Acetaminophen 10–325, 18 tablets
(8) 9/06/2018: Oxycodone-Acetaminophen 5–325, 60 tablets
(9) 8/22/2018: Oxycodone-Acetaminophen 5–325, 60 tablets
(10) 8/17/2018: Oxycodone-Acetaminophen 5–325, 60 tablets
(11) 7/23/2018: Oxycodone-Acetaminophen 5–325, 42 tablets
(12) 7/10/2018: Oxycodone-Acetaminophen 5–325, 84 tablets
(13) 7/03/2018: Oxycodone-Acetaminophen 10–325, 18 tablets
(14) 5/30/2018: Acetaminophen-Codeine #3, 60 tablets
(15) 5/30/2018: Acetaminophen-Codeine #3, 60 tablets (refill)
(16) 5/30/2018: Acetaminophen-Codeine #3, 60 tablets (refill)
(17) 5/21/2018: Oxycodone-Acetaminophen 5–325, 12 tablets
(18) 5/08/2018: Diazepam 5mg, 30 tablets
(19) 4/24/2018: Oxycodone-Acetaminophen 10–325, 28 tablets
(20) 3/16/2018: Oxycodone-Acetaminophen 10–325, 28 tablets
(21) 2/15/2018: Oxycodone-Acetaminophen 10–325, 28 tablets
(22) 2/09/2018: Oxycodone-Acetaminophen 10–325, 12 tablets
(23) 1/23/2018: Oxycodone-Acetaminophen 10–325, 28 tablets
(24) 1/19/2018: Oxycodone-Acetaminophen 10–325, 12 tablets
(25) 1/05/2018: Oxycodone-Acetaminophen

*[A] I have made minor modifications to the RD. I have substituted initials or titles for the names of witnesses and patients to protect their privacy and I have made minor, nonsubstantive, grammatical changes and nonsubstantive, conforming edits. Where I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the ALJ's opinion, I have noted the edits with an asterisk, and I have included specific descriptions of the modifications in brackets following the asterisk or in footnotes marked with a letter and an asterisk. Within those brackets and footnotes, the use of the personal pronoun ''I'' refers to myself—the Administrator.

*[B] I have omitted the RD's discussion of the procedural history to avoid repetition with my introduction.

10–325, 42 tablets
(26) 1/03/2018: Oxycodone-Acetaminophen 10–325, 12 tablets
(27) 12/22/2017: Oxycodone-Acetaminophen 10–325, 42 tablets
(28) 12/08/2017: Oxycodone-Acetaminophen 10–325, 42 tablets
(29) 11/21/2017: Oxycodone-Acetaminophen 10–325, 42 tablets
(30) 11/08/2017: Oxycodone-Acetaminophen 10–325, 42 tablets
(31) 10/25/2017: Oxycodone-Acetaminophen 10–325, 42 tablets
(32) 10/06/2017: Oxycodone-Acetaminophen 10–325, 42 tablets
(33) 9/22/2017: Oxycodone-Acetaminophen 10–325, 42 tablets
(34) 9/14/2017: Diazepam 5mg, 90 tablets
(35) 8/28/2017: Oxycodone-Acetaminophen 10–325, 56 tablets
(36) 8/11/2017: Oxycodone-Acetaminophen 10–325, 56 tablets
(37) 7/27/2017: Oxycodone-Acetaminophen 10–325, 56 tablets
(38) 7/18/2017: Oxycodone-Acetaminophen 10–325, 21 tablets
(39) 7/06/2017: Oxycodone-Acetaminophen 10–325, 28 tablets
(40) 6/16/2017: Oxycodone-Acetaminophen 10–325, 25 tablets
(41) 6/05/2017: Oxycodone-Acetaminophen 10–325, 28 tablets
(42) 5/22/2017: Oxycodone-Acetaminophen 10–325, 48 tablets
(43) 5/08/2017: Lorazepam 2mg, 60 tablets
(44) 4/06/2017: Oxycodone-Acetaminophen 10–325, 48 tablets
(45) 2/24/2017: Carisoprodol 250 mg, 90 tablets
(46) 2/24/2017: Diazepam 2mg, 90 tablets
(47) 2/07/2017: Oxycodone-Acetaminophen 10–325, 60 tablets
(48) 12/28/2016: Oxycodone-Acetaminophen 10–325, 60 tablets
(49) 12/02/2016: Oxycodone-Acetaminophen 10–325, 60 tablets
(50) 11/11/2016: Oxycodone-Acetaminophen 10–325, 60 tablets
(51) 10/24/2016: Oxycodone-Acetaminophen 10–325, 60 tablets
(52) 10/06/2016: Oxycodone-Acetaminophen 10–325, 60 tablets
(53) 9/26/2016: Oxycodone-Acetaminophen 10–325, 30 tablets
(54) 9/14/2016: Oxycodone-Acetaminophen 10–325, 30 tablets
(55) 8/29/2016: Oxycodone-Acetaminophen 10–325, 30 tablets
(56) 8/16/2016: Hydrocodone-Acetaminophen 10–325, 30 tablets
(57) 7/21/2016: Oxycodone-Acetaminophen 10–325, 60 tablets
(58) 6/24/2016: Oxycodone-Acetaminophen 10–325, 30 tablets
(59) 6/24/2016: Diazepam 2mg, 60 tablets
(60) 6/10/2016: Oxycodone-Acetaminophen 10–325, 30 tablets
(61) 5/13/2016: Oxycodone-Acetaminophen 10–325, 60 tablets
(62) 4/21/2016: Oxycodone-Acetaminophen 10–325, 30 tablets
(63) 3/25/2016: Oxycodone-Acetaminophen 10–325, 30 tablets
(64) 2/25/2016: Oxycodone-Acetaminophen 10–325, 30 tablets
(65) 2/05/2016: Oxycodone-Acetaminophen 10–325, 30 tablets
(66) 10/12/2015: Oxycodone-Acetaminophen 10–325, 12 tablets
(67) 10/09/2015: Oxycodone-Acetaminophen 10–325, 12 tablets
(68) 9/25/2015: Oxycodone-Acetaminophen 10–325, 15 tablets
(69) 5/29/2015: Oxycodone-Acetaminophen 10–325, 60 tablets
(70) 5/29/2015: Diazepam 5mg, 60 tablets
(71) 4/05/2015: Oxycodone-Acetaminophen 7.5–325, 60 tablets
(72) 2/15/2015: Oxycodone-Acetaminophen 7.5–325, 30 tablets
(73) 12/21/2014: Oxycodone-Acetaminophen 7.5–325, 30 tablets
(74) 11/01/2014: Oxycodone-Acetaminophen 7.5–325, 90 tablets
(75) 9/11/2014: Hydrocodone-Acetaminophen 7.5–325. 45 tablets
(76) 7/24/2014: Hydrocodone-Acetaminophen 7.5–325, 30 tablets
(77) 6/04/2014: Hydrocodone-Acetaminophen 7.5–325, 15 tablets
(78) 4/15/2014: Hydrocodone-Acetaminophen 7.5–325, 30 tablets

6. The Respondent acted outside the usual course of professional practice in Virginia by issuing controlled substance prescriptions to his wife without establishing a bona fide practitioner-patient relationship and by failing to perform comprehensive examinations.

7. The Respondent acted outside the usual course of professional practice in Virginia by issuing controlled substance prescriptions to his wife without properly documenting the treatment of his wife.

8. The Respondent received prescriptions for controlled substances from L.K., P.A. on February 15, 2018, December 3, 2018, and December 4, 2018.

9. The Respondent received a prescription for a controlled substance from J.A., P.A., on September 14, 2018.

10. Oxycodone is a Schedule II controlled substance pursuant to 21 CFR 1308.12(b)(1)(xiv) and Va. Code Ann. § 54.1–3448.

11. Hydrocodone is a Schedule II controlled substance pursuant to 21 CFR 1308.12(b)(1)(vi) and Va. Code Ann. § 54.1–3448.

12. On March 3, 2019, the Respondent completed the Professional Boundaries and Ethics Course—Extended Edition, a continuing medical education course conducted by the Professional Boundaries Institute (PBI).

13. Respondent Exhibit 2 is a true and correct copy of the Respondent's certificate of completion for the PBI Professional Boundaries and Ethics Course—Extended Edition continuing medical education course.

14. The Respondent completed a PBI Maintenance and Accountability Seminars continuing medical education course of July 11, 2019.

15. Respondent Exhibit 3 is a true and correct copy of the Respondent's certificate of completion for the PBI Maintenance and Accountability Seminars continuing medical education course.

16. The Respondent completed a VCU Health's Safe Opiate Prescribing continuing medical education course on January 1, 2019.

17. Respondent Exhibit 4 is a true and correct copy of the Respondent's certificate of completion for VCU Health's Safe Opiate Prescribing continuing medical education course.

C. Government's Case

The Government's case consisted of testimony from a diversion investigator assigned to the case that yielded these proceedings and a senior investigator from the Virginia Department of Health Professions.

1. Diversion Investigator R.P.

The Government presented the testimony of Diversion Investigator RP. (hereinafter, the DI). The DI testified that he has been a DI for approximately seven years and is currently stationed at the Richmond field office. Tr. 11–12. The DI's testimony narrated the course of the investigation and authenticated a number of Government Exhibits. *Id.* at 11–40.

The DI testified that he worked with Task Force Officer C.E. (hereinafter, the TFO) in the investigation into the Respondent, a physician assistant (PA). *Id.* at 13–14. Their investigation began when the TFO was contacted by Senior Investigator K.L. at the Department of Health Professions (DHP). *Id.* at 13, 15. Senior Investigator K.L. informed DEA that during a DHP investigation of the Respondent, the Respondent admitted to ''issuing prescriptions without legitimate use'' to his wife, father-in-law, a family friend, and a colleague's spouse.[1] *Id.* at 15. She then provided a copy of her investigative report to DEA. *Id.* at 15.

In investigating the Respondent's prescribing history, the DI generated a report from the Prescription Monitoring Program (PMP) regarding the Respondent's prescribing. *Id.* at 16. The DI noted that the Respondent issued his first prescription to his wife approximately a month-and-a-half after he received his DEA COR. *Id.* at 16–17. The DI also accessed the PMP to generate a report relative to the controlled substance prescriptions that

[1] The findings and recommendations in this Recommended Decision are restricted to the charged and preponderantly established misconduct.

had been issued to Respondent's wife.[2] *Id.* at 17. The report revealed that over eighty-five prescriptions were written for her by the Respondent during the previous period of almost five years. *Id.* at 17. Seventy-two of those eighty-five prescriptions were for pain medications. *Id.* at 18. The DI testified that in analyzing the report, he perceived patterns wherein the Respondent, in the DI's view, prescribed a high quantity of controlled substances for what the DI classified as a relatively short span of time. *Id.* at 18–19. The DI concluded that this pattern could support a possible indication of drug diversion. *Id.* The DI found it further curious that the controlled substance prescriptions that the Respondent wrote to his wife used both her maiden name and married name, so that, in the DI's assessment of things, the Respondent ''was actually issuing prescriptions to what appeared at face value to be two different individuals.'' *Id.* at 20.

In addition to a brief encounter with the Respondent, the DI interviewed three individuals: The pharmacist who filed the initial complaint with DHP; a PA coworker of the Respondent, R.K.; and a supervising physician at Radiology Associates of Richmond (RAR), the radiology practice where the Respondent was employed during the events that form the basis of this case.[3] *Id.* at 23–31.

The pharmacist told the DI that she noticed that the Respondent was receiving controlled substance prescriptions from colleagues, and that he was writing prescriptions to his wife under her married and maiden name. *Id.* at 23–24. During her interview with the DI, R.K. admitted that she issued several prescriptions to the Respondent without performing a medical exam or documenting the prescriptions and treatment.[4] *Id.* at 25–26. Regarding one of the prescriptions, R.K. explained that she wrote the scrip because the Respondent had hurt his hand; ''she could visibly see that it was affecting his procedures'' but she ''did not perform an examination, [and] she wrote a prescription based off of what she had observed from afar.'' *Id.* at 28. The DI testified that R.K. told him that she issued prescriptions to the Respondent because ''she trusted him. She trusted that he wasn't taking advantage of her because he had . . . mentored her . . . when she first came into her profession'' and ''she didn't think that he would ask her to do anything that was wrong or illegal.'' *Id.* at 25–26. R.K. also related to the DI that as the Respondent continued to request more prescriptions, she became hesitant and progressively uncomfortable with writing him prescriptions, but continued to anyway. *Id.* at 28.

During his interview, the supervising physician, who supervised the Respondent towards the end of the Respondent's time at RAR, told the DI that the Respondent ''received training on issuing legitimate prescriptions.'' *Id.* at 29–30. According to the DI, the supervising physician also said that he ''had no reason to believe that [the Respondent] had misinterpreted what the regulations were when it comes to issuing prescriptions.'' [5] *Id.*

The DI presented as an objective regulator and investigator with no discernable motive to fabricate or exaggerate. The testimony of this witness was sufficiently detailed, plausible, and internally consistent to be afforded full credibility in this case.

2. Senior Investigator K.L.

The Government also presented testimony from DHP Senior Investigator K.L. (hereinafter, the DHP SI). The DHP SI testified that she has been a senior investigator with DHP [6] for eighteen years, a registered nurse for over thirty years, a master's prepared registered nurse for over twenty-five years, and is currently stationed as an investigator in Henrico County. *Id.* at 44–45 and 48.

The Respondent came to the attention of DHP when the previously-mentioned pharmacist filed a formal complaint on or around December 2018 and the DHP SI was assigned to conduct the investigation. *Id.* at 52–54 and 61–62. The DHP SI testified that during the course of her investigation, she obtained the Respondent's PMP report, collected copies of relevant controlled substance scrips, and interviewed the previously-mentioned pharmacist, RAR employees, and the Respondent. *Id.* at 55. Around the end of January 2019, the DHP SI interviewed the Respondent and questioned him on the prescriptions he issued to his wife and the prescriptions written in his name by his PA colleagues, R.K. and J.A. *Id.* at 63–65. During the course of their conversation, the Respondent informed the DHP SI that some of the controlled substance prescriptions he received from his colleagues were to treat hand pain and cold congestion, but conceded that at no time did his PA colleagues perform any sort of assessment or exam. *Id.* at 65.

According to the DHP SI, the PA colleagues confirmed that ''they did not conduct any type of exam on [the Respondent] and [that] they did not document any of their assessments on him when they provided the prescriptions that he personally requested them to write.'' *Id.* at 57. One of the medications that R.K. wrote for the Respondent was a combination of codeine and guaifenesin, which heightened the concern of the previously-mentioned pharmacist because the medication was not even dispensable as written. *Id.* at 66–67. J.A. told the DHP SI that the Respondent approached him for medication, supposedly to treat a migraine. *Id.* at 69–70. J.A. related to the DHP SI that he knew the controlled substance the Respondent requested was not a typical treatment for migraines, and so decided that he would only prescribe a limited quantity of four pills. *Id.* at 70.

The DHP SI's investigation culminated in a report for the Virginia Board of Medicine that reflected that the Respondent wrote controlled substance prescriptions to his wife with no corroborating records, and that the Respondent received controlled substance prescriptions from his PA colleagues with no corroborating records. *Id.* at 67–68.

Like the DI, the DHP SI presented as an objective regulator and investigator with no discernable motive to fabricate or exaggerate. The testimony of this witness was sufficiently detailed, plausible, and internally consistent to be afforded full credibility in this case.

D. Respondent's Case

The Respondent's affirmative case at the hearing consisted exclusively of his own testimony. The Respondent testified that he received his Bachelor of Arts degree in Biology from Lewis & Clark College in 2003, followed by a Master's degree in Physician Assistant Studies from James Madison University in 2013. Tr. 87. He has been a licensed physician assistant in Virginia since 2014. *Id.* at 90–91. After receiving his

[2] The BD PMP Report, which temporally included all controlled substance prescriptions written to her from January 1, 2014 to the date it was generated on December 18, 2018, was received into the record. GX 3.

[3] The DI attempted to interview another PA, J.A., but learned that he was on vacation out of the country and the DI did not attempt to interview him when he returned. *Id.* at 31.

[4] The DI testified that the interview took place at the U.S. Attorney's Office and was attended by the TFO, an Assistant U.S. Attorney (AUSA), and a legal representative from RAR. *Id.* at 26–27. R.K. was not under arrest during the interview, forced to answer any questions, or offered anything in exchange for cooperating with the DI or the AUSA. *Id.* at 26–28.

[5] The DI testified that the supervising physician was not forced to answer any questions, the interview took place at the U.S. Attorney's Office, and was attended by the TFO, an AUSA, and a legal representative from RAR. *Id.* at 30–31.

[6] The DHP SI explained that DHP is ''the licensing and discipline entity for the Commonwealth of Virginia that licenses healthcare provider[s],'' including physician assistants. *Id.* at 46–47.

license, the Respondent worked at the Center for Gastrointestinal Health in Petersburg, Virginia. *Id.* at 87–88, 94. At this first job the Respondent possessed the requisite authority to prescribe controlled substances, but by his recollection an occasion to do so never arose. *Id.* at 94–95. The Respondent testified that he left this job amicably in March 2015 in order to find another job that would provide family health benefits. *Id.* at 95.

In March 2015, the Respondent began working for RAR in Richmond, Virginia, where he specialized in interventional radiology. *Id.* at 96. As a physician assistant at RAR, the Respondent exercised his COR authority to prescribe controlled substances. *Id.* at 97. Although RAR is a practice devoted to interventional radiology, he explained that the procedure-based nature of the practice did sometimes call for the prescribing of post-procedure controlled pain medications under established protocols. *Id.* at 98–99. The Respondent explained that at RAR, prescribing within the usual course of professional practice meant ''[f]ollowing the protocols of the supervising physician.'' *Id.* at 99–100. The protocols involved meeting with the supervising physician and acquiring from the physician a written treatment plan for each patient. *Id.* at 100. The Respondent also testified that in the course of prescribing a patient a controlled substance he would conduct an ''extremely'' comprehensive exam, including a full history and physical, and then ''thoroughly'' document the findings of the examinations. *Id.* at 100. Once he was notified of DHP's investigation into him, the Respondent transparently notified his supervisors at RAR. *Id.* at 101. He was initially put on administrative leave, but then was afforded the option to resign from the practice, which he exercised in February 2019. *Id.* at 101.

In April 2019, the Respondent secured employment at Alliance Physical Therapy, a physical therapy clinic.[7] *Id.* at 102. The Respondent explained that Alliance Physical Therapy has a strong policy against prescribing controlled substances to patients, and that he ''wanted that job because [he] knew that this was something that just [he] needed to not do. And [he] needed it not to be available.'' [8] *Id.* at 102. However, in one instance, extenuating circumstances arose that required prescribing Tramadol to a patient, which the Respondent prescribed only after conferring with his supervising physician who then made the decision to prescribe a controlled substance. *Id.* at 103–04.

In addressing the allegations brought by the Government, the Respondent admitted to improperly prescribing controlled substances to his wife and offered testimony to potentially help clarify the surrounding circumstances. In 2012, when the Respondent noticed that his wife (B.D.) had developed a severe limp after running, and upon his insistence, his wife consulted an orthopedist. *Id.* at 105. The orthopedist diagnosed B.D. with a CAM lesion on the head of her femur and subsequently performed surgery to reconstruct her hip and treat the CAM lesion. *Id.* at 105–07. According to the Respondent,[9] after the surgery his wife experienced increased pain and developed arthritis, which was diagnosed by orthopedist Dr. J.H. *Id.* at 107–09. Dr. J.H. treated B.D. with non-steroidal anti-inflammatories (NSAIDs), but she developed an ulcer. *Id.* at 109–10. To address her pain, B.D. then took part in physical therapy, yoga, swimming, different types of NSAIDs, Tylenol, and then received injections. *Id.* at 110. The Respondent testified that injections helped with his wife's symptoms, but not long-term. *Id.* at 110–11. In April 2014, after being treated by Dr. J.H. throughout, and not seeking care from another physician, B.D. was ''at her wits' end,'' ''was distraught,'' ''was in pain every day,'' ''was having a hard time just getting around the house,'' ''things got desperate,'' and she asked the Respondent for something to relieve her pain. *Id.* at 111–12. The Respondent wrote his wife a controlled substance prescription, but upon circumspection, if he ''could go back, [he] certainly would not do it again.'' *Id.* at 112.

The Respondent openly admitted that the controlled substance prescriptions he wrote to his wife between April 2014 and November 2018 were unlawful, unethical, unprofessional, wrong, and not valid, and that he even knew it was wrong at the time.[10] *Id.* at 113–14. In explaining his logic behind writing prescriptions that were unlawful and wrong, the Respondent offered the following:

> I mean, it was really a matter of convenience. I saw her quality of life improve. And it just snowballed because of convenience. And through the years of doing it, my anxiety was—got worse and worse. *I knew—I knew it was wrong.* And it's really just—it's fortunate it didn't hurt our relationship, but it made my life quite distraught. *Id.* at 114 (emphasis supplied).

Counsel for the Respondent read through Allegations 8–11 from the OSC, asking for each whether the Respondent understood the allegation and whether the Respondent agreed with the allegation. *Id.* at 133–36. The Respondent testified that he understood and agreed with Allegations 8–11. *Id.* at 133–36.

The Respondent also admitted to improperly receiving controlled substance prescriptions from his PA colleagues. It is the Respondent's recollection that he first approached R.K. for a controlled substance prescription after he underwent hand surgery and his treating surgeon denied him pain medication.[11] *Id.* at 137–38. The Respondent explained that acquiring the prescription from R.K. was wrong and that he knew he was asking her to violate RAR's protocols that required PAs to prescribe controlled substances under the guidance of a physician. *Id.* at 139–40. The Respondent also openly admitted that he agreed with the Government's allegations that he did not have a *bona fide* practitioner-patient relationship with his PA colleagues, that they did not document the treatment they rendered to him, and that he received the controlled substance prescriptions from them outside the usual course of professional practice. *Id.* at 143–44. In his own words, the Respondent described his conduct in regards to receiving the relevant prescriptions from his PA colleagues as ''unprofessional.'' *Id.* at 144–45. The Respondent testified that he took advantage of his colleagues because he knew he could not get the prescriptions he wanted from a doctor and that he knew his PA colleagues were not keeping medical records of his treatment because they could be disciplined for doing so. *Id.* at 151–52. Based on his PA colleagues' conduct, the Respondent agreed that they both

[7] The Respondent testified that he worked at Alliance Physical Therapy for one year before he was furloughed in April 2020 due to the COVID–19 pandemic. *Id.* at 102, 104. He has since interviewed with Commonwealth Radiology, ''another radiologist/interventional radiology group,'' and the Respondent testified that he was transparent with his potential future employers regarding the relevant investigations. *Id.* at 105.

[8] The issue of why the Respondent, who is seeking to continue his status as a DEA registrant, needed to isolate himself from conducting the regulated activity he now seeks to preserve was never developed at the hearing.

[9] No corroborating medical records or other documentation was offered by the Respondent in support of his wife's purported medical issues.

[10] The Respondent also admitted that he prescribed controlled substances to his wife while she was pregnant and that issuing such prescriptions while she was pregnant without proper supervision was potentially dangerous (although the wife's obstetrician was aware of the narcotics she was taking). *Id.* at 152–54.

[11] Again, the Respondent offered no form of corroboration for any of the medical conditions he ascribed to himself or his wife.

knew that their conduct in prescribing controlled substances to the Respondent was improper. *Id.* at 153.

The Respondent testified that in the wake of the allegations against him, he took three continuing medical education (CME) courses to improve his practice. RX 2–4; Tr. 117–119, 127–28. He completed an in-person, thirty-four hour professional boundaries course on March 1 through March 3, 2019. RX 2; Tr. at 118. The Respondent testified that the course taught him about ''getting in the habit of saying no'' as foundational for operating within professional boundaries. Tr. at 118. The Respondent also testified that he participated in a twelve-week telephonic-contact course on maintenance and accountability that was completed on July 11, 2019 (Phone Follow-up Exercise). RX 3; Tr. at 122–23. The Phone Follow-up Exercise was an extension of the first and consistent of twelve one-hour weekly seminars conducted via telephone. Tr. at 122–23. The Respondent explained that the Phone Follow-up Exercise afforded him the opportunity to express the remorse, embarrassment, and anger he felt over his actions, as well as share the tools he was developing to maintain professional boundaries (including taking a position at a practice with a non-narcotic policy, refusing a prescription pad, and having a habit of saying no). *Id.* at 126–27. In addition to the professional boundaries course and the Phone Follow-up Exercise, the Respondent testified that he completed a two-hour online course in safe opiate prescribing through Virginia Commonwealth University's medical school.[12] RX 4; Tr. at 127–29.

The Respondent also testified that moving forward, he intends to comply with all laws regarding controlled substances and that he ''will only prescribe when appropriate and only to patients when it's well documented and for an appropriate reason.'' Tr. at 132. He acknowledged the severity of his repeated intentional acts, but also feels that this has only ever been a personal issue and that his misguidance has never lapsed over into affecting the public. *Id.* at 147–48.

As is generally the case, the Respondent unarguably possesses the greatest interest in the outcome of these proceedings, and hence, the greatest motivation to enhance, modify, or even fabricate his testimony. While the Respondent's testimony was generally consistent, it was not always free from confusing aspects. He stated and admitted that he issued controlled substances to his wife for years knowing that it was wrong, and explained that he understood that it was unlawful, unprofessional, and wrong, which is information that he undoubtedly possessed while the misconduct was underway. The Respondent presented as a knowledgeable professional who, at all times relevant, understood the rules, but yet engaged in an extended course of conduct that he knew was unprofessional, illegal, and dangerous.[13] He even allowed that his actions caused him a considerable level of consternation. The Respondent's testimony that he was aware of and adhered to detailed examination and prescribing protocols regarding RAR patients stands in no small measure of conflict with his extended level of unlawful prescribing, punctuated by the calculated practice of interchanging his wife's maiden and married names. Odd also was the Respondent's assertion that after the commencement of the DHP investigation he began working at a physical therapy clinic that has a strong policy against prescribing controlled substances to patients. He explained that he ''wanted that job because [he] knew that this was something that just [he] needed to not do. And [he] needed it not to be available.'' Tr. 102. The testimony is almost reminiscent of an addictive personality seeking to avoid the temptation of the focus of the addiction; and yet, the Respondent seeks to continue prescribing controlled substances. In an apparent abandonment of his prescribing avoidance, upon his COVID-related furlough, the Respondent is currently pursuing employment at Commonwealth Radiology, where, if successful, it appears his duties will mirror those at RAR, including his controlled substance prescribing responsibilities. It is not so much that the Respondent is incredible, he is not that. It is more that his presentation was confusing, and at times enigmatic.

Other facts necessary for a disposition of this case are set forth in the balance of this Recommended Decision.

II. Discussion

A. Public Interest Determination: The Standard

Under 21 U.S.C. 824(a)(4), the Agency may revoke the COR of a registrant if the registrant ''has committed such acts as would render his registration . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). Congress has circumscribed the definition of public interest in this context by directing consideration of the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

(3) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety. 21 U.S.C. 823(f).

''These factors are to be considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Agency may properly give each factor whatever weight it deems appropriate in determining whether a registrant's COR should be revoked. *Id.; see Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). Moreover, the Agency is ''not required to make findings as to all of the factors,'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *Morall,* 412 F.3d at 173, and is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail, *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (holding that the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors, and that remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest . . . .'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009).

In adjudicating a revocation of a DEA COR, the DEA has the burden of proving that the requirements for the revocation it seeks are satisfied. 21 CFR 1301.44(e). Where the Government has met this burden by making a *prima facie* case for revocation of a registrant's COR, the burden of production then shifts to the registrant to show that, given the totality of the facts and circumstances in the record, revoking the registrant's COR would not be appropriate. *Med. Shoppe-Jonesborough,* 73 FR 364, 387 (2008). Further, ''to rebut the Government's *prima facie* case, [a registrant] is

[12] Inexplicably, the opiate prescribing course certificate indicates that the course was conducted on ''July 11, 2017–December 31, 2020.'' RX 4.

[13] Indeed, no physician who treated his wife before or after his misconduct prescribed controlled substances for her.

required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the re-occurrence of similar acts.'' *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010); *accord Krishna-Iyer,* 74 FR at 464 n.8. In determining whether and to what extent a sanction is appropriate, consideration must be given to both the egregiousness of the offense established by the Government's evidence and the Agency's interest in both specific and general deterrence. *David A. Ruben, M.D.,* 78 FR 38363, 38364, 38385 (2013).

Normal hardships to the registrant, and even to the surrounding community, which are attendant upon lack of registration, are not a relevant consideration. *See Linda Sue Cheek, M.D.,* 76 FR 66972, 66972–73 (2011); *Gregory D. Owens, D.D.S.,* 74 FR 36751, 36757 (2009). Further, the Agency's conclusion that ''past performance is the best predictor of future performance'' has been sustained on review in the courts, *Alra Labs., Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie,* 419 F.3d at 483.[14]

Although the burden of proof at this administrative hearing is a preponderance-of-the-evidence standard, *see Steadman* v. *SEC,* 450 U.S. 91, 100–03 (1981), the Agency's ultimate factual findings will be sustained on review to the extent they are supported by ''substantial evidence,'' *Hoxie,* 419 F.3d at 481. While ''the possibility of drawing two inconsistent conclusions from the evidence'' does not limit the Administrator's ability to find facts on either side of the contested issues in the case, *Shatz* v. *U.S. Dep't of Justice,* 873 F.2d 1089, 1092 (8th Cir. 1989) (internal citation omitted), all ''important aspect[s] of the problem,'' such as a respondent's defense or explanation that runs counter to the Government's evidence, must be considered, *Wedgewood Vill. Pharmacy* v. *DEA,* 509 F.3d 541, 549 (D.C. Cir. 2007); *see Humphreys* v. *DEA,* 96 F.3d 658, 663 (3d Cir. 1996). The ultimate disposition of the case ''must be 'in accordance with' the weight of the evidence, not simply supported by enough evidence 'to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury.' '' *Steadman,* 450 U.S. at 99 (quoting *Consolo* v. *FMC,* 303 U.S. 607, 620 (1966)).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall,* 412 F.3d at 183, but mere unevenness in application does not, standing alone, render a particular discretionary action unwarranted. *Chein* v. *DEA,* 533 F.3d 828, 835 (D.C. Cir. 2008), *cert. denied,* 555 U.S. 1139 (2009); *cf. Dep't of Homeland Security* v. *Regents of Univ. of Cal.,* 140 S. Ct. 1891, 1913 (2020) (holding that an agency must carefully justify significant departures from prior policy where reliance interests are implicated). It is well settled that, because the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this Recommended Decision are entitled to significant deference, *see Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951), and that this Recommended Decision constitutes an important part of the record that must be considered in the Agency's final decision, *see Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Administrator and do not limit the exercise of that discretion. *See* 5 U.S.C. 557(b); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* § 8(a) (1947).

B. Factors Two and Four: The Respondent's Experience Dispensing Controlled Substances and Compliance With Federal, State, and Local Law

The Government has founded its theory for sanction exclusively on Public Interest Factors Two (the Respondent's experience conducting regulated activity) and Four (the Respondent's compliance with state and federal laws related to controlled substances), and it is under those two factors that the lion's share of the evidence of record relates.[15] In this case, the gravamen of the allegations in the OSC, as well as the factual concentration of much of the evidence presented, share as a principal focus the Respondent's prescribing of controlled substances to his (non-patient) wife, and his role in receiving controlled substance prescriptions issued to him by his DEA registrant co-workers. The structure of the Government's theory, and the Respondent's case to meet that theory, renders it analytically logical to consider Public Interest Factors Two and Four together regarding the Respondent's prescribing, and Factor Four independently with respect to the role the Respondent played in securing controlled substance prescriptions from his colleagues. That being said, Factors Two and Four involve analysis of both common and distinct considerations.

Regarding Factor Two, the Respondent is a credentialed and experienced physician assistant who has been treating patients, in various capacities, for around six years. Tr. 90. Likewise, the evidence of record points to issues regarding controlled substance prescribing to his wife (B.D.) and himself; and there is no evidence of record that the Respondent has been the subject of discipline by state or federal authorities relative to his controlled substance prescribing to legitimate patients.*[C] While there is no evidence to contradict the Respondent's contention that he has never let his prescribing deficiencies seep over into other aspects of his medical practice,

[14] The Agency has repeatedly upheld this policy. *See Ronald Lynch, M.D.,* 75 FR 78745, 78754 (2010) (holding that the respondent's attempts to minimize misconduct undermined acceptance of responsibility); *George Mathew, M.D.,* 75 FR 66138, 66140, 66145, 66148 (2010); *George C. Aycock, M.D.,* 74 FR 17529, 17543 (2009); *Krishna-Iyer,* 74 FR at 463; *Steven M. Abbadessa, D.O.,* 74 FR 10077, 10078 (2009); *Med. Shoppe-Jonesborough,* 73 FR at 387.

[15] The record contains no recommendation from any state licensing board or professional disciplinary authority (Factor One), but, aside from cases establishing a complete lack of state authority, the presence or absence of such a recommendation has not historically been a case-dispositive issue under the Agency's precedent. *Patrick W. Stodola, M.D.,* 74 FR 20727, 20730 (2009); *Krishna-Iyer,* 74 FR at 461. Similarly, there is no record evidence of a conviction record relating to regulated activity (Factor Three). Even apart from the fact that the plain language of this factor does not appear to emphasize the absence of such a conviction record, myriad considerations are factored into a decision to initiate, pursue, and dispose of criminal proceedings by federal, state, and local prosecution authorities which lessen the logical impact of the absence of such a record. *See Robert L. Dougherty, M.D.,* 76 FR 16823, 16833 n.13 (2011); *Dewey C. MacKay, M.D.,* 75 FR 49956, 49973 (2010) (''[W]hile a history of criminal convictions for offenses involving the distribution or dispensing of controlled substances is a highly relevant consideration, there are any number of reasons why a registrant may not have been convicted of such an offense, and thus, the absence of such a conviction is of considerably less consequence in the public interest inquiry.''), *aff'd, MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011); *Ladapo O. Shyngle, M.D.,* 74 FR 6056, 6057 n.2 (2009). Therefore, the absence of criminal convictions militates neither for nor against the revocation sought by the Government. Because the Government's allegations and evidence fit squarely within the parameters of Factors Two and Four and do not raise ''other conduct which may threaten the public health and safety,'' 21 U.S.C. 823(f)(5), Factor Five militates neither for nor against the sanction sought by the Government in this case.

*[C] Omitted for brevity.

the Agency has long found that benign experience cannot overcome intentional misconduct, and that the misconduct established by record evidence is considered under both Factors Two and Four. *See Roberto Zayas, M.D.,* 82 FR 21410, 21422 n.27 (2017) (announcing that ''misconduct is misconduct whether it is relevant under Factor Two, Factor Four, or Factor Five, or multiple factors''). It is beyond argument that every scrap of established misconduct in this case is of the intentional variety. Thus, the balance of the evidence related to Factor Two [ ]will be considered below together with Factor Four.

As discussed, *supra,* Factor Four compels consideration of the Respondent's compliance with state and federal laws related to controlled substances. The DEA regulations provide that to be effective, a prescription must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. 21 CFR 1306.04(a). The Supreme Court has opined that, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006). Further, the Agency's authority to revoke a registration is not limited to instances where a practitioner has intentionally diverted controlled substances. *Bienvenido Tan,* 76 FR 17673, 17689 (2011); *see Dewey C. MacKay,* 75 FR at 49974 (holding that revocation is not precluded merely because the conduct was ''unintentional, innocent, or devoid of improper motive'') (citation omitted).

To effectuate the dual goals of conquering drug abuse and controlling both legitimate and illegitimate traffic in controlled substances, ''Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the [Controlled Substances Act (CSA)].'' *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). Consistent with the maintenance of that closed regulatory system, subject to limited exceptions not relevant here, a controlled substance may only be dispensed upon a prescription issued by a practitioner, and such a prescription is unlawful unless it is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a); *see* 21 U.S.C. 829. Furthermore, ''[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and the person knowingly . . . issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances.'' 21 CFR 1306.04(a).

The prescription requirement is designed to ensure that controlled substances are used under the supervision of a doctor, as a bulwark against the risk of addiction and recreational abuse. *George C. Aycock, M.D.,* 74 FR 17529, 17541 (2009) (citing *Gonzales,* 546 U.S. at 274); *see also United States* v. *Moore,* 423 U.S. 122, 135, 142–43 (1975) (noting that evidence established that a physician exceeded the bounds of professional practice when he gave inadequate examinations or none at all, ignored the results of the tests he did make, and took no precautions against misuse and diversion). The prescription requirement likewise stands as a proscription against doctors ''peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales,* 546 U.S. at 274. A registered practitioner is authorized to dispense, which the CSA defines as ''to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of a practitioner.'' 21 U.S.C. 802(10); *see also Rose Mary Jacinta Lewis,* 72 FR 4035, 4040 (2007). The courts have sustained criminal convictions based on the issuing of illegitimate prescriptions where physicians conducted no physical examinations or sham physical examinations. *United States* v. *Alerre,* 430 F.3d 681, 690–91 (4th Cir. 2005), *cert. denied,* 574 U.S. 1113 (2006); *United States* v. *Norris,* 780 F.2d 1207, 1209 (5th Cir. 1986).

''Under the CSA, it is fundamental that a practitioner must establish and maintain a [*bona fide*] doctor-patient relationship in order to act in the usual course of . . . professional practice and to issue a prescription for a legitimate medical purpose.'' *Dewey C. Mackay, M.D.,* 75 FR 49956, 49973 (2010) (citation omitted); *Stodola,* 74 FR at 20731; *Shyngle,* 74 FR at 6057–58. The CSA generally looks to state law to determine whether a *bona fide* doctor-patient relationship was established and maintained. *Stodola,* 74 FR at 20731; *Shyngle,* 74 FR at 6058; *Kamir Garces-Mejias, M.D.,* 72 FR 54931, 54935 (2007); *United Prescription Servs., Inc.,* 72 FR 50397, 50407 (2007).

The CSA authorizes the ''regulat[ion of] medical practice so far as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood,'' *Gonzales,* 546 U.S. at 909–10, and the Agency also evaluates cognizant state standards. *Joseph Gaudio, M.D.,* 74 FR 10083, 10090 (2009); *Garces-Mejias,* 72 FR at 54935; *United Prescription Services, Inc.,* 72 FR 50397, 50407 (2007).*[D]

Here, the relevant provisions of Virginia state law largely mirror the CSA and its regulations where they do not go beyond it. *Compare* Va. Code Ann. § 54.1–3303(C) *with* 21 CFR 1304.06(a). The Virginia Code requires a *bona fide* patient-practitioner relationship to exist for the issuance of any prescriptions (controlled and non-controlled) in the state. Va. Code Ann. § 54.1–3303(B). The elements of a *bona fide* patient-practitioner relationship are spelled out in the code and require that the practitioner must have:

> (i) Obtained or caused to be obtained a medical or drug history of the patient;
>
> (ii) provided information to the patient about the benefits and risks of the drug being prescribed;
>
> (iii) performed or caused to be performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; and
>
> (iv) initiated additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects.

Id.

Except in cases involving a medical emergency, the examination required pursuant to clause (iii) shall be performed by the practitioner prescribing the controlled substance, a practitioner who practices in the same group as the practitioner prescribing the controlled substance, or a consulting practitioner. *Id.* Further, all treatment, both with and without controlled substances, must be properly documented in order to fall within the standard of care as articulated by the state. Va. Admin. Code § 85–50–177 (requiring ''timely, accurate, legible and complete records''). The Virginia Code also prohibits a practitioner from . . . prescrib[ing] a controlled substance to himself or a family member, other than Schedule VI as defined in § 54.1–3455 of the Code of Virginia, unless the prescribing occurs in an emergency situation or in isolated settings where there is no other qualified practitioner available to the patient, or it is for a single episode of an acute illness through one prescribed course of medication. Va. Admin. Code § 85–50–176(B). This provision additionally specifies that when such treatment of

*[D] Omitted for brevity.

self or family does occur, it must be properly documented to demonstrate compliance with the criteria for a *bona fide* patient-practitioner relationship. Va. Admin. Code § 85–50–176(C).

Further, the Virginia Administrative Code cites twenty-four separate categories of unprofessional conduct that can result in disciplinary action. Va. Admin. Code § 54.1–2915. Within these myriad categories, the state has prohibited: ''[p]rescribing or dispensing any controlled substance with intent or knowledge that it will be used otherwise than medicinally, . . . or with intent to evade any law with respect to the sale, use, or disposition of such drug;'' [16] violating any state or federal law ''relating to the manufacture, distribution, dispensing, or administration of drugs;'' [17] and ''[v]iolating or *cooperating with others* in violating any of the provisions of Chapters 1 (§ 54.1–100 *et seq.*), 24 (§ 54.1–2400 *et seq.*) and this chapter [(§ 54.1–2900 *et seq.*)] or regulations of the Board.'' [18] ''Cooperating'' is not defined in the Virginia Administrative Code, but by consciously electing to eschew the term ''conspiracy,'' [19] it is logical to assume that Virginia seeks a broader sweep of conduct that is easier to establish.

In this case, the Respondent stipulated that he ''acted outside the usual course of professional practice in Virginia by issuing controlled substance prescriptions to his wife (B.D.) without establishing a *bona fide* practitioner-patient relationship[,] by failing to perform comprehensive examinations[, and] without properly documenting the treatment of his wife (B.D.).'' Stips 6, 7. Further, during the hearing, the Respondent stated that he understood and agreed with Allegations 8–11. Tr. 133–36. Accordingly, OSC Allegations 4 and 8–11 are *sustained*.

Regarding the controlled substance prescriptions issued to the Respondent by his PA colleagues, the parties stipulated that the Respondent received controlled substance prescriptions from his PA colleagues on every date alleged in the OSC. Stips 8, 9. The Government's theory, in essence, is that by importuning his PA colleagues to write controlled substance prescriptions for his personal use, without routing the matter through the physicians who supervise those PA practitioners, the evidence sustains the gentle standard of ''cooperating with others'' [20] to facilitate their violation of the aforementioned state and federal laws relating to the dispensing of drugs. This aspect of the Government's theory here is enhanced by the highly-regulated nature of controlled substance prescribing and the Respondent's status as a COR holder/PA in the same office as his PA colleagues. The Respondent's awareness of standard office practices and his fellow PAs, coupled with his experience, equipped him with the knowledge of how a direct request to his colleagues would likely be received and acted upon by his PA colleagues. The Respondent freely acknowledged during the hearing that he did not have a *bona fide* practitioner-patient relationship as a patient of his PA colleagues, that they did not document the treatment they rendered to him, and that he received the controlled substance prescriptions from them outside the usual course of professional practice. Tr. 143–44. Respondent's PA colleagues also told investigators that they issued the prescriptions to the Respondent without performing a medical exam or documenting the prescriptions and treatment. *Id.* at 25–26, 57. Notably, the Respondent admitted that he took advantage of his PA colleagues because he knew he could get the scrips he wanted and that they would not document the treatment when he asked them for the scrips. *Id.* at 151–52. He described his own conduct in this regard as ''unprofessional.'' *Id.* at 144–45. Further, in his closing brief, the Respondent stated that he ''unequivocally accept[s] responsibility'' for the ''soliciting of controlled substance treatment from colleagues'' and for ''the misconduct and wrongfulness of his actions relative to the Government's allegations relating to [his] conspiracy with his colleagues.'' ALJX 15 at 7. Accordingly, OSC Allegations 5 and 12–14 are *sustained*.*[E]

Inasmuch as the Respondent's state licensure and COR status are the subject of factual stipulations,[21] OSC Allegations 1 and 2 are also *sustained*.

Thus, a balancing of Factors Two and Four militate strongly in favor of the imposition of the revocation sanction sought by the Government.

III. Sanction

The evidence of record preponderantly establishes that the Respondent has committed acts which render his continued registration inconsistent with the public interest. *See* 21 U.S.C. 824(a)(4). Since the Government has met its burden [22] in demonstrating that the revocation it seeks is authorized, to avoid sanction, it becomes incumbent upon the Respondent to demonstrate that given the totality of the facts and circumstances revocation is not warranted. *See Med. Shoppe-Jonesborough,* 73 FR at 387. That is, upon the preponderant establishment of the Government's *prima facie* case, the burden shifts to the Respondent to show why he should continue to be entrusted with a DEA registration. *See Kaniz F. Khan-Jaffery, M.D.,* 85 FR 45667, 45689 (2020); *Garrett Howard Smith, M.D.,* 83 FR 18882, 18910 (2018). Although by no means the only requirement, in order to rebut the Government's *prima facie* case, the Respondent must demonstrate not only an unequivocal acceptance of responsibility but also a demonstrable plan of action to avoid similar conduct in the future. *See Hassman,* 75 FR at 8236. While those two elements are key, the focus is, and must always be, rooted in a determination as to whether the Agency can have confidence that the Respondent can continue to be entrusted with the weighty and dangerous responsibilities of a registrant. *Cf., Khan-Jaffery, M.D.,* 85 FR at 45689; *Smith, M.D.,* 83 FR at 18910. While analytical frameworks applied to prior Agency actions provide useful guidance and helpful structure, such tools cannot distract the Agency from its critical mission to keep the public safe by only issuing and maintaining CORs in cases where the public is adequately protected.

Agency decisions are clear that a respondent must ''unequivocally admit fault'' as opposed to a ''generalized

[16] Va. Admin. Code § 54.1–2915(A)(8).

[17] Va. Admin. Code § 54.1–2951(A)(17).

[18] Va. Admin. Code § 54.1–2951(A)(18) (emphasis added).

[19] Civil conspiracy in this context requires a more rigorous showing that two or more persons combined to accomplish, by some concerted action, some criminal or unlawful purpose or some lawful purpose or some lawful purpose by a criminal or unlawful means. *Cf. Shirvinski* v. *United States Coast Guard,* 673 F.3d 308, 320 (4th Cir. 2012).

[20] Va. Code Ann. § 54.1–2915(A)(18). [Although not directly on point, it appears that the Virginia Medical Board has applied cooperating with others broadly as the Chief ALJ suggests. *See e.g., In re: Pankaj Merchia, M.D.,* Virginia Department of Health Professions, Board of Medicine, 2017 WL 2537574 (2017) (affirmed, *Pankaj Merchia* v. *Virginia Board of Medicine,* Va. Ct. App. 2018 WL 6313710 (2018) (not reported) (sustaining Board's finding under Va. Code Ann. § 54.1–2915(A)(18)) holding a practitioner responsible for not releasing patients' medical records even though he was not in charge of the recordkeeping functions.)]

[*E] Although I agree with the Chief ALJ that substantial evidence supports these violations, and I note that Respondent did not take exception to his finding, the facts on the record regarding Respondent's unlawful prescribing to his wife over the course of several years alone offer more than enough support for my ultimate conclusion that Respondent's registration is inconsistent with the public interest.

[21] Stips. 1, 2, 3.

[22] *See* 21 CFR 1301.44(e).

acceptance of responsibility.'' *The Medicine Shoppe,* 79 FR 59504, 59510 (2014); *see also Lon F. Alexander, M.D.,* 82 FR 49704, 49728 (2017). To satisfy this burden, the respondent must ''show true remorse'' or an ''acknowledgment of wrongdoing.'' *Leslie,* 68 FR at 15528. The Agency has made it clear that unequivocal acceptance of responsibility is paramount for avoiding a sanction. *Robert L. Dougherty, M.D.,* 76 FR 16823, 16834 (2011) (citing *Krishna-Iyer,* 74 FR at 464). This feature of the Agency's interpretation of its statutory mandate on the exercise of its discretionary function under the CSA has been sustained on review. *Jones Total Health Care Pharmacy, LLC* v. *DEA,* 881 F.3d 823, 830–31 (11th Cir. 2018); *MacKay* v. *DEA,* 664 F.3d 808, 822 (10th Cir. 2011); *Hoxie,* 419 F.3d at 483.

A. Acceptance of Responsibility

On the issue of acceptance, although (as discussed, *supra*) the Respondent's testimony carried with it an intermittently confusing quality, it could not be fairly said that, taken as a whole (to include, at least to some extent, the attorney-authorized admissions in his closing brief) [23] that the Respondent did not accept responsibility. He did.*[F]

Regarding the required demonstration of remedial measures aimed at the avoidance of recurrence, the Respondent (predictably) promised that he would foreswear prescribing to his wife, friends, and relatives, and would presumably no longer seek to importune colleagues to authorize the dispensing of powerful drugs for his personal use. Additionally, the Respondent completed a three-day professional boundaries course, participated in the Phone Follow-up Exercise, and took an opiate prescribing course. RX 2–4.*[G] A fundamental issue here is not so much that the Respondent did not make a remedial plan of sorts, the issue is that the record demonstrates no information that the Respondent learned in the courses what he admittedly did not know while he was committing the misconduct. That is to say, he required no course to provide him with the revelation that writing prescriptions for powerful pain medications to his non-patient wife was a breach of his state and federal obligations. It was obvious that he knew this was the case by the deceitful practices he employed in alternating between his wife's maiden and married names. He admitted that the entire enterprise was causing him consternation, and yet he persevered in this unprofessional debacle for four-and-a-half years. Likewise, he did not suddenly gain understanding that having his PA colleagues (one of whom he was mentoring) prescribe controlled substances for him was beyond the pale. The Respondent understood every one of these lessons at the outset of the story. No moment of sudden realization and enlightenment was borne of two courses and a Phone Follow-up Exercise. The problem is that the Respondent is as aware of his obligations now as he was when his professional life spiraled out of control. A registrant who gains specialized knowledge in the intricacies of documentation from coursework, or incorporates process changes in his/her practice to address a diversion risk are examples of scenarios where a remedial plan can carry significant influence. On this record, where the Respondent knew what to do during every moment of the period in question, the weight that can logically be attached to his remedial steps must be significantly diminished. Stated differently, he knew then and he knows now, and the ''remedial plan'' offered here is essentially an exercise in going through the motions.

B. Specific and General Deterrence

The issue here is appropriately resolved in the remaining guideposts of the Agency's analytical framework. In determining whether and to what extent imposing a sanction is appropriate, consideration must be given to the Agency's interest in both specific and general deterrence and the egregiousness of the offenses established by the Government's evidence. *Ruben,* 78 FR at 38364, 38385. Each of these concepts bears separate consideration here. It is reasonable to conclude that, at least for the present, the Respondent is unlikely to re-commit these specific transgressions. His wife is being treated by a qualified physician (who is not prescribing controlled substances), and his former coworkers presumably know enough now not to trust him in the future. Thus, the issue of specific deterrence does not particularly favor the imposition of a sanction here. [The Chief ALJ found that specific deterrence does not particularly favor the imposition of a sanction here. Although I agree that Respondent might not be able to repeat the exact same behavior he conducted, I am not convinced by his remedial measures or the minimal consequences that he has faced thus far that he will not repeat similar behavior in mishandling his registration for personal gain. There is ample evidence on the record that Respondent knew what he was doing was unlawful. He admits as much. As discussed herein, he repeated the misconduct in prescribing controlled substances to his wife for several years, and made efforts to hide his behavior. He preyed on his colleague whom he had mentored—taking advantage of the imbalance of power in their relationship in order to obtain controlled substances when his own doctor had denied them. When Respondent proclaimed that he ''is not the yes guy anymore,'' Tr. 126, due to his apparently-enlightening ethics class, he implied that his misbehavior was linked to a lack of boundaries due to his over-accommodating personality, and he urged me to believe that suddenly he has re-established those boundaries—that he has broken ''the habit and create[d] new habits to be able to perform within professional boundaries.'' Tr. 118. However, contrary to this favorable self-portrayal, the egregious behavior on the record demonstrates more artful and intentional deceit than simply refusing to say no. All of the misconduct herein occurred after practitioners acting in the course of their professional practice had refused to prescribe controlled substances. *See* Tr. 138. Further, Respondent covered his tracks and manipulated relationships. As sympathetic as Respondent would make the situation sound—that he ''wanted to help [his wife],'' who was in pain, Tr.

[23] ALJX 15.

*[F] I agree with the Chief ALJ that Respondent generally accepted responsibility, did not make excuses, pass blame or mitigate his misconduct—other than perhaps in his self-portrayal as merely someone who has trouble saying ''no.'' *See infra* III.B. It is noted that prior Agency decisions have made it clear that in order to avoid sanction once the Government has established a *prima facie* case, a registrant must do more than say the right thing on the stand and in filings. ''The degree of acceptance of responsibility that is required does not hinge on the respondent uttering ''magic words'' of repentance, but rather on whether the respondent has credibly and candidly demonstrated that he will not repeat the same behavior and endanger the public in a manner that instills confidence in the Administrator.'' *Jeffrey Stein, M.D.,* 84 FR 46968, 49973 (2019).

*[G] Further, I note that these courses were specifically marked with American Medical Association (AMA) credits, which as Respondent admitted were ''the type of credits we all need for continuing education.'' Tr. 121. Although the subject matter of the courses is certainly relevant to Respondent's compliance with the CSA, and in particular, relevant to correcting his misconduct, I do not find significant value to the important question of whether he can be entrusted with a CSA registration in remedial measures that meet continuing education requirements. The record did not expand on whether he had used these credits for that purpose. If he had, that would certainly weigh against my consideration of them as remedial measures in this action. However, even if he did not use them for this dual purpose, I agree with the Chief ALJ that the remedial plan that Respondent offered was not adequate to ensure that I can entrust him with a registration.

142—the fact is that he repeatedly demonstrated behavior that is untrustworthy. I am not convinced that the few days of training that he took in ethics was so impactful as to have reformed him in the manner that he suggests. Therefore, I find that the issue of specific deterrence weighs in favor of revocation.

Regarding general deterrence,] as the regulator in this field, the Agency bears the responsibility to deter similar misconduct on the part of others for the protection of the public at large. *Ruben,* 78 FR at 38385. To the extent that no sanction is imposed, the unambiguous message to the regulated community would be that four-and-a-half years of enabling the (apparently inappropriate) use of powerful controlled drugs for a spouse, while employing the artifice of alternating scrip names, and only stopping when state and federal regulatory authorities are tipped off by a pharmacist, carries with it no consequence. The Respondent's case in this regard might have been somewhat fortified if the level of cunning or the duration of the malfeasance had been more constrained, but the record is what it is.

C. Egregiousness

Considerations of egregiousness likewise support revocation. The Respondent carried on prescribing for his wife (even during her pregnancy) for four-and-a-half years, which is a significant amount of time to carry on with conduct that a person knows is straight-up wrong. The prescribing was not a one-off, an act of momentary desperation, or a misguided accident borne of professional ignorance, and there was no eureka moment. Like pressing his advantage with the PA colleague he mentored, the Respondent's acts were consistently intentional. The intentional nature of the Respondent's acts undermines the ability of the Agency, at least at present, to have confidence that he will responsibly exercise the responsibilities of a DEA registrant.

Accordingly, it is respectfully recommended that the Respondent's DEA COR should be *revoked*, and any pending applications for renewal should be *denied*.

Dated: December 8, 2020.

John J. Mulrooney, II,

Chief Administrative Law Judge.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(f), I hereby revoke DEA Certificate of Registration No. MD3130717 issued to Noah David, P.A. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I hereby deny any pending application of Noah David, P.A. to renew or modify this registration, as well as any other pending application of Noah David, P.A. for registration in Virginia. This Order is effective May 11, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–07688 Filed 4–8–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Douglas A. Blose, M.D.; Decision and Order

On September 28, 2021, a former Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause (hereinafter, OSC) to Douglas A. Blose, M.D. (hereinafter, Registrant) of Downey, California. OSC, at 1 and 3. The OSC proposed the revocation of Registrant's Certificate of Registration No. AB2619510. *Id.* at 1. It alleged that Registrant ''[does not] have authority to dispense or prescribe controlled substances in the State of California, the state in which [he is] registered with the DEA.'' *Id.* (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that on or about March 9, 2020, Registrant executed a Stipulated Surrender of License and Disciplinary Order, pursuant to which he surrendered his California medical license. *Id.* at 2. According to the OSC, Registrant's surrender was accepted by the Medical Board of California on or about March 30, 2020, and took effect on April 29, 2020. *Id.*

The OSC notified Registrant of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 2–3 (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. *Id.* at 3 (citing 21 U.S.C. 824(c)(2)(C)).

Adequacy of Service

In a Declaration dated January 3, 2022, a Diversion Investigator (hereinafter, DI) assigned to the Los Angeles Field Division stated that on or about September 29, 2021, she sent a copy of the OSC by certified mail to Registrant's registered address. Request for Final Agency Action (hereinafter, RFAA), Exhibit (hereinafter, RFAAX) B (DI's Declaration), at 1–3. The DI stated that according to USPS tracking information, the copy of the OSC was delivered on or about October 1, 2021. *Id.* at 2. The DI also stated that on or about October 21, 2021, she mailed a copy of the OSC to Registrant's residential address as reflected on his California driver's license. *Id.* The DI stated that according to USPS tracking information, the second copy of the OSC was delivered on or about October 23, 2021. *Id.* The DI concluded that neither copy of the OSC was returned as undeliverable and that she has not received any communications from Registrant or anyone acting on Registrant's behalf regarding the OSC. *Id.*

The Government forwarded its RFAA, along with the evidentiary record, to this office on January 26, 2022. In its RFAA, the Government represents that more than thirty days have passed since Registrant was served with the OSC and Registrant has not requested a hearing nor otherwise corresponded with DEA regarding the OSC. RFAA, at 2. The Government requests that Registrant's DEA registration be revoked based on his lack of authority to handle controlled substances in California, the state in which he is registered with the DEA. *Id.* at 6.

Based on the DI's Declaration, the Government's written representations, and my review of the record, I find that the Government accomplished service of the OSC on Registrant on or before October 23, 2021. I also find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the DI's Declaration, the Government's written representations, and my review of the record, I find that neither Registrant, nor anyone purporting to represent Registrant, has requested a hearing, submitted a written statement while waiving Registrant's right to a hearing, or submitted a corrective action plan. Accordingly, I find that Registrant has waived his right to a hearing and his right to submit a written statement or corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

Findings of Fact

Registrant's DEA Registration

Registrant is the holder of DEA Certificate of Registration No. AB2619510 at the registered address of 11525 Brookshire Avenue, Suite 101, Downey, California 90241. RFAAX B, at 1. Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules II through V as a practitioner. *Id.* Registrant's registration expires on July 31, 2022. *Id.*

The Status of Registrant's State License

On October 4, 2019, the Medical Board of California (hereinafter, the Board) issued an Accusation against Registrant alleging repeated negligent acts and failure to maintain adequate and accurate records throughout his treatment and care of six specific patients. RFAAX B–1, at 9–15. Further, according to the Accusation, ''on or about September 27, 2019, in a prior disciplinary action . . . [Registrant's] license was revoked with revocation stayed for five (5) years of probation for self-prescribing of controlled substances and conviction of crimes substantially related to qualifications, functions, or duties of a physician and surgeon.'' *Id.* at 16. On March 9, 2020, Registrant entered into a Stipulated Surrender of License and Disciplinary Order (hereinafter, Stipulated Surrender) in which he admitted the truth of the allegations in the Accusation and surrendered his California medical license for the Board's formal acceptance without further process. *Id.* at 4–7. The Stipulated Surrender ordered Registrant's medical license surrendered and was signed by Registrant and his attorney. *Id.* at 5–6. On March 30, 2020, the Board adopted the Stipulated Surrender, effective April 29, 2020. *Id.* at 1.

According to California's online records, of which I take official notice, Registrant's medical license is still surrendered.[1] Medical Board of California License Verification, *https://www.mbc.ca.gov/License-Verification* (last visited date of signature of this Order). Accordingly, I find that Registrant is not licensed to engage in the practice of medicine in California, the state in which he is registered with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71371 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27616, 27617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51104, 51105 (1993); *Bobby Watts, M.D.,* 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton,* 43 FR at 27617.

According to California statute, ''dispense'' means ''to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, furnishing, packaging, labeling, or compounding necessary to prepare the substance for that delivery.'' Cal. Health & Safety Code § 11010 (West, current with urgency legislation through Ch. 6 of 2022 Reg.Sess.). Further, a ''practitioner'' means a person ''licensed, registered, or otherwise permitted, to distribute, dispense, conduct research with respect to, or administer, a controlled substance in the course of professional practice or research in this state.'' *Id.* at § 11026(c).

Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice medicine in California. As discussed above, a physician must be a licensed practitioner to dispense a controlled substance in California. Thus, because Registrant lacks authority to practice medicine in California and, therefore, is not authorized to handle controlled substances in California, Registrant is not eligible to maintain a DEA registration. Accordingly, I will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. AB2619510 issued to Douglas A. Blose, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Douglas A. Blose, M.D. to renew or modify this registration, as well as any other pending application of Douglas A. Blose, M.D. for additional registration in California. This Order is effective May 11, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–07686 Filed 4–8–22; 8:45 am]

BILLING CODE 4410–09–P

[1] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration of finding of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.usdoj.gov.*

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

David H. Betat, M.D.; Decision and Order

On August 21, 2019, a former Assistant Administrator of the Diversion Control Division of the Drug Enforcement Administration (hereinafter, Government) issued an

Order to Show Cause (hereinafter, OSC) seeking to revoke the DEA Certificate of Registration, number BB0500365, of David H. Betat, M.D. (hereinafter, Registrant). Government Request for Final Agency Action (hereinafter, RFAA) Exhibit (hereinafter, RFAAX) 1 (OSC). The OSC sought to revoke Registrant's registration pursuant to 21 U.S.C. 824(a)(4) on the ground that it is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f), and to deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. 823(f). *Id.* at 1.

Specifically, the OSC alleged that Registrant, from at least 2012 through at least 2017, prescribed controlled substances to various patients that were not issued for a legitimate medical purpose, that were beneath the standard of care for the practice of medicine in the State of California, and that were not issued in the usual course of professional practice. *Id.* at 2–4. The OSC further alleged that Registrant's controlled substance prescribing practices violated both federal and state law. *Id.* at 4.

In response to the OSC, Registrant submitted a timely request for a hearing. RFAAX 3 (Request for Hearing for the OSC). The case was subsequently assigned to Administrative Law Judge (hereinafter, ALJ) Mark M. Dowd, who ordered that the Government file its prehearing statement by October 16, 2019, and that Registrant file his prehearing statement by November 1, 2019. RFAAX 4 (Order for Prehearing Statements). Registrant failed to file a prehearing statement by November 1, 2019. ALJ Dowd subsequently issued an order to show cause on November 8, 2019, providing Registrant until November 20, 2019, to file both a prehearing statement and a statement demonstrating good cause for failure to meet the original deadline. *See* RFAAX 5 (ALJ Dowd Order to Show Cause). Registrant did not respond to the ALJ's order to show cause. Consequently, ALJ Dowd issued an order finding that Registrant had waived his right to a hearing and terminating the proceedings. RFAAX 6 (Order Terminating Proceedings).

On August 17, 2020, the Government forwarded its RFAA, along with the evidentiary record in this matter, to my office. The Government seeks a final order of revocation because Registrant has ''committed acts that render his continued registration inconsistent with the public interest under 21 U.S.C. 824(a) and 823(f).'' RFAA, at 3. I issue this Decision and Order after considering the entire record before me, 21 CFR 1301.43(e); and I make the following findings of fact.

I. Findings of Fact

a. Registrant's DEA Registration

Registrant is registered with DEA as a practitioner authorized to handle controlled substances in schedules II through V under DEA Certificate of Registration number BB0500365 at the registered address of 925 Bevins Court, Lakeport, California 95453. RFAAX 7 (Certificate of Registration). Registrant's registration expires by its terms on July 31, 2022. *Id.*

b. Investigation of Registrant

On May 10, 2018, a DEA Diversion Investigator (hereinafter, the DI) served an administrative subpoena on Registrant for patient files reflecting Registrant's treatment of various patients. RFAAX 8 (Declaration of Diversion Investigator), App. A. Registrant provided copies of various patient files in response to DEA's subpoena, including patient files for Patients K.K., G.K., T.L., J.P., and Y.P. RFAAX 8, at 2 and Apps. B–F (Copies of patient files).

In furtherance of the DEA investigation of Registrant, the DI obtained information from the California Controlled Substance Utilization Review Evaluation System (CURES) database regarding Registrant's prescriptions to Patients K.K., G.K., T.L., J.P., and Y.P. for the period of 2012 through 2017. *Id.* at ¶ 13 and App. G (Copy of CURES database report). The DI also issued administrative subpoenas to various pharmacies to obtain copies of Registrant's prescriptions to Patients K.K., G.K., T.L., J.P., and Y.P. *Id.* at ¶ 16. The pharmacies responded with copies of prescriptions for the requested patients. *Id.* at Apps. I–M (Copies of prescriptions from CVS Pharmacy), O–P (Copies of prescriptions from Kmart Pharmacy), R–T, V–X (Copies of prescriptions from North Lake Medical Pharmacies), Z–AA (Copies of prescriptions from Safeway Pharmacy), AC (Copies of prescriptions from Omnicare, Inc.), AE (Copies of prescriptions from Pharmacy Care Concepts), AG–AH (Copies of prescriptions from Lucerne Pharmacy), AJ (Copies of prescriptions from Moran's Pharmacy), AL (Copies of prescriptions from Walmart Pharmacy). In addition to producing copies of Registrant's prescriptions to Patients K.K., G.K, T.L, J.P, and Y.P., two pharmacies informed the DI that there were certain prescriptions they failed to produce because they were unable to locate them or the records had been lost. *Id.* at ¶¶ 48–49, App. AM–AN.

c. The Government Expert's Review of Registrant's Prescriptions

The DEA hired Dr. Timothy A. Munzing to review Registrant's patient files for the patients under review and the CURES report showing Registrant's prescriptions to those patients for the period from 2012–2017. *Id.* at ¶ 15. Dr. Munzing is a physician licensed and practicing in the State of California, who has more than three decades of clinical work and has served as a Medical Expert Reviewer for the Medical Board of California.[1] RFAAX 9, at ¶¶ 1–3 (Declaration of Dr. Munzing); *see also id.* at App. A (Dr. Munzing CV). I find that Dr. Munzing is an expert in the standard of care for prescribing controlled substances in California, and I give his report full credit.

Dr. Munzing's expert report ''review[ed] the management of the five patients [K.K., G.K., T.L., J.P, and Y.P.] and opine[d] on the controlled substance prescriptions, specifically whether they were medically legitimate and in the usual course of professional practice.'' RFAAX 9, App. B, at 4 (Munzing Report) (emphasis omitted). Dr. Munzing concluded, and I agree, that with regard to patients K.K., G.K., T.L., J.P., and Y.P., Registrant repeatedly issued controlled substance prescriptions without a legitimate medical purpose, outside the usual course of professional practice in the State of California, and ''in violation of the minimum standard of care that governs California physicians with respect to the use of controlled substances in pain management.'' *Id.* at ¶ 15.

i. Standard of Care in California

Dr. Munzing attested that several statutes inform the standard of care in California for the use of controlled substances in pain management. RFAAX 9, at ¶ 10. Among them, California Health and Safety Code 11153(a) requires that ''[a] prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.'' California Business and Professional Code 2241.5 permits California physicians to treat patients under their care for pain, including intractable pain, by prescribing controlled substances, but requires them to ''exercise reasonable

[1] Currently named California Department of Consumer Affairs, Division of Investigation, and Health Quality Investigation Unit (''HQIU''). RFAAX 9, at ¶ 3.

care in determining whether a particular patient or condition, or the complexity of a patient's treatment, . . . requires consultation with, or referral to, a more qualified specialist.'' Finally, California Business and Professional Code 2242 provides that ''[p]rescribing, dispensing, or furnishing'' controlled substances to a patient ''without an appropriate prior examination and a medical indication'' is ''unprofessional conduct'' by the prescribing physician. RFAAX 9, at ¶ 10. Dr. Munzing further noted that California's applicable standard for the use of controlled substances in pain management is also informed by the ''Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons,'' Medical Board of California, 7th ed. 2013 (hereinafter, the Guide). *Id.* at ¶ 11.

Dr. Munzing opined that, as informed by the above statutes and the Guide, the California standard of care for the use of controlled substances in pain management requires, among other things, that a physician prescribing controlled substances:

''(1) perform a sufficient physical examination and take a medical history;

(2) make an assessment of the patient's pain, their physical and psychological function, and their history of prior pain treatment;

(3) make an assessment of any underlying or coexisting diseases or conditions and order and perform diagnostic testing if necessary;

(4) discuss with the patient the risks and benefits of the use of controlled substances or any other treatment modules;

(5) review periodically the course of pain treatment and gather any new information, if any, about the etiology of a patient's state of health; and

(6) give special attention to patients who, by their own words and actions, pose a risk for medication misuse and/or diversion.''

Id. at ¶ 12. Dr. Munzing also opined that the California standard of care imposes additional requirements for certain specific controlled substance prescriptions that Registrant prescribed to the subject patients. First, a physician must closely monitor patients prescribed opioid doses equivalent to or greater than 100 mg of morphine per day due to the substantially increased risks of overdose and death.[2] *Id.* at ¶ 13; *see also id.* at App. B, at 62 and 66 (referencing Centers for Disease Control guideline [3] that encourages keeping opioid dosing less than 50 mg per day MED if possible). In particular, Dr. Munzing attested that a California physician must specifically counsel the patient on the risks posed by such prescriptions and document that counseling; conduct urine drug screens of the patient and review the patient's profile in the CURES database at least every 3–4 months; refer the patient for co-management by a specialist in pain management where appropriate; and attempt to lower the medication dosage prescribed as much as possible. *Id.* at ¶ 13.

Second, a physician prescribing both opioids and benzodiazepines to a patient must exercise extra caution because both groups of drugs are respiratory depressants and simultaneous prescriptions can increase the patient's risk of overdose and death. *Id.; see also id.* at App. B, at 63 (referencing Food and Drug Administration 2016 ''Black Box Warning'' on the serious risks associated with the combined use of certain opioid medications and benzodiazepines and the Centers for Disease Control 2016 *Guideline for Prescribing Opioids for Chronic Pain*). Dr. Munzing attested that a physician who simultaneously prescribes both an opioid and a benzodiazepine should document the medical necessity for prescribing both, discuss the risks of prescribing with the patient, and document that conversation. *Id.*

Third, a physician prescribing opioids for pain management must avoid issuing overlapping prescriptions with the same therapeutic effect, commonly referred to as therapeutic duplication. *Id.* at ¶ 13. Fourth, a physician prescribing methadone to a patient for an extended term must exercise special care because methadone increases the risk of cardiac arrhythmia in certain patients. *Id.; see also id.* at App. B, at 64–66 (citing Food and Drug Administration November 2006 ''Black Box Warning'' regarding methadone hydrochloride). In particular, Dr. Munzing attested that a physician should conduct a baseline EKG test and conduct follow-up EKGs at least annually. *Id.*

Finally, Dr. Munzing opined that the California standard of care for the use of controlled substances in pain management requires physicians to be vigilant for the ''red flags'' of drug abuse or diversion of controlled substances. *Id.* at ¶ 14. A physician who encounters a red flag of abuse or diversion must address it, including through documented discussions with the patient, closer monitoring, adjusting the prescribed medication, or discontinuing treatment. *Id.* Dr. Munzing attested that the following are examples of well-known red flags of abuse and diversion of controlled substances: Extended gaps between patient visits or prescription refills; early requests for refills of controlled substances; filling prescriptions at multiple pharmacies, which could indicate the patient is attempting to avoid oversight by the pharmacist; and prescribing a ''Trinity cocktail'' of a narcotic painkiller, a benzodiazepine, and a muscle relaxer, which is combination widely known to be abused and/or diverted and which is dangerous because each component causes respiratory depression. *Id.*

Having read and analyzed all of the record evidence and law, I find that Dr. Munzing's declaration concerning a California physician's standard of care when prescribing controlled substances is supported by substantial evidence—in particular that it is consistent with the explicit text of California law, the Guide, and the Medical Board of California's 2014 *Guidelines for Prescribing Controlled Substances for Pain*.[4] As such, I apply the standard of care of the state of California as described by Dr. Munzing and California law.

ii. The Subject Patients

Patient K.K.

Registrant issued at least 244 controlled substance prescriptions to Patient K.K. between January 2012 and November 2016, including prescriptions for methadone, morphine sulfate, oxycodone, oxycodone-acetaminophen, hydromorphone, and zolpidem tartrate. RFAAX 9, at ¶ 17; *see also* RFAAX 8, App. G (CURES data); RFAAX 8, Apps. I, O, R, V, Z, AG, and AJ (copies of prescriptions from the filling pharmacies). Registrant's prescriptions to K.K. also included various strengths and quantities across different prescriptions for the same controlled substances. For example, at different times, Registrant prescribed morphine sulfate to K.K. in 30mg, 60mg, and 100mg strengths. *See* RFAAX 8, App. G.

[2] Dr. Munzing explained that a patient's daily dosage of opioids is evaluated using morphine milligram equivalency (''MME''), also known as the daily morphine equivalent dosage (''MED''), under which each different opioid is assigned a value to represent its potency relative to morphine sulfate. RFAAX 9, at n. 1.

[3] Although the Government's evidence did not include the Centers for Disease Control and Prevention (CDC), *Guideline for Prescribing Opioids for Chronic Pain,* 2016, it is publically available at: *https://www.cdc.gov/drugoverdose/prescribing/guideline.html.*

[4] Dr. Munzing referenced the 2007 and 2014 Medical Board of California *Guidelines for Prescribing Controlled Substances for Pain* in his expert report. RFAAX 9, App. B, at 66. Although the Government's evidence did not include the Guidelines, the 2014 update is publically available at: *http://www.mbc.ca.gov/Licensees/Prescribing/Pain_Guidelines.pdf.*

After reviewing the prescriptions and Registrant's patient file for Patient K.K., Dr. Munzing noted several deficiencies and departures from the standard of care and usual course of professional practice with respect to Registrant's controlled substance prescriptions for K.K. RFAAX 9, at ¶ 17. First, Registrant repeatedly issued ''dangerous levels of opioids'' to Patient K.K., including daily morphine equivalent doses ranging from over 1,600 mg per day to as high as 3,780 mg per day, without monitoring the patient through checks of the CURES database or co-management by a specialist in pain management.[5] *Id.* Registrant also issued prescriptions to K.K. for opioids with duplicated therapeutic effects, including overlapping prescriptions for oxycodone and oxycodone-acetaminophen and overlapping prescriptions for hydromorphone and oxycodone. *Id.* Furthermore, in Dr. Munzing's expert opinion, Registrant failed to conduct and document an evaluation of Patient K.K., including an adequate physical examination and medical history, sufficient to justify the controlled substance prescriptions that he issued to K.K. *Id.*

Finally, Patient K.K. presented red flags of drug abuse and diversion that Registrant failed to address or document. *Id.* The red flags included early refill requests for controlled substances, the use of multiple pharmacies to fill controlled substance prescriptions, and an extended gap in care during 2013, without an adequate explanation. *Id.*

Based on the above deficiencies, particularly the lack of an appropriate physical exam and medical history prior to Registrant's issuance of controlled substance prescriptions, Dr. Munzing found, and I agree, that the controlled substance prescriptions that Registrant issued to Patient K.K represent ''an extreme departure'' from the standard of care in California and were issued outside the usual course of professional practice. *Id.* at ¶ 18.

Patient G.K.

Registrant issued at least 269 controlled substance prescriptions to Patient G.K. between January 2012 and July 2017, including prescriptions for hydrocodone-acetaminophen, hydromorphone, methadone, oxycodone, oxycodone-acetaminophen, temazepam, and tramadol. RFAAX 9, at ¶ 19; *see also* RFAAX 8, App. G (CURES data); RFAAX 8, Apps. J and P (copies of prescriptions from the filling pharmacies).

After reviewing the prescriptions and Registrant's patient file for Patient G.K., Dr. Munzing noted several deficiencies and departures from the standard of care and usual course of professional practice with respect to Registrant's controlled substance prescriptions for G.K. RFAAX 9, at ¶ 19. Registrant repeatedly issued ''dangerous levels of opioids'' to Patient G.K., including daily morphine equivalent doses ranging from 600 mg per day to as high as 1,820 mg per day, without monitoring the patient through checks of the CURES database, co-management by a specialist in pain management, or discussing and documenting the discussion of the risks posed by the high levels of opioids prescribed. *Id.* There is also no record that Registrant ever conducted EKG testing to detect abnormalities caused by long-term methadone use despite prescribing methadone to Patient G.K. from 2012 through at least 2017. *Id.* Registrant additionally issued prescriptions to G.K. for opioids with duplicated therapeutic effects, including overlapping prescriptions for hydromorphone and oxycodone, and concurrently prescribed G.K. with opioids and benzodiazepines without documenting the medical necessity for prescribing those controlled substances together or document any discussion with G.K. regarding the risks of doing so. *Id.* Furthermore, in Dr. Munzing's expert opinion, Registrant failed to conduct and document an evaluation of Patient G.K., including an adequate physical examination and medical history, sufficient to justify the controlled substance prescriptions that he issued to G.K. *Id.*

Finally, Patient G.K. presented red flags of drug abuse and diversion that Registrant failed to address or document. *Id.* The red flags included early refill requests for controlled substances and the use of multiple pharmacies to fill controlled substance prescriptions. *Id.*

Based on the above deficiencies, particularly the lack of an appropriate physical exam and medical history prior to Registrant's issuance of controlled substance prescriptions, Dr. Munzing found, and I agree, that the controlled substance prescriptions that Registrant issued to Patient G.K represent ''an extreme departure'' from the standard of care in California and were issued outside the usual course of professional practice. *Id.* at ¶ 20.

Patient T.L.

Registrant issued at least 120 controlled substance prescriptions to Patient T.L. between January 2012 and July 2017, including prescriptions for hydromorphone, methadone, and oxycodone. RFAAX 9 at ¶ 21; *see also* RFAAX 8, App. G (CURES data); RFAAX 8, Apps. K, W (copies of prescriptions from the filling pharmacies).

After reviewing the prescriptions and Registrant's patient file for Patient T.L, Dr. Munzing noted several deficiencies and departures from the standard of care and usual course of professional practice with respect to Registrant's controlled substance prescriptions for T.L. RFAAX 9, at ¶ 21. First, Registrant repeatedly issued ''dangerous levels of opioids'' to Patient T.L., including daily morphine equivalent doses ranging from over 1,100 mg per day to as high as 2,380 mg per day. *Id.* Registrant also issued prescriptions to T.L. for opioids with duplicated therapeutic effects, including overlapping prescriptions for hydromorphone and oxycodone. *Id.* Furthermore, in Dr. Munzing's expert opinion, Registrant failed to conduct and document an evaluation of Patient T.L., including an adequate physical examination and medical history, sufficient to justify the controlled substance prescriptions that he issued to T.L. *Id.*

Based on the above deficiencies, particularly the lack of an appropriate physical exam and medical history prior to Registrant's issuance of controlled substance prescriptions, Dr. Munzing found, and I agree, that the controlled substance prescriptions that Registrant issued to Patient T.L represent a departure from the standard of care in California and were issued outside the usual course of professional practice. *Id.* at ¶ 22.

Patient J.P.

Registrant issued at least 409 controlled substance prescriptions to Patient J.P. between January 2012 and July 2017, including prescriptions for clonazepam, diazepam, fentanyl, hydrocodone-acetaminophen,

[5] Dr. Munzing's declaration also states that Registrant's prescriptions to K.K., G.K., T.L., and J.P. fell below the standard of care in part because he prescribed high levels of opioids without monitoring the patients through urine drug screens. RFAAX 9, at ¶¶ 17, 19, 21, and 23. All of the patients' files, however, contain results for at least one urine drug screen during the relevant five year time period. *See, e.g.,* RFAAX 8, at App. B at 122, App. C at 93, App. D at 113, and App. E at 384. Dr. Munzing's declaration and report focused on the absence of urine drug screens, and did not provide an opinion regarding the frequency with which a physician prescribing the levels of opioids that Registrant was prescribing should conduct drug testing to meet the applicable standard of care. Accordingly, I cannot find substantial evidence that Registrant's urine drug screening fell below the standard of care in California based on the record evidence, and therefore, I am not sustaining the Government's allegations related to urine drug testing for any of these patients.

hydromorphone, methadone, morphine sulfate, oxycodone, temazepam, and tapentadol. RFAAX 9, at ¶ 23; *see also* RFAAX 8, App. G (CURES data); RFAAX 8, Apps. L, T, AA, AC, AE, and AH (copies of prescriptions from the filling pharmacies). Registrant's prescriptions to J.P. also included various strengths and quantities across different prescriptions for the same controlled substances. For example, at different times, Registrant prescribed clonazepam to J.P. in .5 mg, 1 mg, and 2 mg strengths. *See* RFAAX 8, App. G.

After reviewing the prescriptions and Registrant's patient file for Patient J.P., Dr. Munzing noted several deficiencies and departures from the standard of care and usual course of professional practice with respect to Registrant's controlled substance prescriptions for J.P. RFAAX 9, at ¶ 23. Registrant repeatedly issued ''dangerous levels of opioids'' to Patient J.P., including daily morphine equivalent doses ranging from 150 mg per day to as high as 2,460 mg per day, without monitoring the patient through checks of the CURES database or co-management by a specialist in pain management. *Id.* The prescribed opioids included prescriptions for methadone ''beginning in 2012 and continuing through at least 2016 even though EKG testing in October 2014 revealed that patient J.P. had developed a prolonged QT interval,'' meaning that, in Dr. Munzing's opinion, ''continued use of methadone put J.P. at increased risk of death.'' *Id.* Registrant also concurrently prescribed J.P. opioids and benzodiazepines without documenting the medical necessity for prescribing those controlled substances together or documenting any discussion with J.P. regarding the risks of doing so. *Id.* Furthermore, in Dr. Munzing's expert opinion, Registrant failed to conduct and document an evaluation of Patient J.P., including an adequate physical examination and medical history, sufficient to justify the controlled substance prescriptions that he issued to J.P. *Id.*

Finally, Patient J.P. presented red flags of drug abuse and diversion that Registrant failed to address or document. *Id.* The red flags included early refill requests for controlled substances and the use of multiple pharmacies to fill controlled substance prescriptions. *Id.*

Based on the above deficiencies, particularly the lack of an appropriate physical exam and medical history prior to Registrant's issuance of controlled substance prescriptions, Dr. Munzing found, and I agree, that the controlled substance prescriptions that Registrant issued to Patient J.P represent ''an extreme departure'' from the standard of care in California and were issued outside the usual course of professional practice. *Id.* at ¶ 24.

Patient Y.P.

Registrant issued at least 122 controlled substance prescriptions to Patient Y.P. between January 2012 and July 2017, including prescriptions for carisoprodol, diazepam, hydrocodone-acetaminophen, and oxycodone-acetaminophen. RFAAX 9, at ¶ 25; *see also* RFAAX 8, App. G (CURES data); RFAAX 8, Apps. M, X, and AL (copies of prescriptions from the filling pharmacies).

After reviewing the prescriptions and Registrant's patient file for Patient Y.P., Dr. Munzing noted several deficiencies and departures from the standard of care and usual course of professional practice with respect to Registrant's controlled substance prescriptions for Y.P. RFAAX 9, at ¶ 25. Registrant concurrently prescribed Y.P. opioids and benzodiazepines without documenting the medical necessity for prescribing those controlled substances together or documenting any discussion with Y.P. regarding the risks of doing so. *Id.* Registrant also repeatedly prescribed the ''Trinity cocktail'' to Patient Y.P., which as noted above, Dr. Munzing opined to be a dangerous combination of controlled substances widely known to be abused and/or diverted. Furthermore, in Dr. Munzing's expert opinion, Registrant failed to conduct and document an evaluation of Patient Y.P., including an adequate physical examination and medical history, sufficient to justify the controlled substance prescriptions that he issued to Y.P. *Id.*

Finally, Patient Y.P. presented red flags of drug abuse and diversion that Registrant failed to address or document. *Id.* The red flags included early refill requests for controlled substances, the use of multiple pharmacies to fill controlled substance prescriptions, and multiple extended gaps in care including from October 2012 to December 2013, from December 2013 to March 2014, from June 2014 to October 2014, and from December 2015 to March 2016. *Id.*

Based on the above deficiencies, particularly the lack of an appropriate physical exam and medical history prior to Registrant's issuance of controlled substance prescriptions and the prescriptions for the ''Trinity cocktail,'' Dr. Munzing found, and I agree, that the controlled substance prescriptions that Registrant issued to Patient Y.P represent ''an extreme departure'' from the standard of care in California and were issued outside the usual course of professional practice. *Id.* at ¶ 26.

II. Discussion

Under Section 304 of the Controlled Substances Act (hereinafter, CSA), ''[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined by such section.'' 21 U.S.C. 824(a)(4). In the case of a ''practitioner,'' defined in 21 U.S.C. 802(21) to include a ''physician,'' Congress directed the Attorney General to consider the following factors in making the public interest determination:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing . . . controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the . . . distribution[ ] or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f). These factors are considered in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003).

According to Agency decisions, I ''may rely on any one or a combination of factors and may give each factor the weight [I] deem[ ] appropriate in determining whether'' to revoke a registration. *Id.; see also Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018) (citing *Akhtar-Zaidi* v. *Drug Enf't Admin.,* 841 F.3d 707, 711 (6th Cir. 2016); *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *U. S. Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482. ''In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer,* M.D., 74 FR 459, 462 (2009). Accordingly, as the Tenth

Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

DEA regulations state, ''[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied.'' 21 CFR 1301.44(e). In this matter, while I have considered all of the factors, the Government's evidence in support of its *prima facie* case is confined to Factors Two and Four.[6] I find that the evidence satisfies the Government's *prima facie* burden of showing that Registrant's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). I further find that Registrant has not produced any evidence to rebut the Government's *prima facie* case. Registrant filed a request for a hearing upon receipt of the OSC but did not make any subsequent filings and failed to respond to an order issued by the ALJ. The ALJ, therefore, properly determined that Registrant had waived his right to a hearing and terminated the proceedings.

a. Factors Two and/or Four—The Registrant's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

Evidence is considered under Public Interest Factors Two and Four when it reflects a registrant's compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. Established violations of the Controlled Substances Act, DEA regulations, or other laws regulating controlled substances at the state or local level are cognizable when considering if a registration is consistent with the public interest.

i. Allegations of Violations of Federal Law

The Government has alleged that from at least January 2012 through at least December 2017, Registrant unlawfully issued prescriptions for controlled substances in violation of the CSA. OSC, at 4. Specifically, the Government alleges that Registrant repeatedly violated 21 CFR 1306.04 by issuing prescriptions for controlled substances to Patients K.K., G.K., T.L., J.P., and Y.P. beneath the standard of care in California, the state in which Registrant holds DEA registration, outside the usual course of professional practice, and without a legitimate medical purpose. *Id.*

According to the CSA's implementing regulations, a lawful controlled substance order or prescription is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). The Supreme Court has stated, in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription, that ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006).

I found above that the Government's expert credibly declared, as supported by California law and the California Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons, that the standard of care in California requires physicians to, among other things, perform a sufficient physical exam and take a medical history, counsel patients on the risks and benefits of the use of particular controlled substances and document the discussions, and give special attention to patients who pose a risk for medication misuse and diversion. Based on the credible and unrebutted opinion of the Government's expert, I also found above that Registrant issued at least 1,164 controlled substance prescriptions, often for extremely high doses of opioids and in dangerous combinations of opioids and benzodiazepines, without performing or documenting physical examinations or conducting medical histories adequate to justify the prescribed medications, and often without counseling the patients on the risks posed by their medications; proper ongoing monitoring; or resolving or documenting resolution of red flags of abuse and/or diversion as required by the standard of care. *See supra* I.c.ii.

My findings demonstrate that Registrant repeatedly violated the applicable standard of care when prescribing controlled substances and that his conduct was not an isolated occurrence, but occurred with multiple patients. *See Kaniz Khan Jaffery,* 85 FR 45667, 45685 (2020); *Wesley Pope, M.D.,* 82 FR 42961, 42986 (2017). For example, I found, based on Dr. Munzing's credible and unrebutted expert opinion, that Registrant did not perform adequate physical exams or take appropriate medical histories before issuing controlled substances to the five subject patients.

I also found that Registrant repeatedly ignored signs of abuse and/or diversion. Dr. Munzing credibly opined that a California physician who prescribes controlled substances for pain management within the standard of care and in the usual course of professional practice must be vigilant for red flags of abuse or diversion of controlled substances and must address any such red flags he encounters, including through ''documented discussions with the patient, closer monitoring, adjusting the medication or quantity of medication prescribed, or discontinuing treatment.'' RFAAX 9, at ¶ 14. As discussed *supra,* I found four of the subject patients presented red flags of abuse and diversion of controlled substances, including early requests for refills of controlled substances. Registrant, however, did not document discussions with the patients regarding the majority of the red flags, and there is no evidence in the patient files that Registrant otherwise addressed the red flags of abuse and diversion presented by Patients K.K., G.K., J.P., and Y.P. Registrant's failure to document and address the red flags was a violation of the standard of care in accordance with the credible and unrebutted opinion of the Government's expert.

For these reasons, in addition to the reasons I detailed *supra* I.c.ii, I find that the Government has presented substantial evidence that between 2012 and 2017 Registrant issued controlled substance prescriptions to the five subject patients that were issued outside the usual course of professional practice and beneath the applicable standard of care in California. Accordingly, I am

[6] As to Factor One, there is no record evidence of disciplinary action against Registrant's state medical license. 21 U.S.C. 823(f)(1). State authority to practice medicine is ''a necessary, but not a sufficient condition for registration . . . .'' *Robert A. Leslie, M.D.,* 68 FR at 15230. Therefore, ''[t]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of Registrant's DEA certification is consistent with the public interest.'' *Roni Dreszer, M.D.,* 76 FR 19434, 19444 (2011).

As to Factor Three, there is no evidence in the record that Registrant has a ''conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(f). However, as prior Agency decisions have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor. *Dewey C. MacKay, M.D.,* 75 FR at 49973. Those Agency decisions have therefore concluded that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

The Government's case includes no allegation under Factor Five.

sustaining the Government's allegation that Registrant violated 21 CFR 1306.04.

ii. Allegations of Violations of California Law

The Government has also alleged that Registrant's prescribing practices in regards to the subject patients violated state law. OSC, at 4–7. Echoing the federal regulations, California law requires that a ''prescription for a controlled substance shall only be issued for a medical purpose by an individual practitioner acting in the usual course of his or her professional practice.'' Cal. Health & Safety Code 11153(a). Therefore, I find that, similarly to 21 CFR 1306.04(a), the record contains substantial evidence that Registrant violated this provision with respect to the controlled substance prescriptions for Patients K.K., G.K., T.L., J.P., and Y.P. I also find based on the uncontroverted evidence that Registrant issued these same controlled substance prescriptions without ''an appropriate prior examination and a medical indication,'' which is a violation of Cal. Bus. & Prof. Code 2242(a).[7]

In sum, I find that the record contains substantial evidence that Registrant issued a multitude of prescriptions for controlled substances, including high dosages of opioids, to multiple patients beneath the applicable standard of care, outside the usual course of the professional practice, and in violation of federal and state law. I, therefore, find that Factors Two and Four weigh in favor of revocation. *See Mark A. Wimbley, M.D.,* 86 FR 20713, 20726 (2021).

III. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Registrant's registration should be revoked because his continued registration is inconsistent with the public interest, the burden shifts to the Registrant to show why he can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18882, 18910 (2018) (collecting cases).

The CSA authorizes the Attorney General to ''promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.'' 21 U.S.C. 871(b). This authority specifically relates ''to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute.'' *Gonzales,* 546 U.S. at 259. ''Because 'past performance is the best predictor of future performance, *ALRA Labs, Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.' '' *Jayam Krishna-Iyer,* 74 FR at 463 (quoting *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Jackson,* 72 FR at 23853; *John H. Kennnedy, M.D.,* 71 FR 35705, 35709 (2006); *Prince George Daniels, D.D.S.,* 60 FR 62884, 62887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant; therefore, the Agency looks at factors, such as the acceptance of responsibility, and the credibility of that acceptance as it relates to the probability of repeat violations or behavior, and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).

In this matter, Registrant did not avail himself of the opportunity to refute the Government's case. As such, Registrant has made no representations as to his future compliance with the CSA or made any demonstration that he can be trusted with a registration. The evidence presented by the Government of Registrant's conduct clearly indicates that he cannot be so entrusted.

Accordingly, I shall order the sanctions the Government requested, as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and § 823(f), I hereby revoke DEA Certificate of Registration No. BB0500365. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of David H. Betat, M.D. to renew or modify this registration, as well as any other pending application of David H. Betat, M.D. for registration in California. This Order is effective May 11, 2022.

Anne Milgram,

Administrator.

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[7] The Government has also alleged that Registrant violated Cal. Bus. & Prof. Code § 2241.5. Section 2241.5 permits California physicians to treat pain, including intractable pain, but requires them, among other requirements, to ''exercise reasonable care in determining whether a particular patient or condition, or the complexity of a patient's treatment, . . . requires consultation with, or referral to, a more qualified specialist.'' Dr. Munzing's expert report did not address whether Registrant failed to exercise reasonable care in determining whether the subject patients' treatment required consultation with, or referral to, a more qualified specialist. Accordingly, I find that the Government has not met its burden to prove by substantial evidence that Registrant violated Cal. Bus. & Prof. Code § 2241.5.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 19–38]

Craig S. Rosenblum, M.D.; Decision and Order

I. Introduction

On August 8, 2019, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration to Craig S. Rosenblum, M.D. (hereinafter, Respondent), of Palm Desert, California. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (Order to Show Cause and Immediate Suspension of Registration (hereinafter collectively, OSC)), at 1. The OSC informed Respondent of the immediate suspension of his DEA Certificates of Registration BR0869719, BA7661564, and DATA-Waiver No. XR0869719 ''because . . . [his] continued registration constitute[d] 'an imminent danger to the public health and safety.' '' [1] *Id.*

The substantive ground for the proceeding, as alleged in the OSC, is that Respondent ''committed such acts as would render . . . [his] registration under 21 U.S.C. 823(f) inconsistent with the public interest. *See* 21 U.S.C. 824(a)(4).'' *Id.* at 2. Specifically, the OSC alleges that Respondent issued unlawful controlled substance prescriptions, that this ''conduct reflects negative experience in prescribing with respect to controlled substances in violation of 21 U.S.C. 823(f)(2),'' and that Respondent ''failed to comply with applicable federal and state laws relating to controlled substances in violation of 21 U.S.C. 823(f)(4).'' *Id.* The OSC also alleges that a California medical expert reviewed Respondent's medical files and Controlled Substance Utilization Review and Evaluation System (hereinafter, CURES) reports and concluded that Respondent's ''issuance of each prescription fell below minimal

[1] Registration No. BR0869719 is assigned to Respondent. Registration No. BA7661564 is assigned to Aurora Surgery Center. OSC, at 2. Nothing in the record transmitted to me challenges Respondent's responsibility for both of these registrations. *See also infra* section III.A.

medical standards applicable to the practice of medicine in California.'' *Id.* at 3. The OSC sets out specifics of Respondent's alleged prescribing for six individuals to support its allegations. *Id.* at 4–10.

According to the OSC, in view of the information before the DEA at the time, the former Acting Administrator preliminarily found that Respondent's continued registration was ''inconsistent with the public interest,'' that Respondent's issuance of multiple controlled substance prescriptions was ''without any legitimate medical purpose,'' and that his ''continued registration during the pendency of these proceedings would constitute 'an imminent danger to the public health or safety' because of the substantial likelihood of an imminent threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of . . . suspension.'' *Id.* at 10–11. Citing 21 U.S.C. 824(d), 21 CFR 1301.36(e), and other authorities, the former Acting Administrator suspended, ''effective immediately'' and ''until a final determination is reached in these proceedings,'' BR0869719, BA7661564, and DATA-Waiver No. XR0869719, and directed the DEA Special Agents and Diversion Investigators serving the OSC to take possession of those certificates. *Id.* at 11.

The OSC notified Respondent of his right to request a hearing on the allegations or to submit a written statement while waiving his right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* (citing 21 CFR 1301.43). According to the Government's Notice of Service, a member of the DEA Riverside District Office personally served the OSC on Respondent on August 9, 2019. ALJX 2 (Government's Notice of Service of Order to Show Cause and Immediate Suspension of Registration dated August 12, 2019), at 1.

By letter dated August 20, 2019, Respondent timely requested a hearing. ALJX 3, at 1. The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Administrative Law Judge Charles Wm. Dorman (hereinafter, ALJ). During the pre-hearing phase of this proceeding, the parties agreed to and submitted 116 joint stipulations (hereinafter, Jt. Stip.) that, at the hearing, the parties accepted as ''binding facts in these proceedings.'' Prehearing Ruling dated September 20, 2019, at 2–10; Parties' Additional Joint Stipulations dated October 28, 2019, at 1–13; Transcript page number (hereinafter, Tr.) 9. The final, agreed-to Stipulations as set out by the ALJ are:

Controlled Substances

1. Tetrahydrocannabinol (hereinafter, THC) is an illicit Schedule I Controlled Substance pursuant to 21 CFR 1308.11(d)(31).

2. Amphetamine salts (Adderall) are Schedule II Controlled Substances pursuant to 21 CFR 1308.12(d)(1).

3. Fentanyl (Duragesic patch) is a Schedule II Controlled Substance pursuant to 21 CFR 1308.12(c)(9).

4. Hydrocodone (Norco) is a Schedule II Controlled Substance pursuant to 21 CFR 1308.12(b)(1)(vi).

5. Hydromorphone (Dilaudid) is a Schedule II Controlled Substance pursuant to 21 CFR 1308.12(b)(1)(vii).

6. Methadone is a Schedule II Controlled Substance pursuant to 21 CFR 1308.12(c)(15).

7. Oxycodone (Oxycontin or Roxicodone) is a Schedule II Controlled Substance pursuant to 21 CFR 1308.12(b)(1)(xiii).

8. Oxycodone-acetaminophen (Percocet) is a Schedule II Controlled Substance pursuant to 21 CFR 1308.12(b)(1)(xiii).

9. Alprazolam (Xanax) is a Schedule IV Controlled Substance pursuant to 21 CFR 1308.14(c)(2).

10. Carisoprodol (Soma) is a Schedule IV Controlled Substance pursuant to 21 CFR 1308.14(c)(6).

11. Clonazepam (Klonopin) is a Schedule IV Controlled Substance pursuant to 21 CFR 1308.14(c)(11).

12. Diazepam (Valium) is a Schedule IV Controlled Substance pursuant to 21 CFR 1308.14(c)(16).

13. Promethazine with codeine is a Schedule V Controlled Substance pursuant to 21 CFR 1308.15(c)(1).

Registrations Associated With Respondent

14. Respondent is registered as a practitioner with the DEA to handle controlled substances in Schedules II through V under DEA COR number BR0869719 at 73–950 Alessandro Drive, Suite 4, Palm Desert, California 92260.

15. Respondent's DEA COR expires by its terms on April 30, 2021.

16. Government Exhibit 1 contains a true and correct copy of Respondent's DEA COR number BR0869719.

17. Respondent operates Aurora Surgery Center LP.

18. Aurora Surgery Center LP is organized in the State of California as a Limited Partnership.

19. Respondent is listed as the one and only General Partner on Aurora Surgery Center LP's Certificate of Limited Partnership.

20. Government Exhibit 2 contains a true and correct copy of the Certificate of Limited Partnership for Aurora Surgery Center LP.

21. Aurora Surgery Center LP is registered as a hospital/clinic with the DEA to handle controlled substances in Schedules II through V under DEA COR number BA7661564 at 73–950 Alessandro Drive, Palm Desert, California 92260.

22. Aurora Surgery Center LP's DEA COR expires by its terms on June 30, 2020.

23. Government Exhibit 1 contains a true and correct copy of Aurora Surgery Center LP's DEA COR number BA7661564.

24. Respondent is a DATA-waived (Drug Addiction Treatment Act) physician certified to treat 100 patients for substance abuse.

25. Respondent's DATA-Waiver Identification number is XR0869719.

26. Respondent is licensed in the State of California to practice medicine pursuant to state license number G59060.

27. Respondent's state medical license expires by its terms on February 29, 2020.

Investigation

28. Government Exhibit 3 contains true and correct copies of the administrative subpoenas issued to Respondent, dated January 16, 2019.

29. Government Exhibit 4 contains true and correct copies of the administrative subpoenas issued to various pharmacies, dated April 19, 2019.

30. Government Exhibit 6 is a true and correct copy of the ''Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons'' published by the Medical Board of California in 2013.

31. Government Exhibit 7 is a true and correct copy of the ''Guidelines for Prescribing Controlled Substances for Pain'' published by the Medical Board of California in November 2014.

32. Government Exhibit 8 is a true and correct copy of ''Calculating Total Daily Dose of Opioids for Safer Dosage'' published by the Centers for Disease Control and Prevention (CDC).

33. Government Exhibit 9 contains a true and correct copy of ''New Safety Measures Announced for Opioid Analgesics, Prescription Opioid Cough Products, and Benzodiazepines'' published by the Food and Drug Administration (FDA).

34. Government Exhibit 9 contains true and correct copies of the FDA labels for Klonopin, Valium, and Xanax.

35. Government Exhibits 10A and 10B contain true and correct copies of the

CURES reports for Respondent's prescribing behavior between January 1, 2018 and August 20, 2019.

Patient A.A.

36. Government Exhibits 12A and 12B contain true and correct copies of Respondent's patient medical file for Patient A.A.

37. On the following 16 occasions, Respondent issued a prescription for 180 tablets of Percocet 10–325 mg, a prescription for 60 tablets of Xanax 2 mg, and a prescription for 180 tablets of methadone 10 mg for Patient A.A.:

a. December 26, 2017
b. February 2, 2018
c. March 7, 2018
d. April 3, 2018
e. May 1, 2018
f. June 1, 2018
g. July 2, 2018
h. August 1, 2018
i. August 31, 2018
j. September 28, 2018
k. October 31, 2018
l. November 30, 2018
m. January 3, 2019
n. January 28, 2019
o. February 27, 2019
p. March 25, 2019

38. Government Exhibit 11 contains true and correct copies of the prescriptions listed in Stipulation 37.

Patient R.B.

39. Government Exhibits 14A and 14B contain true and correct copies of Respondent's patient medical file for Patient R.B.

40. Respondent issued the following 44 prescriptions for Patient R.B.:

a. January 10, 2018: 120 tablets of oxycodone 30 mg and 90 tablets of ibuprofen 800 mg
b. February 7, 2018: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
c. March 7, 2018: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
d. April 4, 2018: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
e. May 1, 2018: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
f. May 31, 2018: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
g. June 27, 2018: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
h. July 25, 2018: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
i. August 22, 2018: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
j. September 17, 2018: 120 tablets of oxycodone 30 mg and 90 tablets of ibuprofen 800 mg
k. October 12, 2018: 120 tablets of oxycodone 30 mg and 90 tablets of ibuprofen 800 mg
l. November 9, 2018: 120 tablets of oxycodone 30 mg and 90 tablets of ibuprofen 800 mg
m. December 10, 2018: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
n. January 9, 2019: 120 tablets of oxycodone 30 mg and 90 tablets of ibuprofen 800 mg
o. February 8, 2019: 120 tablets of oxycodone 30 mg, 120 ml promethazine with codeine 6.25–10 mg syrup, and 90 tablets of ibuprofen 800 mg
p. March 8, 2019: 120 tablets of oxycodone 30 mg and 90 tablets of ibuprofen 800 mg
q. April 5, 2019: 120 tablets of oxycodone 30 mg and 60 tablets of ibuprofen 800 mg

41. Government Exhibit 13 contains true and correct copies of the prescriptions listed in Stipulation 40.

Patient S.D.

42. Government Exhibits 16A, 16B, 16C, and 16D contain true and correct copies of Respondent's patient medical file for Patient S.D.

43. Respondent issued the following 41 prescriptions for Patient S.D.:

a. January 16, 2018: 180 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
b. February 14, 2018: 180 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
c. March 21, 2018: 180 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
d. April 20, 2018: 270 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
e. May 18, 2018: 270 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
f. June 14, 2018: 270 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
g. July 18, 2018: 270 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
h. August 15, 2018: 270 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
i. September 18, 2018: 270 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
j. October 19, 2018: 270 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
k. November 19, 2018: 270 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 60 tablets of Soma 350 mg
l. January 2, 2019: 270 tablets of methadone 10 mg, 180 tablets of Roxicodone 15 mg, and 120 tablets of Soma 350 mg
m. February 4, 2019: 180 tablets of Roxicodone 15 mg and 120 tablets of Soma 350 mg
n. March 1, 2019: 180 tablets of Roxicodone 15 mg and 120 tablets of Soma 350 mg
o. April 2, 2019: 180 tablets of Roxicodone 15 mg

44. Government Exhibit 15 contains true and correct copies of the prescriptions listed in Stipulation 43.

Patient L.D.

45. Government Exhibits 18A and 18B contain true and correct copies of Respondent's patient medical file for Patient L.D.

46. Respondent issued the following 28 prescriptions for Patient L.D.:

a. January 8, 2018: 120 tablets of Valium 5 mg, 360 tablets of Dilaudid 8 mg, 60 tablets of amphetamine salts 30 mg, and 30 Duragesic patches 100 mcg/hour
b. March 5, 2018: 120 tablets of Valium 5 mg, 360 tablets of Dilaudid 8 mg, 60 tablets of amphetamine salts 30 mg, and 30 Duragesic patches 100 mcg/hour
c. May 4, 2018: 120 tablets of Valium 5 mg, 360 tablets of Dilaudid 8 mg, 60 tablets of amphetamine salts 30 mg, and 30 Duragesic patches 100 mcg/hour

d. July 5, 2018: 120 tablets of Valium 5 mg, 360 tablets of Dilaudid 8 mg, 60 tablets of amphetamine salts 30 mg, and 30 Duragesic patches 100 mcg/hour
e. September 5, 2018: 120 tablets of Valium 5 mg, 360 tablets of Dilaudid 8 mg, and 30 Duragesic patches 100 mcg/hour
f. November 5, 2018: 120 tablets of Valium 5 mg, 360 tablets of Dilaudid 8 mg, and 30 Duragesic patches 100 mcg/hour
g. January 4, 2019: 120 tablets of Valium 5 mg, 360 tablets of Dilaudid 8 mg, and 30 Duragesic patches 100 mcg/hour
h. March 4, 2019: 120 tablets of Valium 5 mg, 360 tablets of Dilaudid 8 mg, and 20 Duragesic patches 100 mcg/hour

47. Government Exhibit 17 contains true and correct copies of the prescriptions listed in Stipulation 46.

Patient S.H.

48. Government Exhibit 20A and 20B contains true and correct copies of Respondent's patient medical file for Patient S.H.

49. On the following 17 occasions, Respondent issued a prescription for 90 tablets of Roxicodone 30 mg, a prescription for 90 tablets of Dilaudid 8 mg, and a prescription for 60 tablets of methadone 10 mg for Patient S.H.

a. December 26, 2017
b. January 29, 2018
c. February 20, 2018
d. March 23, 2018
e. April 23, 2018
f. May 21, 2018
g. June 18, 2018
h. July 18, 2018
i. August 15, 2018
j. September 12, 2018
k. October 10, 2018
l. November 7, 2018
m. December 5, 2018
n. January 2, 2019
o. January 30, 2019
p. February 27, 2019
q. March 27, 2019

50. Government Exhibit 19 contains true and correct copies of the prescriptions listed in Stipulation 49.

Patient J.M.

51. Government Exhibits 22A, 22B, 22C, and 22D contain true and correct copies of Respondent's patient medical file for Patient J.M.

52. Respondent issued the following 33 prescriptions for Patient J.M.

a. January 26, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
b. February 23, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
c. March 22, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
d. April 19, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
e. May 16, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
f. June 13, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
g. July 13, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
h. August 9, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
i. September 6, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
j. September 27, 2018: 90 tablets of alprazolam 2 mg
k. October 5, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
l. November 5, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
m. November 26, 2018: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
n. January 4, 2019: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
o. January 31, 2019: 180 tablets of OxyContin 80 mg and 240 tablets of Roxicodone 30 mg
p. February 26, 2019: 180 tablets of OxyContin 80 mg and 150 tablets of Roxicodone 30 mg
q. March 28, 2019: 180 tablets of OxyContin 80 mg and 150 tablets of Roxicodone 30 mg

53. Government Exhibit 21 contains true and correct copies of the prescriptions listed in Stipulation 52.

Exhibits

54. Respondent stipulates to the admissibility of Government Exhibits 1–4 and 6–22.

55. Xanax (alprazolam) is a benzodiazepine.

56. Valium (diazepam) is a benzodiazepine.

57. Klonopin (clonazepam) is a benzodiazepine.

Patient A.A.

58. On the following 16 occasions, Respondent prescribed for Patient A.A. oxycodone for 60 mg a day and methadone for 60 mg a day:

a. December 26, 2017
b. February 2, 2018
c. March 7, 2018
d. April 3, 2018
e. May 1, 2018
f. June 1, 2018
g. July 2, 2018
h. August 1, 2018
i. August 31, 2018
j. September 28, 2018
k. October 31, 2018
l. November 30, 2018
m. January 3, 2019
n. January 28, 2019
o. February 27, 2019
p. March 25, 2019

59. On June 5, 2013, Respondent increased Patient A.A.'s dosage of Percocet (oxycodone-acetaminophen) 10–325 from 90 tablets to 120 tablets.

60. On July 23, 2013, Respondent increased Patient A.A.'s dosage of Percocet (oxycodone-acetaminophen) 10–325 from 120 tablets to 180 tablets.

61. On January 11, 2013, Respondent increased Patient A.A.'s dosage of methadone 10 mg from 90 tablets to 120 tablets.

62. On June 2, 2014, Respondent increased Patient A.A.'s dosage of methadone 10 mg from 120 tablets to 180 tablets.

Patient R.B.

63. Respondent's first documented visit with Patient R.B. occurred on January 8, 2016.

64. During Respondent's January 8, 2016 initial visit with Patient R.B., Patient R.B. reported to Respondent that he was constantly in pain and had previously taken oxycodone and was then currently taking six tablets of Norco (hydrocodone-acetaminophen) 10–325 mg a day.

65. During Respondent's January 8, 2016 initial visit with Patient R.B., Patient R.B. tested positive for THC in a urine drug screen.

66. On January 8, 2016, Respondent issued a prescription for 90 tablets of oxycodone 30 mg to Patient R.B.

67. On February 8, 2016, Respondent had a second visit with Patient R.B.

68. On Respondent's February 8, 2016 second visit with Patient R.B., Patient R.B. reported to Respondent feeling much improved, with a pain level of one or two out of 10.

69. On Respondent's February 8, 2016 second visit with Patient R.B., Patient R.B. tested positive for THC and for a benzodiazepine.

70. On Respondent's February 8, 2016 second visit with Patient R.B., Respondent issued a prescription for 90 tablets of oxycodone 30 mg.

71. On the following occasions, Patient R.B. tested positive for THC in a urine drug screen:

a. January 8, 2016
b. February 8, 2016

c. April 6, 2016
d. May 4, 2016
e. June 7, 2016
f. July 11, 2016
g. August 8, 2016
h. September 7, 2016
i. October 5, 2016
j. November 2, 2016
k. December 2, 2016
l. January 2, 2017
m. January 30, 2017
n. March 1, 2017
o. March 29, 2017
p. April 26, 2017
q. May 24, 2017
r. June 26, 2017
s. July 24, 2017
t. August 23, 2017
u. September 18, 2017
v. October 16, 2017
w. November 15, 2017
x. December 13, 2017
y. February 7, 2018

72. Respondent did not document in Patient R.B.'s patient file any urine drug screens performed for Patient R.B. on January 10, 2018 and between March 7, 2018 and February 8, 2019.

73. On the following 17 occasions, Respondent prescribed Patient R.B. oxycodone of 120 mg a day:

a. January 10, 2018
b. February 7, 2018
c. March 7, 2018
d. April 4, 2018
e. May 1, 2018
f. May 31, 2018
g. June 27, 2018
h. July 25, 2018
i. August 22, 2018
j. September 17, 2018
k. October 12, 2018
l. November 9, 2018
m. December 10, 2018
n. January 9, 2019
o. February 8, 2019
p. March 8, 2019
q. April 5, 2019

74. On an April 6, 2016 visit with Patient R.B., Respondent increased Patient R.B.'s oxycodone 30 mg prescription from 90 tablets to 120 tablets.

75. On an April 6, 2016 visit with Respondent, Respondent documented in R.B.'s medical file that Patient R.B. reported feeling improved.

Patient S.D.

76. On the following occasions, Patient S.D. tested positive for THC:

a. June 19, 2012
b. October 10, 2012
c. December 13, 2012
d. January 11, 2013
e. February 8, 2013
f. March 8, 2013
g. July 12, 2013
h. August 9, 2013
i. September 9, 2013
j. October 7, 2013
k. March 18, 2014
l. April 15, 2014
m. May 14, 2014
n. August 8, 2014
o. October 7, 2014
p. December 9, 2014
q. February 6, 2015
r. March 6, 2015
s. April 29, 2015
t. June 5, 2015
u. July 1, 2015
v. July 29, 2015
w. September 29, 2015
x. December 23, 2015
y. February 24, 2016
z. March 21, 2016
aa. May 23, 2016
bb. July 20, 2016
cc. August 17, 2016
dd. September 16, 2016
ee. October 17, 2016
ff. January 13, 2017
gg. February 13, 2017
hh. March 13, 2017
ii. April 10, 2017
jj. July 5, 2017
kk. August 28, 2017
ll. September 27, 2017
mm. November 22, 2017
nn. December 19, 2017
oo. February 14, 2018
pp. March 21, 2018
qq. April 20, 2018
rr. May 21, 2018
ss. June 14, 2018
tt. August 15, 2018
uu. November 19, 2018

77. On the following three occasions, Respondent prescribed Patient S.D. methadone at 60 mg a day and oxycodone at 90 mg a day:

a. January 16, 2018
b. February 14, 2018
c. March 21, 2018

78. On the following nine occasions, Respondent prescribed Patient S.D. methadone for 90 mg a day and oxycodone for 90 mg a day:

a. April 20, 2018
b. May 18, 2018
c. June 14, 2018
d. July 18, 2018
e. August 15, 2018
f. September 18, 2018
g. October 19, 2018
h. November 19, 2018
i. January 2, 2019

79. On the following three occasions, Respondent prescribed Patient S.D. oxycodone at 90 mg a day:

a. February 4, 2019
b. March 1, 2019
c. April 2, 2019

80. On February 24, 2016, Respondent increased Patient S.D.'s methadone 10 mg prescription from 120 tablets to 180 tablets.

81. On April 20, 2018, Respondent increased Patient S.D.'s methadone 10 mg prescription from 180 tablets to 270 tablets.

Patient L.D.

82. Respondent's first documented visit with Patient L.D. occurred on June 20, 2011.

83. On Respondent's initial June 20, 2011 visit with Patient L.D., Respondent documented in Patient L.D.'s patient file that Patient L.D. was taking amphetamine.

84. During a September 23, 2011 visit, L.D. tested positive for amphetamine on a urine drug screen.

85. As of the September 23, 2011 visit, Respondent had prescribed Patient L.D. amphetamine, hydromorphone, fentanyl, and clonazepam.

86. On the following eight occasions, Respondent prescribed Patient L.D. Duragesic patches at 100 mcg per hour every two days and Dilaudid for 48 mg a day:

a. January 8, 2018
b. March 5, 2018
c. May 4, 2018
d. July 5, 2018
e. September 5, 2018
f. November 5, 2018
g. January 4, 2019
h. March 4, 2019

87. On January 16, 2012, Respondent increased Patient L.D.'s prescription for Dilaudid 8 mg from 90 tablets to 180 tablets.

88. On July 14, 2015, Respondent increased Patient L.D.'s prescription for Duragesic patches 100 mcg/hour from 10 patches (1 patch every 72 hours) to 15 patches (1 patch every 48 hours) for a thirty day supply.

89. In May and July 2014, Respondent documented in Patient L.D.'s patient file that Patient L.D. and her husband had been criminally convicted.

Patient S.H.

90. Respondent's first documented visit with Patient S.H. occurred on August 24, 2010.

91. On Respondent's visit with Patient S.H. on August 4, 2015, Patient S.H. tested positive only for oxycodone.

92. On Respondent's visit with Patient S.H. on August 4, 2015, Patient S.H. reported to Respondent that he was taking Adderall, hydromorphone, methadone, and oxycodone.

93. An X-Ray taken for Patient S.H. on October 7, 2010 reported normal results for neck and spine.

94. An MRI taken for Patient S.H. on April 26, 2011 reported normal results for the spine.

95. An MRI taken for Patient S.H. on January 17, 2012 reported normal results for the neck.

96. On the following occasions, Patient S.H. had been prescribed methadone by Respondent:

a. August 4, 2015
b. September 1, 2015
c. April 24, 2017
d. December 4, 2017

Patient J.M.

97. Respondent's first documented visit with Patient J.M. occurred on May 17, 2011.

98. On Respondent's initial visit with Patient J.M. on May 17, 2011, Patient J.M. reported to Respondent that he had difficulty getting OxyContin authorized and wanted to try oxycodone instead.

99. During a June 17, 2011 visit with Patient J.M., Respondent documented in Patient J.M.'s patient file that Patient J.M. came to the office with his mother.

100. During a June 17, 2011 visit with Patient J.M., Respondent documented in Patient J.M.'s patient file that Patient J.M. came to ''plead mercy'' and ask for a second chance at being treated.

101. During a June 17, 2011 visit with Patient J.M., Respondent issued Patient J.M. a prescription for 180 tablets of oxycodone 30 mg

102. During a June 17, 2011 visit with Patient J.M., Respondent noted in Patient J.M.'s patient file that he would give Patient J.M. ''[o]ne final chance.''

103. On the following occasions, Respondent checked the CURES database for Patient J.M.:

a. May 17, 2011
b. June 13, 2011
c. July 15, 2011
d. September 9, 2011
e. August 10, 2012
f. October 12, 2012
g. March 4, 2013
h. June 28, 2013
i. February 28, 2014
j. November 10, 2014
k. May 4, 2016
l. September 6, 2018

104. On March 23, 2012, Respondent increased Patient J.M.'s oxycodone 30 mg prescription from 180 tablets to 240 tablets.

105. On September 4, 2012, Respondent decreased Patient J.M.'s oxycodone 30 mg prescription from 240 tablets to 180 tablets.

106. On September 21, 2012, Respondent increased Patient J.M.'s oxycodone 30 mg prescription from 180 tablets to 240 tablets.

107. Between August and September 2012, Respondent increased Patient J.M.'s prescription for 90 tablets of OxyContin 60 mg to 180 tablets of OxyContin 80 mg.

108. On the following occasions, Patient J.M. tested positive for the following controlled substances in a urine drug screen:

a. July 15, 2011: benzodiazepine
b. August 12, 2011: THC
c. September 9, 2011: THC
d. December 2, 2011: THC and benzodiazepine
e. January 27, 2012: benzodiazepine
f. March 23, 2012: THC and benzodiazepine
g. May 18, 2012: THC
h. July 12, 2012: THC and benzodiazepine
i. August 10, 2012: THC
j. September 21, 2012: THC and benzodiazepine
k. November 7, 2012: THC and benzodiazepine
l. December 7, 2012: THC
m. January 7, 2013: THC
n. March 4, 2013: THC
o. March 29, 2013: THC and benzodiazepine
p. May 3, 2013: THC
q. June 28, 2013: THC
r. August 27, 2013: THC
s. November 5, 2013: THC
t. December 3, 2013: THC and benzodiazepine
u. December 27, 2013: THC and benzodiazepine
v. January 30, 2014: THC and benzodiazepine
w. February 28, 2014: THC and benzodiazepine
x. April 1, 2014: THC
y. April 30, 2014: THC and benzodiazepine
z. July 23, 2014: THC and benzodiazepine
aa. August 14, 2014: THC and benzodiazepine
bb. October 13, 2014: THC and benzodiazepine
cc. December 8, 2014: THC and benzodiazepine
dd. March 31, 2015: benzodiazepine
ee. April 29, 2015: THC
ff. June 24, 2015: benzodiazepine
gg. August 21, 2015: THC
hh. November 12, 2015: THC and benzodiazepine
ii. April 4, 2016: THC and benzodiazepine
jj. May 4, 2016: benzodiazepine
kk. September 16, 2016: THC and benzodiazepine
ll. October 13, 2016: THC and benzodiazepine
mm. December 12, 2016: benzodiazepine
nn. May 5, 2017: THC and benzodiazepine
oo. August 4, 2017: THC and benzodiazepine
pp. September 29, 2017: THC and benzodiazepine
qq. October 27, 2017: THC and benzodiazepine
rr. November 27, 2017: THC and benzodiazepine
ss. December 21, 2017: THC and benzodiazepine
tt. January 26, 2018: THC and benzodiazepine
uu. September 6, 2018: THC and benzodiazepine

109. During the periods referenced in Paragraph 108, Respondent had not prescribed Patient J.M. a benzodiazepine.

110. On a May 5, 2017 visit with Respondent, Respondent documented in Patient J.M.'s patient file that Patient J.M. had taken a ''headache pill'' from his mother.

111. On a May 5, 2017 visit with Respondent, Patient J.M. tested positive for morphine.

112. As of the May 5, 2017 visit with Respondent, Respondent had not prescribed Patient J.M. any morphine.

113. Respondent's Exhibit 1 is a true and correct copy of the New England Journal of Medicine article ''No Shortcuts to Safer Opioid Prescribing.''

114. Respondent's Exhibit 2 is a true and correct copy of an April 10, 2019 letter from the Center for Disease Control and Prevention to Dr. Alford.

115. Respondent's Exhibit 3 is a true and correct copy of a media statement from the Center for Disease Control and Prevention titled ''CDC Advises Against Misapplication of the Guidelines for Prescribing Opioids for Chronic Pain.''

116. Respondent's Exhibit 4 is a true and correct copy of the American Medical Association Resolution 235 ''Inappropriate Use of CDC Guidelines for Prescribing Opioids D–120.932.''

ALJ's Recommended Rulings, Findings of Fact, Conclusions of Law and Decision dated February 25, 2020 (hereinafter, RD), at 24–40.

The hearing in this matter was held in Los Angeles, California, and, although originally scheduled for four days, lasted five days, November 18–22, 2019. Notice of Hearing dated October 28, 2019, at 1; Transcripts Received dated November 18–22, 2019, at 1–5. The RD is dated February 25, 2020. It recommends that the three registrations at issue be suspended until August 8, 2021, ''but that . . . [the] suspensions not be lifted until . . . [Respondent] has met . . . [two] conditions.'' [2] RD, at 161. The two conditions are (1) completion of courses, other than courses used to

[2] The ALJ ''note[d] that . . . [his] Recommendation would be the same had . . . [he] sustained all of the allegations to which the Government presented expert testimony.'' RD, at 161.

meet any continuing medical education requirement, approved in advance by DEA in prescribing controlled substances and in preparing and maintaining patient medical records, and (2) submission to DEA of a signed ''consent[ ] to inspections by DEA personnel of . . . [Respondent's] medical practice without the need for DEA personnel to obtain an administrative inspection warrant prior to conducting an inspection'' that ''shall be valid for three years from the date . . . [Respondent's registrations] are restored or renewed, whichever occurs latest in time.'' [3] *Id.* The Government filed exceptions to the RD, dated March 16, 2020 (hereinafter, Govt Exceptions).

Having considered the record in its entirety, I conclude that the record establishes, by substantial evidence, that Respondent committed acts rendering his continued registration inconsistent with the public interest. I further conclude that Respondent did not unequivocally accept responsibility for the founded violations and that, even if he had, Respondent did not offer adequate remedial measures.

Accordingly, I conclude that the appropriate sanctions are (1) the revocation of BR0869719 and BA7661564, along with DATA–Waiver No. XR0869719; (2) the denial of any pending application(s) to renew or modify these registrations; (3) the denial of any other pending application(s) by Respondent or by Respondent on behalf of Aurora Surgery Center LP for registration in California; and (4) affirmance of the already issued Order of Immediate Suspension of Registrations. I make the following findings.

II. California Physicians' and Surgeons' Standard of Care

According to the Controlled Substances Act (hereinafter, CSA), ''Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to . . . distribute, . . . dispense, or possess with intent to . . . distribute[ ] or dispense, a controlled substance.'' 21 U.S.C. 841(a)(1). The CSA's implementing regulations state that a lawful controlled substance order or prescription is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a).

The OSC is addressed to Respondent at his registered medical practice in California. Therefore, I also evaluate Respondent's actions according to California law and the applicable California standard of care.[4] California, similar to the CSA, requires, during the time period at issue in this adjudication through to the present, that a ''prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.'' Cal. Health & Safety Code § 11153(a) (Effective April 4, 2011, operative Oct. 1, 2011). This statute explicitly includes two examples of prescriptions that are not legal. First, in salient part, ''an order purporting to be a prescription which is issued not in the usual course of professional treatment'' and, second, ''an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.'' *Id.* California makes the violation of this provision a criminal offense punishable by imprisonment, fine, or both. *Id.*

Other provisions of the California Code further address the characteristics of a lawful controlled substance prescription. For example, the Health and Safety Code prohibits the knowing prescribing of a controlled substance ''to or for any person'' ''[e]xcept in the regular practice of his or her profession.'' Cal. Health & Safety Code § 11154(a) (Current with urgency legislation through Ch. 145 of 2021 Reg.Sess.). Another example is a provision of the Business and Professions Code, in effect during the period of the violations alleged in the OSC, which stated that ''[p]rescribing . . . dangerous drugs . . . without an appropriate prior examination and a medical indication, constitutes unprofessional conduct.'' [5] Cal. Bus. and Prof. Code § 2242(a) (Effective Jan. 1, 2007 to Oct. 10, 2019). By way of further example, section 725(a) of the Business and Professions Code states that ''[r]epeated acts of clearly excessive prescribing . . . of drugs or treatment . . . is unprofessional conduct for a physician.'' Cal. Bus. & Prof. Code § 725(a) (Effective Jan. 1, 2008 to the present). Section 725 makes such clearly excessive prescribing a misdemeanor punishable by fine, imprisonment, or both. The provision explicitly states that a ''practitioner who has a medical basis for prescribing, furnishing, dispensing, or administering dangerous drugs or prescription controlled substances shall not be subject to disciplinary action or prosecution,'' and ''[n]o physician and surgeon shall be subject to disciplinary action pursuant to this section for treating intractable pain in compliance with section 2241.5.'' [6] *Id.*

The ''Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons'' published by the Medical Board of California (hereinafter, MBC) (7th ed. 2013) (hereinafter, MBC Guide to the Laws), informs my interpretation of these California statutes and the applicable California standard of care.[7] According to the MBC Guide to the Laws, ''[o]nly physicians . . . are authorized to write prescriptions under California law'' and ''may prescribe only in the regular practice of their profession, after an appropriate prior examination, and may not furnish any controlled substance to persons not under their care.'' MBC

[3] The RD ''further recommended that if the Administrator has not issued a Final Order . . . prior to the dates that . . . [Respondent's] current . . . [registrations] expire by their own terms, that if . . . [Respondent] has submitted renewal applications, that those renewal applications be approved[,] . . . subject [also] to the two conditions . . . and subject to the condition that . . . [Respondent] not commit any further violations of the . . . [Controlled Substances Act (hereinafter, CSA)] between now and the date of the Final Order.'' RD, at 161.

[4] *See Gonzales* v. *Oregon,* 546 U.S. 243, 269–71 (2006); *see also* OSC, at 2–3.

[5] The California statutory definition of ''dangerous drug'' includes any drug whose dispensing without a prescription is prohibited by federal law. Cal. Bus. & Prof. Code § 4022 (Effective Jan. 1, 2004 to the present).

[6] Section 2241.5 of the California Business & Professions Code, during the time at issue in this proceeding, concerned a physician's prescribing of controlled substances for the treatment of pain or a condition causing pain, including intractable pain. Cal. Bus. & Prof. Code § 2241.5(a) (Effective Jan. 1, 2007 to the present). According to that provision, ''[n]o physician . . . shall be subject to disciplinary action for prescribing dangerous drugs or prescription controlled substances in accordance with this section,'' among other things. Cal. Bus. & Prof. Code § 2241.5(b) (Effective Jan. 1, 2007 to the present). The provision explicitly excepts from its disciplinary action prohibition violations of section 2234 (regarding gross negligence, repeated negligent acts, or incompetence), section 2241 (regarding treatment of an addict), and 2242 (regarding performing an appropriate prior examination and the existence of a medical indication for prescribing dangerous drugs), among others. Cal. Bus. & Prof. Code § 2241.5(c) (Effective Jan. 1, 2007 to the present).

[7] GX 6. Respondent did not object to the admission into evidence of the MBC Guide to the Laws. Tr. 29–30. California law assigns the MBC the responsibilities of, among other things, enforcing the disciplinary and criminal provisions of the California Medical Practice Act, revoking or otherwise limiting certificates after the conclusions of disciplinary actions, reviewing the quality of medical practice carried out by physician and surgeon certificate holders under its jurisdiction, and issuing licenses and certificates under its jurisdiction. Cal. Bus. & Prof. Code § 2004 (Current with urgency legislation through Ch. 145 of 2021 Reg.Sess). Accordingly, the MBC Guide to the Laws informs my understanding of the standard of care applicable in this matter.

Guide to the Laws, at 53. The MBC Guide to the Laws explains that the ''[i]nappropriate prescribing of controlled substances, including opioids, can lead to drug abuse or diversion and can also lead to ineffective management of pain, unnecessary suffering of patients, and increased health costs.'' *Id.* at 55. It reiterates the statutory permission, *supra,* that a ''physician and surgeon . . . may prescribe for . . . a person under his or her treatment for a medical condition dangerous drugs or prescription controlled substances for the treatment of pain or a condition causing pain, including, but not limited to, intractable pain.'' *Id.* at 56.

The MBC Guide to the Laws sets out the California Medical Board's expectation that ''physicians . . . follow the standard of care in managing pain patients.'' *Id.* at 57. The MBC Guide to the Laws states that the standard of care includes the ''accomplish[ment] of a medical history and physical examination,'' meaning ''an assessment of the pain, physical and psychological function; a substance abuse history; history of prior pain treatment; an assessment of underlying or coexisting diseases or conditions and documentation of the presence of a recognized medical indication for the use of a controlled substance.'' *Id.* It explains, among other things, that the ''complexity of the history and physical examination may vary based on the practice location. . . . In continuing care situations for chronic pain management, the physician and surgeon should have a more extensive evaluation of the history, past treatment, diagnostic tests, and physical exam.'' *Id.*

The MBC Guide to the Laws discusses the treatment plan, advising that it ''should state objectives by which the treatment plan can be evaluated, such as pain relief and/or improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned.'' *Id.* It explicitly points out that ''the physician and surgeon should tailor pharmacological therapy to the individual medical needs of each patient'' and that ''[m]ultiple treatment modalities and/or a rehabilitation program may be necessary if the pain is complex or is associated with physical and psychosocial impairment.'' *Id.* The ''annotations'' associated with this section of the MBC Guide to the Laws state that ''[p]hysicians and surgeons may use control of pain, increase in function, and improved quality of life as criteria to evaluate the treatment plan'' and ''[w]hen the patient is requesting opioid medications for his or her pain and inconsistencies are identified in the history, presentation, behaviors or physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.'' *Id.*

The next section of the MBC Guide to the Laws concerns ''informed consent.'' *Id.* at 58. This section states that the ''physician and surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver, or guardian.'' *Id.* The annotation for this section states, in part, that a ''written consent or pain agreement for chronic use is not required but may make it easier for the physician and surgeon to document patient education, the treatment plan, and the informed consent.'' *Id.*

The MBC Guide to the Laws next addresses the matter of ''periodic review.'' *Id.* It makes three points. First, it states that the ''physician and surgeon should periodically review the course of pain treatment of the patient and any new information about the etiology of the pain or the patient's state of health.'' *Id.* Second, it explains that ''[c]ontinuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives.'' *Id.* Third, it elaborates by stating that, ''[i]f the patient's progress is unsatisfactory, the physician and surgeon should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.'' *Id.* Regarding the process of determining whether the response to treatment is satisfactory, the MBC Guide to the Laws states that satisfactory response to treatment ''may be indicated by the patient's decreased pain, increased level of function, or improved quality of life.'' *Id.* It also notes that physicians and surgeons ''should . . . consider[ ]'' ''[i]nformation from family members or other caregivers . . . in determining the patient's response to treatment.'' *Id.*

The next part of the MBC Guide to the Laws is about consultation. *Id.* It states that physicians and surgeons ''should consider referring the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.'' *Id.* It addresses abuse and diversion by stating that ''physicians should give special attention to those pain patients who are at risk for misusing their medications including those whose living arrangements pose a risk for medication misuse or diversion.'' *Id.* It also warns that the ''management of pain in patients with a history of substance abuse requires extra care, monitoring, documentation, and consultation with addiction medicine specialists, and may entail the use of agreements between the provider and the patient that specify the rules for medication use and consequences for misuse.'' *Id.*

The last section in this part of the MBC Guide to the Laws is entitled, ''Records.'' *Id.* at 59. It states that physicians and surgeons ''should keep accurate and complete records according to items above, including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, rationale for changes in the treatment plan or medications, agreements with the patient, and periodic reviews of the treatment plan.'' *Id.* The MBC Guide to the Laws also states that ''[t]here is not a minimum or maximum number of medications which can be prescribed to the patient under either federal or California law.'' *Id.*

In compiling the California standard of care applicable to this matter, I looked for, but did not find, any relevant exceptions to the applicable California standard of care I set out above, such as those suggested by Respondent's Case. *Infra* sections III.E. and III.F.

The record that the ALJ transmitted to me includes opposing interpretations of the applicable California standard of care. *See, e.g.,* RD, at 16–17. My adjudication of these differences begins with the appropriate scope of the testimony of the Government's expert witness, includes comparing the testimony of the parties' experts with the applicable California standard of care I set out above, and concludes with my determinations of which expert's testimony to credit. *Infra* sections III.D., III.E., and III.F.

III. Findings

A. Respondent's DEA Registrations

The parties stipulated that Respondent was registered as a practitioner in schedules II through V under DEA Certificate of Registration No. BR0869719 at 73–950 Alessandro Drive, Suite 4, Palm Desert, California 92260. Jt. Stip. Nos. 14, 16; *see also* Government Exhibit (hereinafter, GX) 1, at 3–4. The parties stipulated that Respondent was also registered as a DATA-waived (Drug Addiction Treatment Act) physician certified to treat 100 patients for substance abuse under DATA–Waiver No. XR0869719. Jt. Stip. Nos. 24–25; *see also* GX 1, at 3–

4. This registration expired on April 30, 2021. Jt. Stip. 15; GX 1, at 3–4.

The parties stipulated that Respondent operated Aurora Surgery Center LP and that Aurora Surgery Center LP was registered as a hospital/clinic in schedules II through V under DEA Certificate of Registration No. BA7661564 at 73–950 Alessandro Drive, Palm Desert, California 92260. Jt. Stip. Nos. 17–21; *see also* GX 1, at 1–2. This registration expired on June 30, 2020. Jt. Stip. 22; GX 1, at 1–2.

The OSC suspended all of these authorities. OSC, at 11. While Respondent disputes the immediate suspensions of these authorities and the allegations in the OSC, he did not submit arguments challenging the propriety of the OSC's inclusion of registration No. BA7661564 in its requested relief. *See, e.g.* Tr. 5; *id.* at 43–47; *id.* at Tr. 47–61; *supra* n.1.

B. The Investigation of Respondent

The Diversion Investigator (hereinafter, DI) began investigating Respondent in March 2018 after several databases flagged Respondent as a ''high-risk opioid prescriber.'' Tr. 27; *see also, e.g.,* Jt. Stip. Nos. 37, 40, 43, 46, 49, 52, 58–62, 76–81, 91–95, 98–102, 104, 106–112. The DI's investigative work regarding Respondent, among other things, showed a ''high volume of [opioid] prescriptions, in the thousands, . . . at maximum dosages with little or no change and several months at a time[,] . . . a lot of drug combinations, opioids with benzodiazepines and opioids with stimulants[, and] . . . the holy trinity of an opioid, . . . a muscle relaxer and a benzodiazepine.'' Tr. 33. The DI testified that ''those stood out immediately. . . . [T]hose are the things that we've been trained to look for in analyzing . . . possible diversion or misuse of controlled substances.'' *Id.*

C. The Allegations of Dispensing Violations [8]

Citing 21 U.S.C. 824(a)(4) and 823(f)(2) and (4), the OSC alleges that Respondent's continued registration is inconsistent with the public interest due to his having issued multiple controlled substance prescriptions outside the usual course of professional practice and without any legitimate medical purpose. OSC, at 2, 3, 10. As already discussed, the parties agreed to and submitted 116 joint stipulations. *Supra* section I. Accordingly, there is factual agreement on a significant number of matters.[9] When there is legally relevant factual disagreement, my resolution of the disagreement involves the applicable law and my credibility assessments.

D. The Government's Case

The Government stated its case as being that Respondent ''churn[ed] out dangerously high dosages of controlled substances month after month without any medical justification.'' Government's Proposed Findings of Fact and Conclusions of Law dated January 24, 2020 (hereinafter, Govt Posthearing), at 1. The Government's arguments include that Respondent prescribed dangerously high dosages of controlled substances for years without performing initial physical examinations and evaluations, without performing periodic urine drug screens (hereinafter, UDSes), without addressing aberrant UDSes, without justifying increased dosages, without justifying dangerous controlled substance combination prescribing, and without adequately resolving indicia of abuse and diversion. *Id.* The Government presented its case with two witness, the DI and its expert witness, Timothy Munzing, M.D., and with about 1,750 pages from Respondent's medical records. *See id.* at 43. According to the Government, Respondent's ''insistence that he simply did not document his reasoning or actions was not credible,'' his ''recollection was faulty,'' he ''essentially admitted that he knew and was okay with his patient's drug abuse,'' and was ''nowhere near contrite.'' *Id.* at 1.

Regarding its expert, the Government offered Dr. Munzing ''as a medical expert in the treatment of pain with controlled substances in the State of California.'' Tr. 68. According to the RD, Dr. Munzing ''is not listed as a pain specialist'' on Kaiser's roster of pain specialists, ''does not have fellowship training in pain management,'' and was accepted ''as a medical expert in the treatment of pain with controlled substances in the State of California'' over Respondent's objection. RD, at 12. According to the RD's third footnote, ''[s]ignificantly, Dr. Munzing was not proffered as an expert in the standard of care in California, or as an expert concerning the usual course of professional practice in California.'' *Id.* at 12, n.3; *see also id.* at 13 (''Although not proffered as an expert in such, Dr. Munzing provided extensive testimony in general terms about the standard of care in California.''); *id.* at 17 (''I find Dr. Munzing's testimony concerning the general standard of care to be credible. Since he was not proffered as an expert in the standard of care in California, or in the usual course of professional practice in California, I give limited weight to that testimony.''). The RD's third footnote also records the ALJ's awareness that the ''Acting Administrator previously accepted Dr. Munzing as an 'expert in standard of care for prescribing controlled substances in California,' in a previously published Agency decision.'' *Id.* at 12, n.3. The footnote elaborates by stating that ''[t]here was no hearing in that case, however, and the Acting Administrator relied on Dr. Munzing's declaration, with no expert evidence presented by the respondent.'' *Id.*

As the RD also notes, Respondent objected to the Government's proffer of Dr. Munzing and the ALJ determined that Respondent wanted to voir dire Dr. Munzing. Tr. 68. Voir dire ensued.[10] *Id.* at 69–83. Respondent's voir dire addressed Dr. Munzing's exposure to, and knowledge of, the applicable standard of care. *See, e.g., id.* at 71 (Respondent during voir dire: ''Now you mentioned that you took a couple of courses on pain management and that's how you began to get your exposure to pain . . . standards of care?''); *id.* at 72 (Dr. Munzing during voir dire: ''I am considered to be a specialist in the prescribing of opiates as far as for pain.''); *id.* at 81 (Respondent during voir dire: ''Do you believe as a physician . . . that a physician who's treating 30 patients for a particular condition over

[8] ''Dispense,'' among other things, means ''to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing . . . of a controlled substance.'' 21 U.S.C. 802(10).

[9] Although he stated that he ''would normally accept stipulations between the parties without question,'' the ALJ ''cannot accept'' Stipulation 52j because ''[a]ll parties apparently missed the fact that the actual prescription for alprazolam in September 2018, that is contained in the administrative record, was [not] written by . . . [Respondent]. RD, at 148. I agree with the ALJ, although I note that Stipulation 52j is irrelevant to my Decision/Order given the magnitude and seriousness of the unlawful controlled substance prescribing evidenced elsewhere in the record.

[10] During Dr. Munzing's direct testimony and during Respondent's cross examination of Dr. Munzing, Respondent moved to strike portions of Dr. Munzing's testimony. I do not always agree with the ALJ's decisions to sustain Respondent's objections and to strike Dr. Munzing's testimony. *See, e.g.,* Tr. 305–06 (Respondent's interruption of Dr. Munzing's response to Respondent's question with his motion to strike Dr. Munzing's in-process answer as non-responsive and the ALJ sustaining the motion); *id.* at 384–85; *id.* at 562–63; *but see id.* at 387–88. Other times, I agree with the ALJ's handling of Respondent's motions to strike Dr. Munzing's testimony. *See, e.g. id.* at 334–35 (ALJ's second and third rulings during a line of questioning denying motions to strike because the ALJ ''ha[s]n't heard the rest of the answer yet'' and because the ALJ ''think[s] it's not as responsive as . . . [Respondent] wanted''). To benefit Respondent, despite my disagreement, I accept all of the ALJ's rulings on Respondent's objections and I do not consider any of Dr. Munzing's stricken testimony in my Decision/Order.

10 years and a patient [sic] who has treated 3,000 patients, that the person who treated the 3,000 patients might have a better understanding of the medications and the impacts and the standard of care?''). After the conclusion of Respondent's voir dire, the Government again offered Dr. Munzing ''as an expert on the treatment of pain with controlled substances in California.'' *Id.* at 83. The ALJ ruled immediately, stating that he ''recognize[d] Dr. Munzing as an expert, relying upon the *Gonzalez* case, 76 FR [63118], a 2011 case from DEA'' and ordered the Government to proceed with questioning. *Id.* at 83–84. I find substantial evidence in Respondent's voir dire of Dr. Munzing that it was clear to Respondent that the Government was offering Dr. Munzing as an expert in the applicable standard of care.[11]

While the RD finds ''Dr. Munzing's testimony to be thorough, detailed, and internally consistent,'' it is also critical of it and lists ''several aspects'' of Dr. Munzing's ''testimony and qualifications'' that ''detract from his overall credibility.'' RD, at 14; *see also id.* at 15–17. For example, the RD states that Dr. Munzing ''was going out of his way to assist the Government in presenting its case,'' ''was not simply stating his professional expert opinion in an unbiased manner,'' ''refused to concede rather obvious points,'' ''frequently volunteered testimony beyond a pending question, testimony beneficial to the Government . . . [that] was distracting and unnecessarily extended the hearing,'' and ''did not seem as familiar with the facts or the law as he should have been as an expert witness.'' *Id.* at 14–16.

I do not share all of the RD's perspectives and conclusions about Dr. Munzing.[12] Regarding the ''rather obvious points'' that the RD states Dr. Munzing ''refused to concede,'' the RD cites Dr. Munzing's refusal to state that Respondent ''had more experience treating chronic pain patients than he did.'' *Id.* The RD correctly characterizes Dr. Munzing's testimony to be that Respondent ''may have more experience in the procedural end of it, but 'in the area of appropriate pain management, I, not sure I would say that.' '' *Id.* The RD criticizes Dr. Munzing by stating that ''the questions asked nothing about appropriate care.'' [13] *Id.*

By way of further example, the RD states that, ''when asked the general question of whether a doctor [Respondent] who had treated 3,000 patients for a particular condition might have a better understanding of how to treat those patients than a doctor who had only treated 30, Dr. Munzing would not agree.'' *Id.* at 14–15. ''Rather,'' the RD criticizes Dr. Munzing, stating ''he answered another question. 'Having reviewed some of those patients I have great concern . . . .' It was a general question, but even during voir dire Dr. Munzing was testifying about how bad of a doctor he believed . . . [Respondent] to be.'' [14] *Id.* at 15.

I do not share these RD criticisms. For example, when Respondent asked Dr. Munzing whether Respondent ''has significantly more experience treating chronic pain patients than you do,'' Dr. Munzing's response agreed, in part, when he said that Respondent did have more experience ''especially in the procedural end of it.'' Tr. 80. I credit Dr. Munzing because he gave an honest answer, even admitting the dearth of his experience ''in the procedural end of it.'' *Id.* In the context of this proceeding, I further note Dr. Munzing's obvious appreciation that my responsibilities under the CSA do not call for me to rubber stamp a registrant's controlled substance prescribing based on the ''significantly more experience'' he might have ''treating chronic pain patients than'' the Government's expert witness. *Id.* Instead, Dr. Munzing's responses to Respondent's voir dire show me that Dr. Munzing knows to distinguish between the number of individuals a registrant has seen in his practice and the registrant's compliance with the applicable standard of care when ''treating'' those individuals. *See id.*

As already discussed, when the ALJ recognized Dr. Munzing as an expert, he stated that he was doing so ''relying upon the *Gonzalez* case.'' [15] *Id.* at 84. He did not, however, identify the relevant portion of *Gonzalez* upon which he was relying. *Id.* My review of the Chief ALJ's (adopted) Recommended Decision in *Gonzalez,* as I endeavor to understand the ALJ's thought process, indicates that

[11] *See also United States* v. *Diaz,* 876 F.3d 1194, 1199 (9th Cir. 2017) (citing *United States* v. *Chube,* 538 F.3d 693, 698 (7th Cir. 2008) (''When all is said and done, we agree with the Government that it is impossible sensibly to discuss the question whether a physician was acting outside the usual course of professional practice and without a legitimate medical purpose without mentioning the usual standard of care.'')).

[12] Regarding ''not seem[ing] as familiar with the facts or the law as he should have been as an expert witness,'' the RD states ''[f]or example, Dr. Munzing relied on the . . . [Centers for Disease Control and Prevention's Guideline for Prescribing Opioids for Chronic Pain—United States (2016) (hereinafter, CDC Guidelines)] when formulating his opinions in this case'' and ''[i]t is obvious that he did not learn that those Guidelines did not apply to . . . [Respondent] until after he began to testify.'' RD, at 16. On these points, I note several occasions during voir dire when Dr. Munzing provided his view of the CDC Guidelines, Respondent objected as ''not responsive,'' and the ALJ sustained the objection. For example, on voir dire, Respondent asked Dr. Munzing: ''With respect to the CDC guidelines, is it your opinion they apply to pain specialists or not?'' Tr. 82. Dr. Munzing responded by stating that ''these are guidelines. These are not required. But the general principles, I think, are good principles for everyone who is prescribing controlled substances. Again, they're not required.'' *Id.* When Respondent moved to strike ''as not responsive,'' the ALJ sustained his motion. *Id.; see also id.* at 77 (Respondent's questioning of Dr. Munging: ''Q: Are you aware that the CDC guidelines in 2016 applied to primary care and to family medicine but are not intended to apply to pain specialists? A: Well, the CDC guidelines are guidelines strictly. They're not standard of care. And so the intent is to protect patients and patient safety.'' Respondent: ''Move to strike as not responsive, Your Honor. Judge Dorman: Granted.''). These struck responses of Dr. Munzing concerning the CDC Guidelines do state that the CDC Guidelines are not the standard of care, that there is no requirement for Respondent to have followed them, and, nevertheless, that they are ''good principles'' commended to ''everyone who is prescribing controlled substances.'' *Id.* at 77, 82. Accordingly, I disagree with the RD that Dr. Munzing is ''not . . . as familiar with the facts or the law as he should have been as an expert witness,'' impacting Dr. Munzing's ''overall credibility.'' RD, at 16; *see also, e.g.,* Tr. 532 (Dr. Munzing's testimony that his opinion does not depend on the strict application of the CDC guidelines); *id.* at 533 (Dr. Munzing's testimony that CDC is only one of many entities that issue controlled substance related guidelines, along with the American Academy of Pain Medicine, the American Pain Society, and the Agency Directors in Washington, and noting that only one aspect of his report dealt with the CDC's perspective on Morphine Milligram Equivalents).

[13] I note that ''appropriate pain management'' and ''appropriate care'' are relevant to my adjudication of the OSC.

[14] The question Respondent asked that the RD quotes Dr. Munzing as answering was: ''Do you believe as a physician that a patient—that a physician who's treating 30 patients for a particular condition over 10 years and a patient [sic] who has treated 3,000 patients, that the person who treated the 3,000 patients might have a better understanding of the medications and the impacts and the standard of care?'' Tr. 81. In other words, contrary to what the RD suggests, Respondent *did ask* Dr. Munzing about Respondent's ''understanding of . . . the standard of care,'' as well as Respondent's ''understanding of'' controlled substances and the impact of controlled substances. *Id.* According to the transcript, I also note, Dr. Munzing did *not* state that he treated ''30 patients for a particular condition over 10 years.'' Instead, after Respondent asked Dr. Munzing, ''Since 2011, approximately how many patients have you managed for chronic pain,'' Dr. Munzing responded ''[p]robably in the neighborhood of 30 to 50 *on an ongoing basis.*'' *Id.* at 71. Respondent followed up, asking, ''With respect to, *I think you said between 30 and 50 patients total that you've managed in the last 10 years with chronic pain,* what percentage of those were you prescribing medications to?'' *Id.* at 72 (emphasis added). Dr. Munzing responded that, ''I should probably rephrase that, is [sic] those are the ones who probably were being prescribed probably about 30 opiates on an ongoing basis. If you want to know total patients with chronic pain at any time, that would be hundreds.'' *Id.*

[15] In *Carlos Gonzalez, M.D.,* 76 FR 63118 (2011), the then-Administrator adopted the Recommended Decision of the Chief Administrative Law Judge, John J. Mulrooney, II, ''except as discussed below.'' 76 FR at 63118.

the Government expert ''was offered and accepted as an expert in the area of pain management.'' 76 FR at 63125. I note that the Government, in this matter, similarly offered Dr. Munzing ''as an expert in the treatment of pain with controlled substances in California.'' Tr. 68.

In *Gonzalez,* the Chief ALJ criticized the report of the Government's expert witness as being ''confusing and singularly unhelpful,'' and ''disorganized, unfocused, and written in a manner that bespeaks a free association narration of documents and other items provided to him by the Government in no particular order.'' 76 FR at 63125. The Chief ALJ was also critical that the Government's expert in *Gonzalez* was ''asked to review a mass of paper wherein patient charts that were eventually properly admitted into evidence are interspersed with DEA investigative reports and other documents that were not.'' *Id.* The RD in this matter gives no indication that the ALJ has these, or similar, criticisms.

At the same time, the Chief ALJ's (adopted) Recommended Decision in *Gonzales* attributes to the Government's expert witness, and relies on, input regarding the applicable standard of care and whether the respondent prescribed and dispensed controlled substances other than for a legitimate medical purpose or outside the usual course of professional practice. *See, e.g.,* 76 FR at 63145–46 (''The uncontroverted and persuasive testimony of the Government's expert . . . established, by a preponderance of the evidence, that the Respondent's prescribing practices fell well below the applicable standard in Florida regarding the controlled substances prescribed and dispensed to the undercover agents, as well as to the patients whose charts he reviewed. On this record, the Government has established that the Respondent employed his . . . [registration] and/or allowed/enabled others to do so in a manner where controlled substances were prescribed and dispensed for other than a legitimate medical purpose or outside the usual course of professional practice, based on the absence of acceptable physician-patient relationships and even minimal due care in documentation as those concepts are dealt with under federal and Florida state law.''). In other words, despite concerning issues, such as with the expert's report, the Chief ALJ, in *Gonzalez,* credited the testimony of the Government's expert witness in his (adopted) Recommended Decision.

In sum, the meaning of the ALJ's statement, that he admitted Dr. Munzing as an expert witness ''relying upon the *Gonzalez* case,'' is not apparent from the RD. It is clear, though, that the words the Government used at this and the *Gonzalez* hearings to proffer its expert witnesses are strikingly similar. It is also clear that the Chief ALJ relied on the testimony of the Government's expert witness in *Gonzalez* about the applicable standard of care, respondent's compliance with the applicable standard of care, and whether respondent's controlled substance prescribing and dispensing were for other than a legitimate medical purpose or outside the usual course of professional practice. *Supra.* The RD's third footnote and other statements about the scope of Dr. Munzing's proffered expertise, therefore, do not appear to be consistent with the ALJ's reliance on *Gonzalez* when accepting Dr. Munzing as an expert witness.[16] *Supra.* I conclude and find, including based on the Government's proffer of Dr. Munzing as ''an expert in the treatment of pain with controlled substances in California'' and on the ALJ's identification of *Gonzalez,* that the appropriate scope of Dr. Munzing's expert witness testimony includes the applicable standard of care for Respondent's controlled substance prescribing in California, whether Respondent's controlled substance prescribing complied with the applicable standard of care, and whether Respondent's controlled substance prescribing was outside the usual course of professional practice.

The RD further minimizes Dr. Munzing as an expert witness by concluding that the ''expert qualifications'' of Respondent's expert witness, Dr. Standiford Helm, II, are ''superior qualifications to testify concerning pain management'' and that, ''[i]n fact, . . . [Respondent's] credentials, based upon experience and training, surpass Dr. Munzing's credentials with respect to pain management.'' RD, at 16. The RD, adding the ''standard of care'' to these ''pain management'' conclusions, then states that, ''Thus, on issues of pain management, and the standard of care concerning pain patients, I will give greater weight to the testimonies of Dr. Helm and to that of . . . [Respondent]'' than to Dr. Munzing.[17] *Id.* at 16–17. Based on my analysis of the applicable standard of care, *supra,* and my review of the entire record transmitted to me, I reach a different conclusion.

My responsibilities under the CSA and the content of the OSC issued to Respondent mean that the focuses of my adjudication of this matter include the applicable standard of care for controlled substance prescribing, whether Respondent issued controlled substance prescriptions in compliance with the applicable standard of care, and whether Respondent issued controlled substance prescriptions outside the usual course of professional practice. While the experience of an expert is important in my assessment of the weight to give the expert's testimony, the reliability of that testimony is paramount. According to the Supreme Court, evidence and expert testimony must '' 'assist the trier of fact to understand the evidence or to determine a fact in issue.' This condition goes primarily to relevance,'' and ''any and all scientific testimony or evidence admitted . . . [must] not only [be] relevant, but reliable.'' *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579, 589, 591 (1993). In assessing reliability, an expert's experience, standing alone, is not a sufficient foundation for rendering reliable *any* conceivable opinion an expert may express. *See, e.g., United States* v. *Frazier,* 387 F.3d 1244, 1261 (11th Cir. 2004). Further, an expert's overwhelming qualifications may bear on the reliability of his testimony, but they are by no means a guarantor of reliability. *See, e.g., Quiet Technology DC–8, Inc.* v. *Hurel-Dubois UK Ltd.,* 326 F.3d 1333, 1341 (11th Cir. 2003). Accordingly, I use ''what is known,'' in this situation, the applicable standard of care drawn from California law and issuances of the MBC, *supra* section II, to evaluate the reliability of the record expert witness testimony, not merely each expert's experience and training. *See, e.g., United States* v. *Frazier,* 387 F.3d at 1261.

Dr. Munzing testified that the MBC Guide to the Laws ''informed . . . [his] opinion on what the standard of care is in California and what is done in the usual course of professional practice.''

[16] In addition, I note that the ALJ explicitly allowed Dr. Munzing to give his opinion about the standard of care and the usual course of professional practice, without raising the scope of Dr. Munzing's expert testimony. *See, e.g.,* Tr. 206 (ALJ overruling Respondent's ''vague and ambiguous as to time, and asked and answered'' objection to the Government's question to Dr. Munzing of whether ''[i]n . . . [his] opinion, did that combination of prescriptions [methadone, Roxicodone, and Soma] issued by . . . [Respondent] meet the standard of care or was issued in the usual course of professional practice?'').

[17] The RD continues, ''[t]hat being said, I find Dr. Munzing's testimony concerning the general standard of care to be credible. Since he was not proffered as an expert in the standard of care in California, or in the usual course of professional practice in California, I give limited weight to that testimony.'' RD, at 17.

Tr. 85. He also testified that the ''main categories'' of the MBC Guide to the Laws are ''very consistent with the general practice of medicine . . . even though the fine details may pertain to controlled substances.'' *Id.* at 87–88. Dr. Munzing testified about the main categories of the applicable standard of care as addressed in the MBC Guide to the Laws and the ''fine details.'' *Id.* at 528 (Dr. Munzing's testimony identifying history, physical examination, evaluation, minimizing risk, and the dangers of combination of medicines); *see also, e.g., id.* at 87–89 (Dr. Munzing specifically agreeing with the Annotation in the MBC Guide to the Laws that ''[i]n continuing care situations for chronic pain management, the physician and surgeon should have a more extensive evaluation of the history, past treatment, diagnostic tests and physical exam'').[18]

Dr. Munzing's testimony in response to questions about whether the applicable standard of care or the usual course of professional practice in California for the treatment of pain with controlled substances depends on the specialty of the prescribing physician is consistent with the MBC Guide to the Laws.[19] Dr. Munzing testified that the applicable standard of care and usual course of professional practice in California apply equally to any physician prescribing controlled substances for chronic pain over a long period of time regardless of the physician's specialty. *Id.* at 123–25. He specifically testified that ''taking history, do[ing] an exam, trying to mitigate risk, informed consent, those key aspects are really whether you're in family medicine, internal medicine, pain management, whoever is doing that, whoever's prescribing those medications.'' *Id.* at 124; *see also id.* at 124–25 (''[W]hen I'm working hand in hand with our pain management specialist, . . . we basically are following the same standards.''); *id.* at 528 (Dr. Munzing's testimony that the basic elements of the applicable standard of care are the same regardless of prescriber's medical specialty).

Dr. Munzing testified that the applicable standard of care addresses taking history, doing a physical examination, developing a treatment plan and objectives, obtaining informed consent, conducting periodic reviews, consulting, and record documentation. *Id.* at 531, citing MBC Guide to the Laws, at 57–61; *see also* Tr. 575–80 (Dr. Munzing responding to the ALJ's questions about what a doctor is required to do when issuing a new controlled substance prescription and what, if anything, a doctor is required to document when increasing the strength or the quantity of a previously prescribed controlled substance).

Regarding the applicable standard of care first prong of ''History/Physical Examination,'' Dr. Munzing's testimony tracked and elaborated on the MBC Guide to the Laws. He testified that ''certainly one would do a general exam looking at are the medications affecting you in general,'' specifically mentioning an exam of the heart and lung. Tr. 361. Regarding the specifics of the musculoskeletal exam, Dr. Munzing testified that the physician looks at the patient ''at rest and seeing certain movement, flexion, extension, lateral extension, rotation, straight leg raising test.'' *Id.* Dr. Munzing testified that neurological function is also part of the requisite examination to inform the physician about how the patient is doing, specifically mentioning sensory motor and deep tendon reflexes. *Id.* Dr. Munzing specifically testified that part of the physician's physical examination is ''actually touch[ing]'' the patient to discern abnormalities and areas of tenderness, and the change in those abnormalities and tender areas over time. *Id.* at 362. I find that Dr. Munzing's testimony is consistent with, and usefully and helpfully elaborates on, the ''History/Physical Examination'' section of the MBC Guide to the Laws. MBC Guide to the Laws, at 59.

Regarding the applicable standard of care third prong of Informed Consent, Dr. Munzing explained that ''for most of us, the most dangerous thing that we do is write a prescription for a controlled substance.'' Tr. 89. He testified that ''consistent with the practice of medicine, . . . we need to inform the patient about . . . the potential risks, the potential benefits, the alternatives.'' *Id.* at 89–90. He stated that, for controlled substances, an informed consent includes why the controlled substance is being prescribed, what the potential risks are, what the side effects, from mild to addiction, overdose, and death, could include, and that there are potential complications. *Id.* at 90–91. Dr. Munzing also testified that it is insufficient only to give a patient a document that says these are the potential hazards or benefits and risks of taking this particular drug and to maintain that document in the medical record. *Id.* at 596 (Dr. Munzing's testimony that if a doctor documents that he gave the patient the informed consent and they discussed it, that ''shows that you actually did that rather than someone at the front desk just saying sign this, it's one of 10 forms you find when you come to the office'' and the doctor need not write down everything discussed).[20]

Dr. Munzing testified about the fourth prong of the applicable standard of care, Periodic Review, describing it as how to see ''whether or not . . . our [chronic pain] management [is] working . . .[,] [a]re they getting better?'' *Id.* at 91. He explained that the Periodic Review involves determining whether there are ways to decrease pain, to improve function, to mitigate the risk, and to assess compliance. *Id.* He also testified that urine drug tests and checking CURES are part of Periodic Reviews. *Id.* When the pain improves, Dr. Munzing testified, ''many times we can then, and really should, try to decrease the risk by decreasing the medication and looking for safer alternatives.'' *Id.*

Regarding the meaning of the fifth prong of the applicable standard of care,

[18] Dr. Munzing defined ''chronic pain'' as ''probably over three months in nature . . . [although] [s]ome may use a shorter time frame or longer, but . . . three months is a time frame that many people will utilize. And so acute pain is what suddenly happens. It usually gets better, but sometimes it reverts into an ongoing, . . . chronic pain, and that's for a longer period of time.'' Tr. 89.

[19] The Medical Board of California ''expects *physicians and surgeons* to follow the standard of care in managing pain patients.'' MBC Guide to the Laws, at 59 (emphases added). I see nothing in the MBC Guide to the Laws that states, allows, or suggests a different application of its contents based on the prescriber's medical specialty.

In the second annotation to the section entitled ''History/Physical Examination,'' the MBC Guide to the Laws notes a differentiation based on where the medical treatment is provided. *Id.* That differentiation concerns the complexity of the history and physical examination ''based on the practice *location,*'' not based on the specialty of the physician or surgeon. *Id.* (emphasis added). ''In the emergency department, the operating room, at night or on the week-ends,'' the MBC Guide to the Laws states, ''the physician and surgeon may not always be able to verify the patient's history and past medical treatment.'' *Id.* This annotation in the MBC Guide to the Laws elaborates, without making a distinction based on the specialty of the treating physician/surgeon, stating ''[i]n continuing care situations for chronic pain management, the physician and surgeon should have a more extensive evaluation of the history, past treatment, diagnostic tests, and physical exam.'' *Id.; see also supra* section II.

[20] When the ALJ asked Dr. Munzing whether, if a doctor fails to document informed consent to a controlled substance prescription, that prescription is issued outside the usual course of professional practice and for no legitimate medical purpose, Dr. Munzing responded that he ''would say that if that's the only thing that's missing, . . . [he] would probably not call it outside—. . . [he] would be concerned, but . . [he] wouldn't strictly—and also it depends on the dosages. . . . [I]f we're on huge amounts, then yes. . . . [I]f we're on large amounts, combination, things like that, but if someone is on again, hydrocodone five milligrams twice a day, no, I wouldn't say that if everything else looks fine, but if you're on high dosages, which are defined whether it be 90, 120, 200, if you're on dangerous combinations, then yes, you must have, like anything else that is potentially hazardous, even taking off a mole off your arm which is pretty minimal, you must have some informed consent.'' Tr. 594–95.

Consultation, Dr. Munzing's testimony described it as ''if people are not getting better . . . or they're getting worse,'' then there is a consultation with the appropriate specialist. *Id.* at 92–93. In addition to giving examples of a need for a cardiology, pain management, and interventionalist consultation, he testified that ''it may very well be an addiction medicine specialist to see whether or not they feel there's evidence that this person may have, in addition to a pain issue, . . . an opioid use disorder or addictive . . . issue.'' *Id.* at 93. Concerning the ''special attention'' called for by the Consultation prong of the applicable standard of care ''to those pain patients who are at risk for misusing their medications including those whose living arrangements pose a risk for medication misuse or diversion,'' Dr. Munzing testified that ''[w]hen you're looking at patients, you also have to look at their social situation and who they're living with or they're being around.'' *Id.* He elaborated by testifying that there are ''certain situations where someone may be at risk for having medications stolen . . . whether it be family members or someone in their social milieu.'' *Id.* Dr. Munzing further elaborated by stating that being around ''people who potentially have legal issues, unless you know the specifics, it may be that they may be congregating with people who are putting the medications at higher risk for being diverted from a legitimate to an illegitimate basis.'' *Id.* at 93–94.

Concerning records, the sixth prong of the applicable standard of care, Dr. Munzing testified that ''[i]t's vitally important to have accurate, complete medical records.'' *Id.* at 115. ''This is not an area where you want to skimp,'' he stated. *Id.* Specifically, according to Dr. Munzing, ''at every visit one needs to make sure that they document what they do and don't document things that weren't done.'' [21] *Id.* Dr. Munzing highlighted two areas for medical record documentation. First, he testified that ''it's important to document what you do when you have that variances [sic] to explain those so people can look at it and go, okay, the doctor paid attention to it, whether it be an abnormal lab test, imaging test, urine drug test, CURES that doesn't look right, and so the doctor paid attention to it, addressed it.'' *Id.* Second, Dr. Munzing identified addressing the pain management plan and the management of the patient in the records, testifying that the records need to show that the physician is ''not just throwing [a] controlled substance at it but in the great scheme of things and making efforts to try to mitigate the risk . . . making attempts to try to bring down the medications whenever possible and reduce the potential interactions between opiates and other medications.'' *Id.* at 115–16.

Dr. Munzing testified about the medical care Respondent provided, and controlled substance prescriptions Respondent issued to, A.A., R.B., S.D., L.D., S.H., and J.M. *Id.* at 125–301). He testified about why the applicable standard of care requires physicians to reduce the daily morphine milligram equivalents (hereinafter, MME) they prescribe.[22] *Id.* at 113. He framed his testimony by stating that physicians ''take care of patients for all kinds of issues that are inherently dangerous, and constantly look[ ] at how can we minimize and reduce the risk to the patient.'' [23] *Id.* at 112. He stated that ''really . . . there is no safe, inherent safe dosage in opiate.'' *Id.* at 119. Dr. Munzing cited studies showing that opiates, ''even at the level of 50 . . . [MME/day, increase] the risk for overdose and death.'' *Id.* at 113. He continued his testimony by stating that ''[o]nce you get to 100 [MME/day], it goes up even farther. It's approximately 8.9 times more risky for overdose than someone who is on a very low dosage.'' *Id.; see also id.* at 120 (Dr. Munzing's testimony that ''[s]tudies have shown that when you go over 120, the risk of developing opiate abuse or opiate use disorder goes up . . .[,] [t]he numbers are as high as 20 to 30 percent over that amount''). Dr. Munzing testified that the applicable standard of care ''requires that we try to mitigate the risk any way possible.'' *Id.* He testified that there are patients for whom opiates cannot be reduced and that there are patients who are ''optimized'' at a low dosage that is ''not a very dangerous level, and so it may be that you continue.'' *Id.* ''But,'' Dr. Munzing testified, ''when someone's on the higher end, probably, you know, somewhere over 100, 120, 150 . . . [MME/day], if there are ways we can bring them down, you're greatly benefitting them because they are in the higher risk kind of category.'' [24] *Id.* at 114; *see also id.* at 807–10 (Dr. Helm's testimony that he thinks it is ''obvious'' that higher doses of controlled substances carry higher risk and that, if a physician is going to prescribe high doses, the physician has ''got to document why these doses are appropriate'').

Similarly, Dr. Munzing also testified about how, consistent with the applicable standard of care and the usual course of professional practice, a physician increases the dosage of a controlled substance. *Id.* at 91–92. According to Dr. Munzing, a physician would increase the dosage of a controlled substance due to ''continued symptoms and . . . potentially worsening symptoms.'' *Id.* at 92. Before increasing the dosage of a controlled substance, the applicable standard of care calls for an updated history to determine, for example, whether there was a sudden injury or accident, and an evaluation of the severity of the associated symptoms, for example, determining whether there are neurological and other symptoms. *Id.* Following the applicable standard of

[21] Dr. Munzing testified that, with electronic medical records, ''it's sometimes easy to get things in the records that didn't really happen.'' Tr. 115.

[22] Dr. Munzing also testified that there is no ''maximum MME . . . that a physician can no longer prescribe,'' that ''there are medically necessary reasons for why a physician might prescribe more than 90 MME to treat pain,'' but that ''[n]inety is certainly recognizing that the risks kind of continue going up, and so one constantly needs to look at the potential risks and potential benefits.'' Tr. 118–19.

[23] A non-controlled substance example that Dr. Munzing offered is the use of chemotherapy. Tr. 113. While chemotherapy has risks, he stated, it is given to cancer patients. *Id.* As soon as possible, he added, the patient is taken off chemotherapy to discontinue those risks. *Id.* ''[S]o that really pertains to medicine in general, not only to controlled substances,'' Dr. Munzing testified. *Id.*

[24] The Government asked Dr. Munzing whether ''Calculating Total Daily Dose of Opioids for Safer Dosage,'' GX 8, a two-page CDC document, ''inform[ed] . . . [his] opinion on what the standard of care is for what physicians should do in the usual course of professional practice in California.'' Tr. 116. Dr. Munzing answered that ''I don't know that this document does, but the general concepts do because they're consistent with a lot of other—the CDC guidelines and others. And so I don't know that this sheet of paper did, but the concepts certainly do.'' *Id.* This and other testimony show that Dr. Munzing familiarizes himself with relevant published literature and uses material in that literature that is consistent with the applicable standard of care to assist his implementation of the applicable standard of care. *See, e.g., id.* at 110 (Dr. Munzing's testimony referring to published literature, in this instance, about the frequency of conducting UDSes based on the dosage of the prescribed controlled substance); *id.* at 112–13 (Dr. Munzing's reference to studies showing that opiates increase the risk for overdose and death and that twice the MME per day of those opiates increases that risk about 8.9 times); *id.* at 113–14 (Dr. Munzing's reference to two entities' definitions of ''high'' opiate ranges, analysis of those ranges, and use of that authoritative input to implement the applicable standard of care to reduce the risk to, and benefit, patients); *id.* at 119–20 (Dr. Munzing's reference to organizations and agencies that are now recommending more frequent urine drug tests when high dosages of opiates are being prescribed); *id.* at 335. Dr. Munzing's practice of familiarizing himself with relevant published literature and using material in that literature that is consistent with the applicable standard of care to assist his implementation of that standard of care contributes to the value of his testimony to my adjudication of the OSC. Accordingly, as already discussed, I disagree with the RD's conclusion that Dr. Munzing ''did not seem as familiar with the facts or the law as he should have been as an expert witness,'' citing, as an example, Dr. Munzing's statements about the CDC Guidelines. RD, at 16.

care, the physician would do a thorough exam of the pained area, which may or may not call for imaging and laboratory testing. *Id.* According to Dr. Munzing, under the applicable standard of care, the physician is ''to determine that what . . . [the physician is] doing needs to be increased[, to] weigh that with the increased risk or potential risk . . . [to] the patient, . . . typically looking at kind of a multidisciplinary, multimodal way of managing[, and to determine] are there safer alternatives that we can bring in, whether it be physical therapy or others, that might be of benefit that may be safer.'' *Id.* Dr. Munzing also stated that ''certainly, when you go over 90 [MME], one needs to make it clear to the patient that . . . the risk . . . is higher and so, again, the informed consent.'' *Id.* at 119.

Regarding monitoring, given the increased risk that increased MME may lead to opiate abuse or opioid use disorder, Dr. Munzing testified about the physician's continuing need to look for whether there is ''any evidence that there's any opioid abuse going on, addiction going on.'' *Id.* at 120. ''[S]o,'' he stated, ''it's more intense monitoring once you're over'' 120 MME. *Id.* Referencing ''a number of organizations and agencies . . . [that] are recommending more frequent urine drug tests,'' Dr. Munzing's testimony stated that ''monitoring . . . [patients] more closely . . . , seeing them more frequently, urine drug tests more frequently, checking CURES or the PDMPs more frequently to ensure that they're actually complying with what you're doing.'' [25] *Id.* at 119–20. Dr. Munzing stated that there are patients who ''desperately need'' high dosages of opioids, ''but one would want to ensure that they're in full compliance with what you're prescribing and that you're benefitting [them]—and, again, once you're over . . . [120 MME] constantly trying to see when can we start to step down if at all possible.'' [26] *Id.* at 120.

Dr. Munzing also testified about the need for physicians to be looking out for red flags of abuse or diversion.[27] *Id.* at 95–96; *see also id.* at 581–82 (Dr. Munzing responding to the ALJ's question about what, if anything, a doctor should do if a patient requests a particular medication). Stating that ''there's probably a list of at least 20 or more'' red flags, Dr. Munzing specifically identified refilling medications early; escalating dosages of opiates; seeing multiple physicians to get controlled substances; using multiple pharmacies; driving long distances to see the physician or provider; and having opiates in combination with benzodiazepines, with benzodiazepines and muscle relaxants, and with stimulants.[28] *Id.* at 95.

The Government asked Dr. Munzing to address urine drug testing. *Id.* at 102. Dr. Munzing explained that controlled substances are ''scheduled because they're dangerous drugs in many ways.'' *Id.* at 100. According to his testimony, ''[i]t's vitally important when you're prescribing controlled substances . . . to do the best that we can as prescribers to ensure that the patient is complying with what we're prescribing'' to determine, for example, ''if there's any conflicts between medications'' and to try to ''mitigate the risk of the treatments'' and to ''optimize treatment.'' *Id.* at 100, 102. Dr. Munzing testified that drug testing indicates ''whether or not . . . medications that you're prescribing [are] showing up as they should . . . [and whether] other things [are] showing up that shouldn't be there.'' [29] *Id.* at 102.

Dr. Munzing described aberrant drug test results. *Id.* at 103–09. He testified that a positive test for a substance that the physician did not prescribe is an aberrant result, that ''it's your responsibility to try to find out why that is there,'' that the result of the inquiry ''should be very well documented in the record,'' and that, ''if it's not legitimate, then what are your actions based on the non-legitimate result?'' *Id.* at 103–04; *see also id.* at 584–85 (Dr. Munzing's testimony responding to the ALJ's question about whether the applicable standard of care requires a doctor to document an aberrant UDS result); *id.* at 775 (Dr. Helm's testimony ''agree[ing] that there should be, and this holds throughout whenever there's a UDS which is not consistent for whatever reason, including this one, that yes, there should be a discussion of your findings on the UDS''). Dr. Munzing also testified that a negative test for a drug that the physician prescribed, when the testing took place less than 30 days after a 30-day prescription was filled, is aberrant. *Id.* at 104. He testified that it's ''incumbent'' on the physician ''to try to investigate'' the negative result. *Id.; see also id.* at 111 (Dr. Munzing's testimony equating his use of the word ''incumbent'' with the ''standard of care in the usual course of professional practice''). For example, he testified, it could be negative due to the ''sensitivity of the test, if they're on a fairly low dosage.'' *Id.* at 105; *see also id.* at 110–11 (citing GX 7, at 19). In such a situation, Dr. Munzing stated that he has ''called the toxicology lab, talked to the person, and they said, oh, well, the number was this[, . . .] [i]t's just under that and so they're really taking it, but it comes across negative.'' *Id.* at 105; *see also id.* at 110–11. Dr. Munzing again testified that the physician's inquiry would be ''well documented in the record so someone looking at it . . . [knows] that they are taking it, but it just doesn't test positive because we're looking at a negative positive, not at a

[25] ''PDMP'' means a Prescription Drug Monitoring Program, such as CURES.

[26] I note that there are instances when Dr. Munzing's testimony sets out the applicable standard of care even though he does not explicitly state that he is doing so. *See, e.g.,* Tr. 119–20.

[27] Regarding the section in the MBC Guidelines for Prescribing Controlled Substances for Pain (2014) (hereinafter, MBC Guidelines for Prescribing) addressing ''Ongoing Patient Assessment'' and Dr. Munzing's testimony about it, they also are consistent with the MBC Guide to the Laws. *See, e.g.,* MBC Guide to the Laws, at 58 (material addressing periodic reviews).

The Government also asked Dr. Munzing to testify about the section called ''Compliance Monitoring'' in the MBC Guidelines for Prescribing. Tr. 100–01. Dr. Munzing testified that ''compliance monitoring'' is ''trying to do the best that we can as prescribers to ensure that the patient is complying with what we're prescribing.'' *Id.* at 100. When asked for examples of what physicians can do to ensure compliance, Dr. Munzing's testimony addressed ''monitoring and checking'' CURES which, he stated, is ''[n]ow . . . mandatory in the State of California . . . whether it be in primary care, specialty care, pain medication—pain management, we have to check all patients on chronic controlled substance medications on at least an every four-month basis.'' *Id.* at 101. ''And,'' he testified, ''if you start a new medication, you've got to check it again.'' *Id.* In response to the ALJ's questioning, Dr. Munzing testified that checking CURES became mandatory on October 2, 2018. *Id.* Some of the controlled substance prescribing about which the parties stipulated occurred after October 2, 2018. *See, e.g.,* Stipulations 37 (A.A.), 40 (R.B.), 43 (S.D.), 49 (S.H.), and 52 (J.M.).

[28] Dr. Munzing's testimony is consistent with the section called ''Important Information for Patients'' in the Food & Drug Administration's (hereinafter, FDA) publication entitled ''New Safety Measures Announced for Opioid Analgesics, Prescription Opioid Cough Products, and Benzodiazepines'' August 31, 2016, GX 9, at 1–2. That section states, in part, that ''FDA is warning patients and their caregivers about the serious risks of taking opioids along with benzodiazepines or other central nervous system (CNS) depressant medicines, including alcohol. Serious risks include unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, coma, and death. These risks result because both opioids and benzodiazepines impact the CNS, which controls most of the functions of the brain and body. . . . If you are taking both opioids and benzodiazepines together, consult your health care provider to see if continued combined use is needed.'' *Id.*

[29] Dr. Munzing testified that the frequency of conducting urine drug testing ''depends on a lot of issues.'' Tr. 109. Dr. Munzing stated that ''a lot depends on the dosage that they're on. Are they on a low dosage, a medium dosage, a high dosage? And are they on multiple controlled substances? Is it just one opiate, or is it an opiate and other medications? And so a lot goes into the determination, but at least once a year, and on high dosage, probably once a month.'' *Id.* at 110.

numerical number.'' *Id.* at 105; *see also id.* at 111–12.

Dr. Munzing testified that a negative UDS result for a prescription drug, filled more than thirty days before the UDS, is aberrant. *Id.* at 106. He stated that the way such an aberrant result is handled depends on the circumstances. *Id.* When the drug that tested negative is a very high dose of a prescription drug, the individual for whom the drug was prescribed is ''probably going through withdrawal'' if the individual is ''really . . . out'' of the drug. *Id.* at 106–07. Consequently, ''you need to inquire of them, are you having withdrawal symptoms?'' and employ one of the standardized objective withdrawal scales to assess the presence of withdrawal. *Id.* at 107. Dr. Munzing also testified that ''if people desperately need these medications, they usually will do everything possible not to run out.'' *Id.* With that starting point, Dr. Munzing testified that he would ''use that as an opportunity . . . to start bringing you down, not necessarily to zero, but start cranking it down a little bit over time and using that as an opportunity.'' *Id.* Dr. Munzing immediately added, ''[b]ut that again would be well documented in the records.'' *Id.*

Dr. Munzing also testified that, for non-cancer pain patients, it is not safe to use marijuana while also taking prescribed opioids due to the ''inherent risks of THC'' and ''it's . . . [his] responsibility as a treating physician to try to keep you as safe as possible in . . . managing . . . patients . . . [a]nd if there's something else coming into that that . . . [he] can't determine what dosage of THC, . . . it just puts the patient at much higher risk.'' *Id.* at 108–09; *see also id.* at 701–02 (Dr. Helm's testimony about THC). He also testified that he has ''seen a few people where they encourage the use of THC as they are tapering down significantly, and so you can see that this is part of their management plan.'' *Id.* at 109. In this instance, ''[a]gain, that would be very well documented in the medical records exactly what the plan is, how we're going to reduce that.'' *Id.*

When the aberrant result is due to non-compliance with the treatment, the applicable standard of care informs the physician's response based on the cause of the aberrancy, Dr. Munzing testified. *Id.* at 106. For example, Dr. Munzing testified, the physician may treat for addiction, do more frequent compliance monitoring, or change treatment. *Id.* ''So,'' Dr. Munzing testified, ''it all depends on what you determined was the cause of the aberrancy . . . [b]ut whatever you choose to do, it needs to be well documented so it's obvious for anyone else looking at it.'' *Id.*

E. Respondent's Case

Respondent testified and called one witness, Dr. Standiford Helm, II, his expert. *Id.* at 628. According to Respondent's case, he, as a fellowship-trained pain specialist, received extensive training in both medication and procedural pain treatments, has an unblemished medical record, has never been sued for medical malpractice, and has never had any disciplinary action brought against his license, presumably meaning his medical license. Respondent's Post-Hearing Brief dated January 24, 2020 (hereinafter, Resp Posthearing), at 2, 21–22. His position is that, due to the ''totally inaccurate and baseless opinion'' of the Government expert, eight ''DEA agents raid[ed] his office and then had his DEA certificate suspended.'' *Id.* at 2. According to Respondent, ''[t]here was never any malpractice lawsuit; no patient overdose; no patient harm; no adverse Medical Board action; nor any criminal activity or even suspicion of malfeasance.'' *Id.* Respondent's position is that ''this process has been ruinous to . . . [his] career and dangerous to his patients'' and the ''destruction of a fellowship-trained professional all occurred because a family doctor offered inaccurate opinions without bothering to read the complete medical records and who lacked basic knowledge on many topics related to opiates.'' *Id.* Respondent testified that ''[u]nfortunately, everything has become so difficult these days. And again, . . . [he has] been doing this for 30 years, and . . . [his] training is very, very different.'' Tr. 920.

Respondent testified about each of his medical files at issue in the OSC and, in the process, gave his perspective on many matters relevant to this adjudication. Regarding UDSes, Respondent testified about his use of UDSes in his practice, stating that ''we do our very best to check'' UDSes and ''have done it for years and years and years,'' and that they are ''just one component of patient compliance.'' *Id.* at 1099–100; *see also id.* (Respondent's testimony that CURES is another way to check compliance although he ''clearly understand[s]'' that CURES only shows prescriptions that are filled, not prescribed drugs that are being ingested); *id.* at 1120–22 (Respondent's testimony confirming that S.D. received carisoprodol prescription from him and from another physician within two weeks of each other, and admitting that he has no recollection of addressing that with S.D.).

According to Respondent's testimony, ''under the best circumstances'' it ''would be preferable'' to have UDS results before seeing the patient ''but [that] didn't always happen.'' *Id.* at 1098. He testified that he did not recall whether he conducted a UDS and did not document it, or whether he did not conduct a UDS. *Id.* at 933 (Respondent's testimony that it does not appear that he ordered a UDS for A.A. in 2011); *id.* at 935–41 (Respondent's testimony that he was ordering UDSes in 2011 but that he did not recall whether he had A.A. take a UDS on her first two visits with him and did not document having done so, or whether he did not have A.A. take a UDS on those first two visits).

Respondent testified that he did not consider a UDS to be aberrant if it is negative for a substance he prescribed, admitting that his ''attorney then, you know, corrected me on that statement.'' *Id.; see also, e.g., id.* at 1077–78, 1085; *but see id.* at 1144–51 (Respondent's testimony that UDSes are ''appropriate'' when a drug he prescribed is missing because, even though it was not documented, he ''discussed with the patient every single time'' and because Respondent had a ''clear understanding'' with at least one of his patients that the patient ''only took medication that was needed'' and that he ''could afford'' financially). Instead, Respondent testified, he used UDS to look for the presence of substances that he had not prescribed. *Id.* at 1098; *id.* at 910–15 (Respondent's testimony that he ''wanted to make sure that there was no illicit substances being used'').

Regarding an A.A. visit when her UDS was aberrant because it was negative for the Percocet he had prescribed, Respondent testified that ''she only had three Percocet a day . . . [a]nd if she had excessive knee pain, for the last two weeks, she obviously finished her Percocet early.'' *Id.* at 938. When asked if taking medication early was a deviation from his prescribing instructions, Respondent testified that it ''[m]ight be a deviation from instructions, but she had an acute exacerbation of pain that she was trying to treat.'' *Id.* at 938–39; *see also id.* at 950 (Respondent's testimony about another aberrant A.A. UDS). Regarding A.A.'s methadone-negative UDS in February of 2013, Respondent testified that ''in this particular case, she took more [m]ethadone. And she saved the Oxy for the end. So she's playing around—again assuming no operator error. Assuming no manufacturer's error. Assuming they didn't read the fake lines. I mean I have to assume all these things.'' *Id.* at 957. Respondent testified that he had no problem with

A.A.'s ''playing around'' with the controlled substances he had prescribed for her, testifying that ''she had an allowance of four [m]ethadone a day. And she took them earlier because she was having these issues with pain, and she was saving the Oxycodone for later. But she was using her allowance.'' *Id.* at 958. He compared A.A.'s ''us[ing] her allowance'' of controlled substances with a child who receives a $5.00 allowance, uses it all on Monday, and does not have ''any money the rest of the week,'' testifying that A.A. is a ''grown-up . . . [who] can make . . . those [controlled substance dosing] decisions.'' *Id.* at 946.

When asked if such a deviation from his prescribed controlled substance dosing was grounds for terminating the doctor-patient relationship, Respondent interrupted the question, responding ''[u]nder no . . . circumstances.'' *Id.* at 939. He testified that A.A. ''had three Percocet a day . . . [,] 30 milligrams. I know in today's world three Percocet is devastating. I get it. But three Percocet is not devast[at]ing to an opioid-tolerant patient who's had three back surgeries, has significant pain, and has been on pain medication for a long time.'' *Id.* According to Respondent's testimony, A.A.'s negative UDSes ''tell[ ] me that she's not taking any medications that she wasn't prescribed. And that's what's important.'' *Id.* at 953; *see also id.* at 944–45 (Respondent's testimony that ''if she was taking more Percocet, that's fine. . . . It's a sign not of abuse, and not of diversion. It's a sign that she's not having adequate pain relief''); *id.* at 964 (Respondent's testimony describing A.A. as someone who ''is following the rules'' and, therefore, her increasing the Percocet dosage he prescribed for her ''was no issue'').

When asked why he did not document his thoughts about A.A.'s aberrant UDS, Respondent testified that ''[b]ecause I'm sure this visit went on forever and ever. And I'm injecting her knee, and I'm doing everything. And it was just, it was not of significance to me. . . . I'm just saying, it was not of concern to me.'' *Id.* at 940. Also during his testimony, Respondent dismissed his inaccurately documented medical records by stating that he was ''so busy talking to the patient'' and ''again, from this chart, that's not a big problem, because it's historically her left knee,'' not her right knee as he had inaccurately documented. *Id.* at 962–63. In his testimony, Respondent admitted that he is ''the keeper of . . . [his medical] records'' and stated that he was ''not restoring backwards.'' *Id.* at 972. According to Respondent's testimony, ''a lot of the [medical] records have been read wrong and interpreted wrong because I'm doing a million things at once, and people are trying to read the exact word.'' *Id.*

Additionally, Respondent's case highlighted that his medical records show he explored surgical options, physical therapy, and the like, reduced the controlled substances he prescribed, complied with documentation requirements, and reduced pain.[30] *See, e.g., id.* at 377 (surgery option explored); *id.* at 738 (surgery option explored); *id.* at 437 (injection); *id.* at 451–52 (injection); *id.* at 453 (physical therapy); *id.* at 742–43 (intrathecal pump); *id.* at 461–62 (increase non-opioid therapy); *id.* at 446 (decrease controlled substances prescribed); *id.* at 478–80 in conjunction with GX 14B, at 31–42 (Respondent's medical records for R.B. showing that Respondent increased oxycodone 30 mg prescription to 150 tablets on June 26, 2017, due to new ''hand pain'' (finger fracture) injury, reissued the increased number of oxycodone 30 mg tablets on July 24, 2017, reduced the number of oxycodone 30 mg tablets prescribed to 140 tablets on August 23, 2017, and returned the number of oxycodone 30 mg prescribed to the prescription's May 24, 2017 amount of 120 tablets on October 16, 2017);[31] Tr. 692 (Dr. Helm's testimony that Respondent, for S.D., substituted Zanaflex for Soma and tried to wean S.D. off Norco); *id.* at 434–35, 663 (spinal cord stimulator trial); *id.* at 488–89 in conjunction with GX 18B, at 141 (Respondent's medical records for L.D. stating ''[w]ould like to attempt to decrease narcotics'' and showing that Respondent decreased the Fentanyl patch he prescribed for her from 100 micrograms every other day to 75 micrograms every other day); *see also* Tr. 490 (discontinuation of Fentanyl patch); *but see id.* at 504–05 in conjunction with GX 18B, at 76–81 (showing that Respondent resumed prescribing Fentanyl patches (every three days) after L.D. slipped and sprained her left knee, and then increased the prescription to every other day);[32] Tr. 414–15 (documentation of A.A.'s daughter stealing controlled substances Respondent prescribed for A.A.); *id.* at 476 (medical records showing that the controlled substances Respondent prescribed ''appeared to be reducing'' R.B.'s pain); *id.* at 485 (Dr. Munzing's testimony that Respondent managed R.B.'s pain); *id.* at 515 (Dr. Munzing's testimony that, based on Respondent's notes, L.D.'s pain appeared to decrease); *id.* at 519–20 (Dr. Munzing's testimony that S.H.'s function improved over time); *id.* at 526 (Dr. Munzing's testimony that ''pain medication is helping . . . [S.H.] be more productive'').

Based on substantial record evidence, however, Respondent was not successful at rebutting the OSC's allegations that he prescribed controlled substances beneath the applicable standard of care and outside the usual course of professional practice, including that Respondent failed to conduct the requisite physical examinations, failed to obtain the requisite history, failed to develop an appropriate treatment plan, failed to conduct appropriate monitoring of those for whom Respondent prescribed controlled substances, and failed to comply with recordkeeping requirements. *Supra* section II.; *infra* section III.F.

[30] I note, however, that Dr. Helm, Respondent's expert, testified that the difference between when a physician first writes a prescription for an opioid patient versus when a pain specialist assumes care of the patient is that the ''option we have of looking at non-opioid alternatives has been taken away from us.'' Tr. 631–32.

[31] *See also* Tr. 558–60 (Dr. Munzing's testimony) and *id.* at 684 (Dr. Helm's testimony).

I note that Respondent's medical records for R.B. on this point are not accurate and, therefore, that they do not comply with the applicable standard of care. MBC Guide to the Laws, at 61 (accurate and complete medical records). For four visits, from July 24, 2017 through October 16, 2017, Respondent inaccurately stated under ''Current Medications'' the number of oxycodone 30 mg tablets he last prescribed for R.B. GX 14B, at 32–38; *see also* GX 18B, at 70–78 (inaccuracies in medical records concerning Respondent's prescribing of Fentanyl patches to L.D.). I further note that I did not consider these matters in my Decision/Order because they were not noticed or litigated by consent.

[32] *See also* Tr. 554–58 (Dr. Munzing's testimony that, although the x-ray of L.D.'s knee was ''normal'' (GX 18A, at 39), an x-ray may not show all injuries, and that a Fentanyl patch is a controlled substance for chronic pain, not for treating an acute injury, such as a knee injured due to a slip, for a brief period of time); *id.* at 570–71 (re-cross); *id.* at 573, 614 (re-direct).

I credit Dr. Munzing's testimony that Fentanyl patches are normally written for every three days, not every other day as Respondent prescribed them for L.D. Tr. 489.

Further, there is substantial record evidence that Respondent did not identify as problematic requests for specific controlled substances by name and self-dosing contrary to his prescribed dosing orders. *See, e.g.,* Tr. 966 (Respondent's testimony that A.A. ''all of a sudden'' said she would like to try Oxycodone instead of Methadone and that is ''perfectly fine'' with him); *id.* at 1030–32 (Respondent's testimony about L.D.'s non-appointment appearance at Respondent's office ''with a crippling illness'' for which she asked Respondent, and received, a Fentanyl patch (12.5 microgram) prescription, her ensuing complaint that the dosage he issued for her was too low, L.D.'s subsequent ''classic'' self-dosing ''up to 75 micrograms,'' and his description of L.D. as ''an actress, to be honest''); *see also id.* at 1124–28 in conjunction with GX 18B, at 79–81 (Respondent's testimony that L.D. ''historically treated her pain with either 75 microgram or 100 microgram [Fentanyl] patches,'' that he re-started L.D. on 12.5 microgram per hour Fentanyl patches ''because she had not been on it for quite some time,'' that L.D. ''found the dosage strength of 75 micrograms per hour helpful in this—what turned out to be a very devastating injury and cascade of events, this all made absolute perfect sense,'' and that he was thus justified to prescribe 75 micrograms per hour Fentanyl patches on a visit when L.D.'s UDS was positive only for benzodiazepine); Tr. 1101–04 (Respondent's testimony that it is not unusual for his patients, ''within . . . [the] allotted allowance of the month'' to choose to ''vary,'' despite his prescribing instructions, the amount of controlled substances ingested each day ''based on . . . activity level and based on what . . . needed to [be] accomplish[ed] that day'' and that he would tell them ''there would be a maximum amount that . . . [he] would be comfortable with'' their ingesting each day); *id.* at 1039–42, 1108 (Respondent's testimony that he complied with R.B.'s request for a specific controlled substance prescription—stating that he ''felt for this man'' given his experiences with his 86 year-old father whom he ''can't really take anywhere because he has this cough that embarrasses the entire family in a restaurant and everything else like that,'' minimizing the controlled substance prescribing as ''22 doses of cough syrup a month,'' and pointing out that he stopped prescribing controlled substances on behalf of other doctors because he ''didn't want to be further involved in it'').

I decline to adopt Respondent's excuses and arguments to overlook his failures to follow the applicable standard of care and to act within the usual course of professional practice. *See, e.g., id.* at 452 (the prolonged use of anti-inflammatories can cause serious organ damage); *id.* at 456 (a loose screw was subsequently discovered in S.D.'s spine justifying Respondent's ''dramatically increased'' controlled substance prescribing); *id.* at 481–83 in conjunction with GX 14B, at 11 (a pulmonologist may have subsequently prescribed Promethazine); Tr. 419–20 (there is no record evidence that Respondent's controlled substance prescribing led to respiratory depression, overdose, or side effects); *see also id.* at 535 (Dr. Munzing's testimony that ''just because someone doesn't have a terrible outcome doesn't mean that what you did was correct and right''); *id.* at 1153–54 (Respondent's testimony stating his belief that another pain doctor picking up his medical records ''would gain a much greater knowledge from . . . [his] records than they would many other physician's records,'' instead of answering the ALJ's direct questions of whether ''they would be able to pick up from where you left off based on the content of your records'' and whether ''they [would] understand what you had'').

Having read and analyzed all of the record evidence, I find that Respondent is the witness with the most at stake in this adjudication. I find that, while Respondent's testimony does include reliable statements, it also includes statement that lack credibility, are implausible, and/or are not persuasive. I find that Respondent's testimony must be considered with much caution, and where his testimony conflicts with credible record evidence and the applicable standard of care, I do not credit it. *Supra* section II and section III.D.; *infra.*

According to Respondent's case, the Government's expert witness is trained in family medicine, not in pain medicine, and did not do, let alone complete, a fellowship in pain management. Resp Posthearing, at 23. The testimony of the Government's expert witness, Respondent charges, ''was rife with error,'' including its reference to the CDC Guidelines during his evaluation of the controlled substance prescribing of Respondent, a pain management specialist. *Id.*

According to Respondent's case, his expert witness, Dr. Standiford Helm, II, is a ''pre-eminent expert in the area of pain management,'' ''holds diplomate status with a number of organizations specializing in the treatment of pain,'' and has affiliations with various pain organizations and ''top journals in the area of pain management.'' *Id.* at 25–26. Dr. Helm, according to Respondent, ''is one of the authors of pain guidelines for . . . [the American Society of Interventional Pain Physicians (hereinafter, ASIPP)], and those guidelines were used as evidence in this hearing'' and ''has served as an expert reviewer for the Medical Board of California for pain specialists, because he is a pain specialist.'' [33] *Id.* at 26. Respondent offered, and the ALJ accepted, Dr. Helm ''as an expert in support of . . . [Respondent] and the care rendered by . . . [Respondent] to the patients in the areas of pain management and for these specific treatments for the patients at issue.'' Tr. 628.

According to Dr. Helm's testimony, he was trained in internal medicine and anesthesiology, became involved in pain management ''[p]robably about '82,'' and ''evolved'' with the field as the field evolved.[34] *Id.* at 620–21. He was ''able to be grandfathered'' when ''the first boarding became available in 1993'' and ''then just continued from there to the point where since then . . . [he has] been very active nationally and internationally, lectured and written and continued to do those things.'' *Id.* at 621. Dr. Helm testified that he received research support from the manufacturer of opioids in this case, Purdue Pharma, one of whose founders was a ''marketing genius'' who ''probably helped develop the [opioid] problem.'' *Id.* at 626–27.

Dr. Helm testified that a doctor is required to do several things when issuing a new controlled substance prescription: ''review whatever records are available,'' including ''whatever past medical records you have and have

[33] Dr. Helm testified that, as an author of the ASIPP Guidelines, he agrees with their content, specifically addressing the ASIPP Guidelines' statements about pain contracts and obtaining informed consent. Tr. 758. Yet, Dr. Helm testified that Respondent's pain contract, while not in compliance with the ASIPP Guidelines, ''can be accepted as an informed consent agreement although it . . . could be more fully documented and, you know, if you wanted to, the language could be changed from any form of . . . opioids or narcotics to any controlled substances, you know, there is that variation.'' *Id.* at 758–59; *see also id.* at 748–50 (Dr. Helm's testimony about Respondent's pain contract and its non-compliance with the MBC Guidelines for Prescribing concerning obtaining a patient's informed consent about the ''risk'' of using controlled substances). Dr. Helm's testimony also stated that ''not complying with this [sic] specific guidelines and deviating from standard of care are two different—two different entities, two different thesis [sic].'' *Id.* at 759.

[34] Respondent's Exhibit (hereinafter, RX) 5 is Dr. Helm's *curriculum vitae.*

access to;'' ''meet with the patient;'' ''obtain a thorough history;'' ''perform an exam, really focused on, attempting to find out what the cause of the pain is, if you can;'' ''integrate that data, come up with a treatment plan;'' ''get[ ] a urine drug screen;'' ''risk stratification;'' and ''obtain[ ] informed consent and pain agreement.'' [35] *Id.* at 864–65. I find that Dr. Helm's response lists half of the elements of the applicable standard of care.[36] *Supra* section II.

Dr. Helm's testimonial elaboration on, and application of, these elements and on other matters pertaining to the applicable standard of care, however, fall far short and I do not credit them.[37] For example, Dr. Helm's testimony was inconsistent. While initially testifying that a UDS is one of the things a doctor is required to do when issuing a new controlled substance prescription, he subsequently testified that ''as long as the physician is seeing the patient and carrying out an exam and coming to a determination absent either one of those data points—either the CURES or the UDS, it is still within the course of professional practice.'' Tr. 870–71. Further, Dr. Helm testified that a doctor is required to have a ''legitimate encounter'' with the individual before he writes a controlled substance prescription and, during that ''legitimate encounter,'' is to get a ''current history,'' ''perform[ ] [an] appropriate exam,'' and ''com[e] to a determination.'' *Id.* at 871. According to Dr. Helm, then, if one of the elements he initially testified to being required before the issuance of a new controlled substance prescription is not performed, ''even if those errors are made, you're still within the professional practice.'' *Id.*

By way of further example, Dr. Helm was asked whether Respondent's patient contracts satisfy informed consent. *Id.* at 876. Dr. Helm testified that those contracts ''referred to side effects'' but ''they didn't specifically discuss some of the specific risks, tolerance, death.'' *Id.* Dr. Helm testimony concluded, though, that, although they are not ''optimal,'' the contracts are ''close enough to at least be acceptable.'' *Id.*

Regarding his testimony that a doctor must ''perform an exam, really focused on, attempting to find out what the cause of the pain is, if you can'' and ''integrate that data, come up with a treatment plan,'' Dr. Helm testified that Respondent's initial prescribing of amphetamine salts for L.D. preceded Respondent's noting the chronic fatigue syndrome diagnosis in the medical records for L.D.'s third visit. *Id.* at 879–82; *accord id.* at 1122–24 (Respondent's testimony). Nevertheless, Dr. Helm excused Respondent's failure, testifying that Respondent was ''maintaining a medication'' that a different medical professional had previously prescribed. *Id.* at 880; *but see id.* at 1135–36 (Respondent's failure to answer fully the ALJ's question about the purported ''list of . . . [L.D.'s] meds'' and physicians at GX 18A, 82–83) and *infra* n.38. Dr . Helm testified that he viewed Respondent's failure as ''an error in documentation,'' but not an ''error in documentation [that] takes it outside the usual course of professional practice.'' [38] Tr. 880.

Regarding UDSes, Dr. Helm testified that the controlled substance prescriptions Respondent issued on the visit at which L.D.'s UDS was positive for cocaine were issued within the usual course of professional practice, even though Respondent did not ''resolv[e]'' the cocaine aberrancy. *Id.* at 882. Dr. Helm's testimony was that Respondent's actions were a ''documentation problem, rather than taking [sic] outside the practice of medicine.'' *Id.* at 885; *but see id.* at 1136–37 (Respondent's testimony that the cocaine-positive UDS of L.D. ''must have been a click of the box error'' because ''one thing my boys did if there was ever an elicit [sic] drug, they immediately brought the dipstick to me and we evaluated it together''); *id.* at 1025–26 (Respondent's testimony that L.D. ''did not use cocaine,'' that he phoned L.D. after reviewing the medical records the week before the hearing and received L.D.'s ''confirmation'' that she did not use cocaine, that he trusts his patients because they are ''honest'' with him, and that he has to ''assume'' the cocaine-positive result was the error of one of his employees who ''clicked the wrong box''). Instead of explaining his ''documentation problem'' assessment, however, Dr. Helm warned against stopping opioid prescriptions ''abruptly unless you had documentation that the[y] weren't taking the opioids just because of the withdrawal issue.'' *Id.* at 883. Dr. Helm's testimony did not elaborate on what ''documentation that the[y] weren't taking the opioids'' he believes is needed, how a physician would obtain that documentation, and the bases for his conclusion that Respondent's failure to address the cocaine UDS aberrancy was a ''documentation problem.'' *Id.* at 882–83, 885. He did testify, however, that he is ''not aware of anywhere where it is codified that one needs to—and forget UDS—any inappropriate result or after, whether again, malignancy, tests, whatever it's going to be—anything that would require—high blood pressure—it would require a response despite the absence of codification.'' *Id.* at 884–85.

Dr. Helm testified that there is no upper limit for the MME dosages a physician can prescribe, stated that guidelines exist but do not determine the standard of care, and defined the standard of care as ''what a reasonably trained physician in the community would do in similar circumstances at a similar time.'' *Id.* at 625–26; *see also id.* at 630; *id.* at 807–11. According to his testimony, guidelines do not apply equally to all specialties in the area of opioid prescribing, stating that the CDC guidelines, explicitly, and MBC guidelines, implicitly, apply to primary care physicians.[39] *Id.* at 630. Dr. Helm's testimony was that the MBC guidelines implicitly apply to primary care physicians ''because they refer repeatedly to consultations not only to pain management but to other

[35] Dr. Helm also stated that a pain management doctor is to ''review a CURES Report.'' Tr. 864–65.

[36] Dr. Helm was also asked ''[w]hat, if anything, [is] a doctor acting with [sic] the usual course of professional practice required to do . . . to document an increase in strength or quantity of a previously prescribed prescription?'' Tr. 873–74. Since the question is not specifically about controlled substance prescriptions, Dr. Helm's response is not relevant to my adjudication of this matter.

[37] I credit none of Dr. Helm's responses to questions calling for a legal analysis as it is not in his expertise to provide a legal opinion. *See, e.g.,* Tr. 864–892. To his credit, Dr. Helm testified that he ''attempted'' to read *Gonzales* v. *Oregon,* found it ''very hard to read,'' called it ''interesting'' that ''DEA deferred to the state'' about the ''usual course of professional practice within California,'' and ''defer[red] to the Court'' on such matters. *Id.* at 870, 884, 873. Dr. Helm's ''deferral'' testimony and other testimony about the meaning and scope of the ''usual course of professional practice'' and the applicable standard of care support my decision to give limited weight to Dr. Helm's testimony. *See, e.g., id.* at 867–68, 870–73.

[38] Respondent subsequently testified that the only refill L.D. said she needed during her first visit with Respondent was amphetamine salts. Tr. 1019. Respondent testified that ''[m]aybe this [medical record] note is not as long as it should be. But obviously this was a very complex patient . . . [a]nd so . . . a lot of time was taken in the history and establishing a relationship.'' *Id.* 1020; *see also id.* at 1020–21 (Respondent's testimony, when asked if it was an oversight for him not to document that chronic fatigue syndrome was the diagnosis on which his amphetamine salts prescription for L.D. was based, that he ''was so busy writing down, you know, symptoms, and so busy doing other things, that . . . [he] just really didn't get to the problem list at the time''). Respondent testified that he ''was comfortable with'' issuing L.D. a prescription for amphetamine salts because he ''had a list of all of her physicians'' and ''[t]here's the CURES Report in the chart that confirms all of that information.'' *Id.* at 1020. Respondent's testimony does not include details about the source of the list of L.D.'s physicians, does not explain how the CURES Report confirms ''all of that information,'' and does not include information showing that the first visit amphetamine salt prescription complies with the applicable standard of care.

[39] Dr. Helm did not further identify the ''CDC guidelines'' he was referencing.

specialties, too.'' *Id.* Dr. Helm was asked, but did not answer, whether the MBC Guidelines for Prescribing are relevant to pain care specialists.[40] *Id.* at 762. He testified that ''pain physicians can take it wherever we want to, but you've got to justify why you're so doing.'' *Id.* at 763. Respondent asked Dr. Helm if he ''would say that a pain care specialist has an even higher standard of care that they should follow rather than just the primary care physician,'' and Dr. Helm stated in agreement, ''Basically.'' *Id.*

Dr. Helm testified about the medical care Respondent provided, and controlled substance prescriptions Respondent issued to, A.A., R.B., S.D., L.D., S.H., and J.M. Tr. 632–897; *infra* section III.F. I find that Dr. Helm's testimony focused largely on describing, explaining, and even justifying or excusing Respondent's medical records and actions those medical records state that Respondent took, as opposed to addressing Respondent's compliance or non-compliance with the applicable standard of care and the usual course of professional practice and whether the OSC's allegations are founded and whether I should entrust Respondent with a controlled substance registration. For example, when Respondent's counsel specifically asked Dr. Helm whether Respondent's treatment plan for A.A. was appropriate, Dr. Helm responded that ''he gave early refills,'' ''[p]ost-dated triplicate for the Methadone, and then it was just continued following up for the psychological evaluation and plan to proceed to the epidural'' before being cut off by Respondent's counsel's next question. Tr. 646–47; *see also id.* at 680–81 (Dr. Helm's not responding to a question about Respondent's compliance with the standard of care, Respondent's counsel's rephrasing the question to ask about whether Respondent's controlled substance prescribing was ''acceptable,'' and Dr. Helm's response to the re-phrased question); *id.* at 731–32 (Dr. Helm's testimony, when asked, ''[i]n view of the totality of the care and the notes and the history and the information provided, how would you describe . . . [Respondent's] treatment, of this patient,'' that ''[y]ou know, I think he's allowing this gentleman to function, to support a multi-generational essentially family, although the girlfriend's not married. But he's supporting the kids, her and his grandmother, and he surely is, you know, providing a benefit to them, and there's no threat here or risk to public safety''); *id.* at 683 (Dr. Helm, answering Respondent's counsel's question about if there is any reason to doubt R.B. was in increased pain and would benefit from more medication, by stating that it is ''[r]easonable to have increased pain after a car accident''); *id.* at 715 (Dr. Helm's testimony that Respondent's medical records ''clearly showed'' that L.D.'s criminal involvement was ''business,'' but no direct response to Respondent's counsel's question of whether Respondent ''adequately document[ed]'' L.D.'s criminal status); *id.* at 687 (Dr. Helm's summary testimony, without explanation, after Respondent's counsel asked if the controlled substance prescriptions that Respondent issued to R.B. were ''medically justified,'' that ''[t]here was a legitimate medical purpose and they were done in the course of professional practice''); *id.* at 741 (Dr. Helm's conclusory testimony that continuing controlled substance prescriptions ''to allow . . . [J.M.] to perform [activities of daily living] and have quality of life despite his physical limitations'' is ''an appropriate goal for the opioid therapy'').

Another example, regarding the requisite physical examination, is Dr. Helm's testimony about Respondent's medical records for A.A. He testified about the ''type of exams done by pain specialists in the treatment of chronic pain,'' stating that Respondent conducted an ''appropriate lumbar exam'' of A.A. that was a ''focused musculoskeletal exam.'' *Id.* at 635–36; *see also id.* at 644. Dr. Helm approvingly testified about Respondent's focus on A.A.'s back, gait, response to palpation of ''various areas of the back,'' range of motion, lower extremity exam, muscle strength, reflexes, and sensation, concluding ''that's really the gist of it.'' *Id.* at 636; *see also id.* at 740 (Dr. Helm's agreement with Respondent's counsel that Respondent's examination of J.M. on all visits was ''appropriate'' without testimony about the applicable standard of care and the usual course of professional practice). Dr. Helm mentioned the heart and lungs ''because the surgery centers want[ ]'' that information ''but it's not, you know, that doesn't influence the diagnosis.'' *Id.* Dr. Helm did not address the applicable standard of care and the usual course of professional practice regarding a pain management physician's conduct of a heart or lung examination, let alone testify about the connection between the condition of a patience's heart or lung and a pain management physician's assessment of the appropriateness of prescribing a controlled substance.

A further example is Dr. Helm's testimony about the reasonableness and consistency with the standard of care of Respondent's controlled substance prescribing. Regarding A.A., for example, Dr. Helm testified that, ''[s]ure,'' the controlled substances Respondent prescribed during A.A.'s first two visits were ''reasonable and consistent with the standard of care as a pain physician,'' elaborating only that ''as long as she was getting pain relief and increased function with the medications with no side effects and there are no signs of aberrancy.'' *Id.* at 639.

Also regarding A.A., as another example, Dr. Helm testified that it was appropriate for Respondent to increase the methadone he prescribed for her on January 11, 2013, stating that ''the pain meds are worse'' and Respondent is ''carrying out a further evaluation to solve—to see if there's anything that could be identified and in the interim increasing the medications.'' *Id.* at 658. Dr. Helm testified that one methadone-negative UDS ''really it isn't a basis for . . . [a] run to action on because of one negative in the face of multiple positives.'' *Id.* at 892. He did not explain his testimony that increased methadone prescribing was ''appropriate'' in the context of Respondent's continuation of it through June 5, 2013, despite one UDS that was negative for methadone, and of Respondent's discontinuation of it, on June 28, 2013, based on a note that ''Pt would like to try Oxycontin'' and prescribing ''Oxycontin 10 mg[ ] #120 1 QID'' and ''Percocet 10/325 #120 1 QID prn.'' GX 12B, at 114; Tr. 658–60 (Dr. Helm's testimony about June 5, 2013, including A.A.'s subsequent hospitalization ''for concern of suicide''); *see also id.* 740–41 (Dr. Helm's testimony, without elaboration, that it was ''appropriate and reasonable'' for Respondent to prescribe ''anxiety-provoking . . . large quantities of narcotics'' to J.M.). Dr. Helm also did not explain his repeated testimony that Respondent's methadone prescribing for A.A. was appropriate in the face of his testimony that methadone is ''disproportionately a cause of death because the half[-]life in the body is longer than the period of pain relief'' and his agreement that there is no evidence in A.A.'s medical records that

[40] *See also* Tr. 530 (Dr. Munzing's testimony, stating that ''the guidelines aren't the standard of care and if one is in substantial compliance with the guidelines, and with any other laws that dictate the prescribing, one would be compliant with the standard of care. But could one be within the standard of care and not do one little thing within the guidelines? In my mind, yes it could be, but a substantial compliance with the guidelines, which is what . . . we all do when we're practicing is we are in substantial compliance with whatever the guidelines are for taking care of the patients for whichever problems'').

Respondent had A.A. undergo an electrocardiogram, as the ASIPP guidelines that Dr. Helm co-authored recommend, to prevent such ''big problem[s]'' as cardiac arrythmia and heart pump failure. *Id.* at 842–45; *see also id.* at 842 (Dr Helm's testimony that ''[m]ethadone's great advantage is that it's cheap'').

Regarding Respondent's monitoring of those for whom he prescribed controlled substances and his use of UDSes, Dr. Helm agreed with Respondent's counsel that there were ''several'' aberrant UDSes in Respondent's medical files. *Id.* at 650. He testified that an aberrant UDS is the ''absence of what's prescribed or the presence of what is not prescribed.'' *Id.* at 846. Regarding how to handle aberrant UDSes, Dr. Helm testified that, ''as a pain physician,'' he would ''want to discuss with the patient . . . two things.'' *Id.* at 648. First, he testified, a pain physician would want to ''find out what's going on,'' document awareness of the aberrancy, and provide counseling about how to ingest the controlled substance. *Id.* Second, Dr. Helm testified that a pain physician would want to send the urine sample out for confirmatory testing.'' *Id.* at 648–49. Dr. Helm clearly testified an aberrant UDS is ''obviously something that should be—I, you know, I have in other scenarios and continue here to say that these results need to be documented, these findings need to be documented . . . [and] [t]hey're not.'' [41] *Id.* at 651; *see also id.* at 833 (Dr. Helm's testimony that ''every aberrancy on the UDS should be documented''); *id.* at 831 (Dr. Helm's testimony that his position is ''if it's not documented it didn't happen'').

After specifically criticizing Respondent's handling of aberrant UDSes, however, Dr. Helm minimized Respondent's failures, testifying that the instances of aberrant UDSes in Respondent's medical records are ''unlikely to represent any abuse or diversion or present any risk to the public'' due to the ''analysis of the patient, and these patients, there seems to be all the confirmatory evidence from the social environment and the CURES.'' *Id.* at 649–51; *see also id.* at 896 (Dr. Helm's testimony that ''we're looking at documentation errors rather than a causative concern for public safety''). When asked about Respondent's failure to conduct UDSes for a year, Dr. Helm testified that Respondent's previous ''custom and practice was to do them, so not doing them is not related to a failure, indifference to urine drug screens.'' *Id.* at 765. Dr. Helm declined to conclude that Respondent's re-prescribing of methadone after repeated non-negative methadone UDSes was more than a ''consistent lack of documentation on that issue, and throughout all the charts.'' *Id.* at 851. Instead, Dr. Helm testified that an aberrant UDS is ''not one that in isolation should be the determinate as to what you do'' and that he ''look[s] at the totality of the data,'' including ''the patient's response to the medications, ability to function, reported decreased pain, reported increased function'' and would ''continue it.'' [42] *Id.* at 846–51; *see also id.* at 897.

At the end of his direct testimony, Dr. Helm stated his views of Respondent as a pain physician. *Id.* at 746–47. He testified that Respondent prescribed high doses of controlled substances, justifying that prescribing by stating ''but . . . his patients on high doses are having functional improvement.'' *Id.* at 746. Dr. Helm testified that Respondent monitored his patients, adding the excuse that the UDSes Respondent conducted were ''hampered by the inability to get confirmatory tests.'' [43] *Id.* He testified that Respondent ''strongly documented'' psycho-social status, which was ''confirmed by the presence of family members.'' [44] *Id.* Dr. Helm added that Respondent's medical record ''documentation is far better than that which . . . [he has] seen in many, many records that . . . [he has] reviewed.'' *Id.* at 747.

Dr. Helm disagreed with Dr. Munzing's ''criticisms overall'' of Respondent. *Id.* He testified that Respondent's pain medicine adjustments ''were not arbitrary'' and that ''the notes document rationales for the adjustments.'' *Id.* Dr. Helm testified that Respondent's ''high doses are high,'' that ''we know [high doses] do have increased risks,'' but that Respondent ''is providing the monitoring, which the author of the CDC guidelines requests be done.'' [45] *Id.* He concluded his direct testimony by referencing Respondent's UDSes and stating that he does not ''see'' that Respondent ''represents a risk.'' *Id.*

Although Dr. Helm's testimony specifically addressed Respondent's high dose prescribing, ''pain medicine adjustments,'' UDS practices, monitoring, use of CURES, and medical record documentation, it did not address them squarely in the context of the applicable standard of care and the usual course of professional practice. As already discussed, Dr. Helm's testimony contained limited and unconvincing evaluations of Respondent's controlled substance prescribing against the applicable standard of care and the usual course of professional practice. Accordingly, I give Dr. Helm's testimony limited weight in this Decision/Order.

Based on my analysis of the applicable standard of care and the existence of substantial record evidence, I credit the standard of care-related testimony of Dr. Munzing when there is a conflict between his testimony and the standard of care-related testimony of Dr. Helm or of Respondent. *Supra* sections II, III.D., and III.E.

Respondent also submitted documentary evidence, including about seventy-five pages of letters from supporters who describe themselves as physicians, patients, or family members of patients whom Respondent has treated. RX 8, at 1–76. It appears, from my having read the legible portions of the letters, that Respondent reached out regarding his ''alleged misuse of prescribing drugs.'' [46] RX 8, at 74. Although the content of RX 8 indicates the strong and positive feelings and opinions of many individuals about Respondent, I can only afford that content limited weight in this adjudication because of my limited ability to assess the credibility of the letters given their written form. *See Michael S. Moore, M.D.,* 76 FR 45867, 45873 (2011) (evaluating the weight to be attached to letters provided by the respondent's hospital administrators and peers in light of the fact that the authors were not subjected to the rigors of cross examination). Further, the content of RX 8 provides limited evidence about whether Respondent

[41] Dr. Helm did not agree with Respondent's counsel that Respondent ''was ahead of the curve in terms of what he was doing to monitor patients.'' Tr. 652. Instead, Dr. Helm's responded: ''I would say that he and I are some of the few doctors in the state who still remember that back in the day you had to fax in requests for the CURES back before then Attorney General Brown went electronic with it in 2009.'' *Id.*

[42] *See also* Tr. 746–47 (Dr. Helm's testimony about J.M.'s July 13, 2018 visit with Respondent and CURES reports, stating that they ''are all consistent and compliant suggest[ing] that the UDS results, while they should be more clearly documented, . . . do not . . . provide any evidence of risk to the public, so he's really doing well''); *see also id.* at 768–69.

[43] Dr. Helm testified that it is expensive to send UDS results for confirmation. Tr. 642.

[44] Dr. Helm agreed, however, that family and friends ''may not necessarily be a good source of checking for compliance'' as ''they, too, might be abusing or diverting,'' and that family and friends attending a visit with Respondent is ''not really a substitute'' for not doing UDSes. Tr. 766–67.

[45] Again, Dr. Helm did not further identify the ''CDC guidelines'' he was referencing. I note, though, that Respondent's position in this matter is that the ''CDC Guidelines'' do not apply to Respondent.

[46] The content of RX 8 alludes to the communication but does not include it.

prescribed controlled substance in conformity with the applicable standard of care, an issue central to my legal responsibilities in this adjudication. Heart-felt statements of individuals who have suffered, or who continue to suffer, tremendously from pain, if not specific or presented in a context that allows me to apply the controlling legal standards, are of limited value in an adjudication such as this one. Accordingly, I find that the substantial record evidence of Respondent's multiple controlled substance-related violations outweighs the evidence in RX 8.

F. Allegation That Respondent Issued Controlled Substance Prescriptions Beneath the Applicable Standard of Care and Outside the Usual Course of Professional Practice

Having read and analyzed all of the record evidence, I find substantial record evidence that Respondent issued many controlled substance prescriptions beneath the applicable standard of care and outside the usual course of professional practice. Accordingly, I find that the Government has presented a *prima facie* case, as outlined below.[47]

Regarding the Xanax 2 mg controlled substance prescription that Respondent issued to A.A. on October 8, 2013, I credit Dr. Munzing's testimony. Tr. 132–36; *supra* sections II, III.D., and III.E; *see* GX 12B, at 104–06. I find substantial record evidence that Respondent's first prescribing of Xanax to A.A. was at its ''highest dosage'' for anxiety, was at A.A.'s request (''Cannot afford to see PCP; only sees him for Prilosec and Xanax. Would like me to prescribe her these meds.''), was not associated with a ''real detailed history regarding anxiety as should be included if one is going to take over the management of prescribing a benzodiazepine such as Xanax for anxiety,'' was not issued after documented consideration of a ''safer, noncontrolled medication[ ] that can be used for anxiety,'' was issued ''in conjunction with an opiate'' and, therefore, posed a ''significantly increased risk'' to A.A. and was a ''significant red flag for abuse or diversion.'' Tr. 133–36; GX 12B, at 104–06; *see also* Tr. 431–33; *id.* at 228–29 (L.D.).

Respondent testified about his decision to do A.A. that ''favor,'' to ''accommodate'' her. Tr. 1106–08. He testified that even though prescribing benzodiazepines was ''something . . . [he'd] really never done in . . . [his] practice,'' he had a ''relationship'' with A.A., seeing A.A. ''monthly for at least two years.'' *Id.* at 1106. Respondent testified that he ''did not see where . . . [Xanax] was interfering with her function.'' *Id.* at 1106–07. ''In fact,'' he testified, Xanax ''improved her anxiety and it improved her level of functioning and the like.'' *Id.* at 1107. Accordingly, when A.A. said that she ''could save some money as her funds were limited,'' Respondent decided to ''accommodate'' her. *Id.* Respondent admitted that he continued to prescribe Xanax for A.A. ''in the face of UDSes that did not detect levels of . . . [Xanax] in her body.'' *Id.* When asked whether it ''was ever a concern to him'' that A.A.'s UDSes ''did not detect levels'' of Xanax in her body, Respondent testified that A.A. ''never obtained that medication from anyone else,'' and ''if the time came at the visit where it had already been out of her system, which implied that she took a little bit more earlier in the month[,] she had her monthly allowance and she did with it what she pleased.'' *Id.; see also supra* section III.E.

Accordingly, I find substantial record evidence that Respondent's first issuance of Xanax 2 mg to A.A. was beneath the applicable standard of care and outside the usual course of professional practice.

Regarding the parties' stipulations that, on June 5, 2013, Respondent increased the monthly amount of Percocet 10/325 he prescribed for A.A. from 90 to 120 tablets, and that the next month, on July 23, 2013, Respondent again increased the monthly amount of Percocet 10/325 he prescribed for A.A. from 120 to 180 tablets, I credit Dr. Munzing's testimony responding to whether the prescriptions ''met the standard of care in California and were issued in the usual course of professional practice.'' [48] *Supra* sections II, III.D., and III.E. Dr. Munzing testified that Respondent's Percocet prescriptions for A.A. did not meet the standard of care in California and were not issued in the usual course of professional practice. Jt. Stips. 59 and 60; Tr. 137–41 (Dr. Munzing's testimony that A.A. is ''already on an extremely high dosage of opioids and no real justification [in the medical records] to increase that,'' ''it appeared to have been increased . . . without medical justification and essentially increased it and then just kept on going rather than looking for an opportunity to over time gradually reduce it by some other management of the need other than just . . . prescribing opioids,'' and ''they're not medically justified, not used in professional practice, but it's not just because of that one visit. It's because other visits that I reviewed, my opinion was the same, is that, both where it went up but also ongoing, there wasn't an ongoing plan and the patient was being put at risk over long periods of time . . . . I could easily conclude that they were not medically justified.''); *but cf.* Tr. 661–63 (Dr. Helm's testimony that Respondent's increasing the Percocet prescription was ''medically justified based upon . . . [A.A.'s] complaints and examination and history'' and the side effects she experienced from Gabapentin). I credit Dr. Munzing's testimony over Dr. Helm's testimony when the two conflict. *Supra* sections II, III.D., and III.E.

Accordingly, I find substantial record evidence that Respondent's prescription of 120 tablets of Percocet 10/325 for A.A. on June 5, 2013, an increase from 90 tablets, and his prescriptions of 180 tablets of Percocet 10/325 for A.A. the next month on July 23, 2013, through March 25, 2019, were issued beneath the applicable standard of care and outside the usual course of professional practice. GX 11, at 1–31.

The parties also stipulated that, on January 11, 2013, Respondent increased the monthly amount of methadone 10 mg he prescribed for A.A. from 90 to 120 tablets, and that on June 2, 2014, Respondent again increased the monthly amount of methadone 10 mg he prescribed for A.A. from 120 tablets to 180 tablets. Jt. Stips. 61 and 62. According to Respondent's testimony, ''one source of pain in the back could

[47] The OSC's allegations include that Respondent prescribed controlled substances at daily MME levels above 90 mg per day although the CDC ''recommends avoiding or carefully justifying'' doing so. *See, e.g.,* OSC, at 4–7, 9–10. The Government's questioning of Dr. Munzing included asking him whether Respondent's medical records documented reasons or justifications for prescribing the specific MME value associated with specific controlled substance prescriptions. *See, e.g.,* Tr. 128–31, 167, 185. This questioning by the Government, though, followed Dr. Munzing's testimony that, for example, there is no maximum MME above which a physician may prescribe and ''[t]here are occasions when one needs to go beyond the 90.'' *Id.* at 118. Dr. Munzing's testimony, when he offered to explain his response with an analogy, was cut off by a ''nonresponsive'' objection by Respondent. *Id.* at 119–22 (colloquy including ALJ's ruling sustaining the objection and his subsequent recap and explanation of his ruling). Given the entirety of the record transmitted to me, including the many examples of Respondent's controlled substance prescribing beneath the applicable standard of care and outside the usual course of professional practice, there is no need for me to consider the OSC's MME-levels-above-90-mg/day allegations, I am not doing so, and those allegations play no role in this Decision/Order. *Cf. id.* at 188 in conjunction with Jt. Stip. 79 (Dr. Munzing's testimony that Respondent's prescribing 90 mg/day of oxycodone for S.D. on February 4, 2019, March 1, 2019, and April 2, 2019, was beneath the applicable standard of care and outside the usual course of professional practice ''because we just don't have any information'').

[48] The medical records for the June 5, 2013 visit state that A.A. experienced left knee pain for three weeks and that Respondent gave A.A. an intra-articular steroid knee injection under ''strict aseptic technique'' during that visit. GX 12B, at 115–17.

be adhesions in the epidural space'' from ''inserting these percutaneous leads into the epidural space'' that ''do break up adhesions and stuff like that'' and ''there is a tiny bit of a therapeutic kind of thing there when you break up some adhesions.'' Tr. 1141. He testified that A.A. ''varied her dose from three to six tablets [of methadone] a day'' meaning that she ''had increased her activity level because she was doing things at—that she didn't necessarily do'' because ''she was able to figure out, 'If I took more medication on a particular day, I was able to accomplish greater tasks.' '' *Id.* at 1142. Respondent's testimony about this matter included an example: ''I can go to Costco if I take an extra [methadone] tablet.'' [49] *Id.; see also id.* at 141–44; *id.* at 665–74 (Dr. Helm's testimony stating Respondent ''documented increased pain reports and that would provide the basis for an increase'' and concluding that ''someone could argue should you increase or not, but that's a medical judgment''). Respondent's testimony about these matters did not address safety concerns or risks to A.A. of her self-dosing methadone. *Supra* section III.E. (Dr. Helm's testimony that methadone is disproportionately a cause of death because its half-life in the body is longer than the period of pain relief).

I credit Dr. Munzing's testimony regarding the medical records Respondent created about these methadone increases. *Supra* sections II, III.D., and III.E. Dr. Munzing addressed the first part of the paragraph called ''Pain HPI'' for the January 11, 2013 visit, which states A.A. ''appeared to be improved after the stimulator was tried.'' GX 12B, at 80. He testified that ''one would not certainly want to increase . . . [methadone] when there's improvement.'' Tr. 142; *see also id.* at 551–52; *id.* at 566–67. Regarding the last part of the same ''Pain HPI'' paragraph which states ''[h]igher dose of MTD necessary lately due to the intensity of her complaints,'' Dr. Munzing testified that A.A. was already at high risk due to very high dosages and the combination of medicines. *Id.* at 143; GX 12B, at 80; *see also* Tr. 551 (Dr. Munzing's testimony that increasing methadone from four a day to six a day is a ''large jump''); *id.* at 666 (Dr. Helm's testimony that ''some consider'' Respondent's doses high). Dr. Munzing testified that ''there are other alternatives, safer alternatives than just continuing to increase the dosage of medicine and putting a patient at much higher risk than they already are.'' Tr. 143; *see also id.* at 673 (Dr. Helm's testimony that, although A.A. reported benefits at the higher dose, ''it's something you don't want to encourage going forward'' because ''patient safety is the number one concern''); *id.* at 773 (Dr. Helm's testimony that ''there's no question you don't want patients taking meds *ad lib,* and I would share that, you know, while I get somebody who tells me that they have to do something it really raises an eyebrow because I don't want them to be just doing whatever it is they feel to do because—what they feel like they should do because that does create great risk''); *id.* at 773, 778 (Dr. Helm's testimony that Respondent did not document a conversation with A.A. about her not having taken the methadone as prescribed, that Dr. Helm agrees ''that is a documentation issue,'' and, consequently, that ''[w]e don't know what's going on'') in conjunction with *id.* at 782 (Dr. Helm's testimony, positing without a factual basis, that Respondent's failure to document is not a public health issue, but that Dr. Helm's ''practice would be . . . if she'[s] taking less to provide less'') and *id.* at 674 (Dr. Helm's testimony that ''what's remarkable about these patients is that by and large they did present improved benefit, which is unusual for the high-dose opioid patients,'' citing the Opioid Pain Consortium FDA-mandated study about opioid-induced hyperalgesia); *id.* at 885–889. I credit Dr. Munzing's testimony over Dr. Helm's testimony when the two conflict, and I afford Respondent's testimony limited credibility as the respondent in this adjudication. *Supra* sections II, III.D., and III.E.

Accordingly, I find substantial record evidence that Respondent issued the methadone prescriptions for A.A. in GX 11 beneath the applicable standard of care and outside the usual course of professional practice.[50] Tr. 144; GX 11, at 1–31.

The parties stipulated that Respondent's first medical record-documented visit with R.B. took place on January 8, 2016. Jt. Stip. 63. During that initial visit, the parties stipulated, R.B. told Respondent that he ''was constantly in pain and had previously taken oxycodone and was then currently taking six tablets of Norco (hydrocodone-acetaminophen) 10/325 mg[ ] a day.'' Jt. Stip. 64. R.B.'s urine drug screen from that first visit, according to the parties' stipulation, was positive for THC. Jt. Stip. 65. The urine drug screen results did not corroborate R.B.'s statement to Respondent that he ''was then currently taking six tablets of Norco . . . a day.'' Jt. Stip. 64. The parties further stipulated that Respondent issued R.B. a controlled substance prescription for 90 tablets of oxycodone 30 mg at this initial visit. Jt. Stip. 66.

Based on my review of the record evidence regarding R.B.'s first visit with Respondent, I find substantial record evidence that Respondent issued a controlled substance prescription to R.B., for 90 tablets of oxycodone 30 mg, without documenting his knowledge of R.B.'s medical history based on input directly from R.B.'s previous physician or physician assistant, without documenting that he addressed R.B.'s in-house, positive THC urine drug screen, and without documenting that he assessed R.B. for the risk of opioid abuse. Tr. 155–56 (Dr. Munzing's testimony, including that he ''do[es]n't see any further history and specifics in detail regarding other drug use,'' that ''there's no kind of detailed evaluation of both current and also past drug use and is there any history,'' that he ''do[es]n't see any kind of opioid risk tool or other screening for—there's SOAPP . . . and also the ORG, Opioid Risk Tool, that gives you an idea about risk for abuse,'' and that he ''do[es]n't see any specifics in past medical records that would verify a lot of this . . . [s]o you're going essentially from zero . . . immediately to 135, so . . . [he has] great concerns about that visit''); MBC Guide to the Laws, at 59–61; *see also* GX 14B, at 72–74; *compare* Tr. 675–78 (Dr. Helm's testimony that it was ''medically appropriate'' to ''initiate care'' and ''appropriate treatment'' for Respondent to prescribe oxycodone because it was of benefit in the past and the R.B. reported he was not benefitting from Norco) with *id.* at 784–85 (Dr. Helm's testimony agreeing that a physician ''can't just rely on what another physician did in . . . [his] own decisions to prescribe a particular controlled substance''). I credit Dr. Munzing's testimony.

Accordingly, I find substantial record evidence that Respondent issued the first 90 tablet oxycodone 30 mg

[49] The ALJ stated, after hearing this portion of Respondent's testimony, that ''I don't understand your answer.'' Tr. 1142.

[50] The Government alleged that Respondent's Xanax prescriptions were not legitimate because he continued them in the face of A.A.'s aberrant urine drug screens. Tr. 144–53. The Government's case did not note, analyze, or address the ''prn'' notation on the Xanax prescriptions. Accordingly, I find that the Government did not present a *prima facie* case on this allegation. *See, e.g.,* GX 11, 1–31.

The record evidence, though, that Respondent conducted urine drug screens, yet did not analyze and note, let alone act on, the results is puzzling at best. At worst, it raises serious questions about Respondent's knowledge about, and implementation of, controlled substance-related best practices. *Supra* section III.E. The Government did not pursue these matters and, accordingly, they play no role in my Decision/Order.

prescription for R.B. beneath the applicable standard of care and outside the usual course of professional practice. MBC Guide to the Laws, at 59–61.

Regarding the record evidence concerning R.B.'s second visit with Respondent, I find substantial record evidence that R.B. reported feeling ''much improved'' with ''[s]ome of . . . [his] pain . . . even down to a 1–2/10.'' GX 14B, at 70; *see also* Tr. 156, 159–60. I credit Dr. Munzing's testimony that ''you have to take in the whole context . . . [a]nd . . . [Respondent] should not have issued that prescription. You have . . . aberrant urine drug tests that aren't being explained . . . [and R.B.] starts out [saying he] is much improved. Well, if you're much improved, then maybe we've overshot and we can . . . give you much less.'' Tr. 159–60. I find no record evidence that Respondent documented use of his professional judgment to evaluate R.B.'s changed pain report and to consider adjusting the 90 tablet oxycodone 30 mg therapy he initiated on R.B.'s prior visit. GX 14B, at 70–71.

Accordingly, I find substantial record evidence that Respondent issued the second 90 tablet oxycodone 30 mg prescription for R.B. beneath the applicable standard of care and outside the usual course of professional practice. MBC Guide to the Laws, at 59–61.

Also concerning R.B.'s second visit with Respondent, there is substantial record evidence that the in-house UDS was again positive for THC and was also positive for oxycodone, opioid, and benzodiazepine. GX 14B, at 71; *see also* Tr. 157–58. However, there is no record evidence that Respondent ever issued R.B. a prescription for THC or for a benzodiazepine. *See, e.g.,* Tr. 1114–15. I credit Dr. Munzing's testimony, and I find substantial record evidence that this second-visit, in-house UDS was aberrant and that Respondent's medical record for this visit with R.B. does not document that he addressed this aberrancy in any way. *Id.* at 157–58; *supra* sections II, III.D., and III.E.

Accordingly, I find further substantial record evidence that Respondent issued the second 90 tablet oxycodone 30 mg prescription for R.B. beneath the applicable standard of care and outside the usual course of professional practice. GX 14B, at 71; MBC Guide to the Laws, at 60–61.

Further, the parties stipulated that Respondent increased the oxycodone 30 mg prescription for R.B. from 90 tablets to 120 tablets on April 6, 2016. Jt. Stip. 74; GX 14B, at 69. During the same visit, however, the substantial record evidence shows that Respondent documented in R.B.'s medical record that R.B. reported ''[f]eeling much improved,'' that ''all complaints of pain are less,'' and that R.B. exercised daily, predominantly by walking four to six miles. GX 14B, at 68; *see also* Jt. Stip. 75. I find no evidence in Respondent's medical record for the April 6, 2016 visit with R.B. that Respondent documented the professional judgment and analysis that led him to increase the oxycodone 30 mg prescription he issued for R.B. from 90 to 120 tablets. Tr. 170–71; *see also* GX 14B, at 68–69; Tr. 678–79 (Dr. Helm's testimony that the rationale for Respondent's prescribing ''would have to be . . . decrease pain and increase function'').

Accordingly, I find substantial record evidence that Respondent issued the April 6, 2016 120 tablet oxycodone 30 mg prescription for R.B. beneath the applicable standard of care and outside the usual course of professional practice. GX 14B, at 68–69; MBC Guide to the Laws, at 59–61.

I find substantial record evidence that Respondent prescribed R.B. the controlled cough medicine promethazine with codeine. *See, e.g.,* GX 14B, at 13–24. According to Dr. Munzing's testimony, which I credit, promethazine with codeine is a highly abused controlled substance. Tr. 172; *supra* sections II, III.D., and III.E. I find substantial record evidence that Respondent's medical record for R.B.'s February 7, 2018 visit states that R.B.'s primary care physician ''will no longer prescribe . . . [R.B.] the cough syrup'' and that Respondent issued R.B. a prescription for that controlled substance, including a refill, on that day. GX 14B, at 24; *see also* Tr. 1108. Dr. Munzing's analysis of Respondent's medical records for R.B., which I credit, includes that Respondent did not document conducting a lung examination or evaluation of R.B. prior to issuing this controlled substance prescription. Tr. 173; *supra* sections II, III.D., and III.E.; *see also* Tr. 480–81 and *id.* at 1109 (Respondent's testimony that he ''never delved into'' why R.B. had the cough and the ''bottom line is, he had a cough''). Dr. Munzing's testimony about Respondent's medical records states, and I credit his testimony, that the ''primary physician has cut . . . [R.B.] off[, w]e don't know why[, i]t's not explored[,] and it's not documented why the primary physician cut him off.'' *Id.* at 174; *supra* sections II, III.D., and III.E. I also find that Dr. Munzing credibly testified that Respondent is a pain management doctor, not a pulmonologist, and credibly questioned whether Respondent is the ''right person'' to diagnose a pulmonary matter and to evaluate whether this controlled substance is the appropriate way to treat this pulmonary matter. Tr. 174; *see also id.* at 481. Specifically, Dr. Munzing testified, and I credit his testimony, that ''prescribing promethazine with codeine on a chronic, ongoing basis is not the treatment for anything and is high risk for abuse.'' *Id.* at 176; *supra* sections II, III.D., and III.E.; *but cf.* Tr. 684–85 (Dr. Helm's testimony answering ''[s]ure'' when asked whether it was ''within the standard of care'' for Respondent to ''agree to take over prescribing'' the promethazine with codeine because ''the primary care physician bluntly had been low-hanging fruit for the Medical Board in terms of their prescribing, so . . . many of them just don't want to prescribe controlled substances, and it is very consistent with the environment'') and *id.* at 1108 (Respondent's similar testimony).

Accordingly, I find substantial record evidence that Respondent issued the February 7, 2018 promethazine with codeine prescription for R.B. beneath the applicable standard of care and outside the usual course of professional practice. MBC Guide to the Laws, at 59–61.

In sum, based on all of the record evidence, I find substantial record evidence that Respondent issued controlled substance prescriptions for R.B. below the applicable standard of care and outside the usual course of professional practice. MBC Guide to the Laws, at 59–61; *see also, e.g.,* Tr. 164; *id.* at 166; *id.* at 175–77.

There is substantial record evidence that Respondent's controlled substance prescribing for S.D. was below the applicable standard of care and outside the usual course of professional practice. For example, there is substantial record evidence that Respondent concurrently issued on twelve occasions between January 2018 and January 2019, and S.D. filled, controlled substance prescriptions for methadone 10 mg, Roxicodone 15 mg, and carisoprodol 350 mg. GX 15, at 1–24. There is also substantial record evidence that the number of tablets Respondent prescribed for S.D. during this period increased from 180 to 270 tablets of methadone and from 60 to 120 tablets of carisoprodol. *Id.* According to Dr. Munzing's testimony, which I credit, Respondent issued these prescriptions beneath the applicable standard of care and outside the usual course of professional practice. Tr. 206–207 (Dr. Munzing's testimony that ''based on not just the prescription but . . . what we've reviewed, the medical records, is that that's not medically justified, not

usual professional practice); *supra* sections II, III.D., and III.E.

Accordingly, I find substantial record evidence that Respondent issued these controlled substance prescriptions for S.D. below the applicable standard of care and outside the usual course of professional practice. MBC Guide to the Laws, at 59–61.

The parties stipulated that Respondent prescribed 90 mg of oxycodone/day for S.D. on February 4, 2019, March 1, 2019, and April 2, 2019. Jt. Stip. 79. According to Dr. Munzing's testimony, which I credit, Respondent's issuance of these three stipulated prescriptions did not comply with the applicable standard of care and was outside the usual course of professional practice because Respondent did not document their issuance in S.D.'s medical records. Tr. 188 (Dr. Munzing's testimony that these prescriptions were issued beneath the applicable standard of care and outside the usual course of professional practice); *supra* sections II, III.D., and III.E.

Accordingly, I find substantial record evidence that Respondent issued these controlled substance prescriptions for S.D. below the applicable standard of care and outside the usual course of professional practice. MBC Guide to the Laws, at 59–61.

The parties stipulated that, on February 24, 2016, Respondent increased the methadone prescription for S.D. from 120 tablets to 180 tablets. Jt. Stip. 80; GX 16D, at 76–77. According to Dr. Munzing's testimony, which I credit, the medical record Respondent created for S.D.'s February 24, 2016 visit, documents a ''very minimal exam'' on which the increased dosage ''couldn't be based.'' GX 16D, at 76–77; Tr. 188–89 (Dr. Munzing's testimony, including that, ''without an exam, without a lot of details . . . I don't see anything that would justify that increase''); *supra* sections II, III.D., and III.E.

Similarly, the parties stipulated that, on April 20, 2018, Respondent increased the methadone prescription for S.D. from 180 tablets to 270 tablets. Jt. Stip. 81; GX 16D, at 23–25 (''current meds are inadequate in controlling her pain even if she takes them exactly on schedule'' and ''[d]ue to inadequate pain relief, increase MTD 10 mg to #270 3 tabs TID prn. Continue other meds; appropriate refills given''). According to Dr. Munzing's testimony, which I credit, Respondent's April 20, 2018 prescription for S.D., increasing the methadone prescribed from 180 tablets to 270 tablets, was issued beneath the applicable standard of care and outside the usual course of professional practice. Tr. 190–91; *supra* sections II, III.D., and III.E. Dr. Munzing testified, regarding these methadone tablet increases, that they put S.D. ''at incredibly high risk,'' particularly because of S.D,'s age, and that there is no medical record documentation that S.D. was made aware of and consented to that ''incredibly high risk.'' Tr. 191–92.

Accordingly, I find substantial record evidence that Respondent issued his February 24, 2015 and April 20, 2018 methadone prescriptions for S.D. below the applicable standard of care and outside the usual course of professional practice.[51] MBC Guide to the Laws, at 59–61.

The parties stipulated that the first visit of Respondent with L.D. was on June 20, 2011. Jt. Stip. 82; *see also* GX 18B, at 145–46. The parties also stipulated, about this first visit, that Respondent documented that L.D. was ''taking amphetamine.'' Jt. Stip. 83; *see also* GX 18B, at 145. According to his medical records for L.D.'s first visit on June 20, 2011, Respondent documented ''[r]efill of Amphetamine salts given.'' GX 18B, at 146. Dr. Munzing testified, and I credit his testimony, that Respondent's medical record for L.D.'s first visit is ''completely unclear '' about why L.D. was taking amphetamine. Tr. 208; *see also id.* at 491–92 (Dr. Munzing's testimony that Respondent's medical records document that L.D. complained of pain, do not document that L.D. complained of fatigue, do not document an exhaustive review of symptoms, and do not document an evaluation or diagnosis of chronic fatigue syndrome); *id.* at 568–69; *id.* at 709–10 (Dr. Helm's testimony that the medical records for L.D.'s first visit with Respondent show no diagnosis for which Respondent prescribed amphetamine salt); *id.* at 797–99 (Dr. Helm's testimony that a diagnosis (chronic fatigue syndrome) that might call for treatment with amphetamine salt first appears in the medical records for L.D.'s third visit). Dr. Munzing further testified that Respondent's medical records for L.D.'s June 20, 2011 visit include ''no diagnosis of ADHD, attention deficit hyperactivity disorder, or similar'' diagnosis. *Id.* at 208. Dr. Munzing also testified that, ''typically, for most conditions, including the one that it's typically prescribed for, ADHD, when someone is on high doses of opioids, there are alternatives which generally are not controlled and are much safer, not addicting. And so one would typically not use . . . an amphetamine salt.'' *Id.* at 212–13. Dr. Munzing additionally testified that amphetamine salt ''would not typically be a medication prescribed by a pain medication pain management doctor.''[52] *Id.* at 209; *see also id.* at 491 (amphetamine salt is not a regularly labeled treatment for chronic fatigue syndrome); *id.* at 573–75. I credit Dr. Munzing's testimony. *Supra* sections II, III.D., and III.E. In addition, I note that there is agreement between Dr. Munzing and Dr. Helm on some of these matters. *Supra.*

Accordingly, I find, based on substantial record evidence, that Respondent's issuance to L.D. of a prescription for amphetamine salt on L.D.'s first visit with him was beneath the applicable standard of care and outside the usual course of professional practice. MBC Guide to the Laws, at 59.

Although Respondent's medical records for L.D. reference the criminal incarceration, up-coming trial, conviction, and sentencing of L.D.'s former spouse and L.D.'s up-coming sentencing hearing, I find no credible record evidence that they address whether the underlying criminal bases for these events were related to drugs.[53] GX 18B, at 82, 88. Dr. Munzing testified that such criminal-related litigation is a ''huge red flag'' that Respondent ''left wide open'' and ''all one needs to do is document and resolve the red flag.'' Tr. 232, 496–99; *see also id.* at 504. He testified that a ''medical record doesn't need the specifics, but it certainly does need to know does it have anything to do with the issues that we're dealing with here, and it was silent to that effect.'' *Id.* at 231; *cf. id.* at 715 (Dr. Helm's testimony that Respondent's medical records ''clearly showed'' that L.D.'s criminal involvement was ''business,'' but no direct response to Respondent's counsel's question of

[51] *See also* Tr. 190 (Dr. Munzing's testimony that S.D. ''has chronic significant medical problem[s]'' and ''[n]o one's arguing that'').

[52] According to a document in GX 18A entitled ''[L.D.'s] Doctors & Medication List,'' a pulmonologist prescribed L.D. amphetamine. GX 18A, at 82. The document is not dated and does not indicate its origin. Although Respondent testified about the document, his testimony did not address the document's origin. *Supra* section III.E.

[53] I note, in contrast, that Respondent's medical records for A.A. state that A.A.'s ''[d]aughter has been stealing her medications regularly, police report filed. Patient will now file a restraining order against her daughter,'' and that Dr. Munzing's testimony agrees with Respondent's counsel that ''[t]hat's all a very reasonable explanation to deal with stolen medication.'' GX 12B, at 154; Tr. 415. For A.A.'s next visit, Respondent wrote in the medical record that ''[d]aughter no longer living with her and therefore no further issues with meds being stolen,'' and that Dr. Munzing's testimony agrees with Respondent's counsel that that ''was good follow[-]up with respect to the daughter having stolen medications.'' GX 12B, at 151; Tr. 416; *see also id.* at 639–40 (Dr. Helm's testimony).

whether Respondent ''adequately document[ed]'' L.D.'s criminal status). ''[I]t's something that would be fairly simple to close that red flag, but was not addressed, was not done,'' Dr. Munzing further testified. *Id.* at 232. I credit Dr. Munzing's testimony that these criminal litigation-related medical records of Respondent are beneath the applicable standard of care and outside the usual course of professional practice. *Supra* sections II, III.D., and III.E.

Accordingly, I find substantial record evidence that Respondent's medical records pertaining to these criminal litigation-related matters are beneath the applicable standard of care and outside the usual course of professional practice. MBC Guide to the Laws, at 61.

As already discussed, the record evidence addresses the UDSes that Respondent conducted. *Supra* sections III.D. and III.E; *see also, e.g.,* GX 12, 14, 16, 18, 20, 22. Regarding Respondent's January 9, 2017 visit with L.D., for example, I find substantial record evidence that Respondent conducted a UDS and that Respondent's medical records show the UDS results to have been positive for benzodiazepine and opioid. GX 18B, at 35. I further find substantial record evidence that Respondent's medical records for that visit with L.D. also show that L.D.'s ''[m]eds include . . . [a]mphetamine salt 30 mg qd,'' that L.D.'s ''Current Medications'' section includes ''Amphetamine Salt Combo 30 mg Tab—Dispense: 30: 1 TABLET ORAL Q Day; Started: 06/20/2011,'' and that the ''Working Treatment Plan'' section states ''2 months scripts given for Amp Salt, DP, and Dilaudid 8 mg[ ]'' [54] *Id.* at 34–36. According to Dr. Munzing's testimony, which I credit, L.D.'s January 9, 2017 UDS result is ''[a]bsolutely'' aberrant—because it did not show a positive result for amphetamine salt—and Respondent did not address the aberrancy in the medical record. Tr. 234–35; *supra* sections II, III.D., and III.E.; *see also* Tr. 234–35 (Dr. Munzing's testimony that Respondent's compliance monitoring, including 2017 aberrant UDSes, ''certainly falls far short of the standard of care''), *id.* at 502–03 and GX 18B, at 101 (Respondent's May 14, 2013 medical records for L.D. noting ''[i]ntolerable'' pain, spasm, ''exacerbating RUE pain,'' and tension headache, yet recording UDS results as negative for prescribed controlled substances and being ''silent'' about, and recording no explanation for, the aberrancy, particularly when viewed in conjunction with the noted ''[i]ntolerable'' pain), and Tr. 236–37 (S.H.).[55]

Accordingly, I find substantial record evidence that Respondent acted beneath the applicable standard of care and outside the usual course of professional practice by failing to address an aberrant UDS and, despite the aberrancy, issued for L.D. a prescription for a two-month supply of amphetamine salt.[56] *See, e.g.,* MBC Guide to the Laws, at 60.

According to the parties' stipulation, J.M.'s first documented visit with Respondent was on May 17, 2011. Jt. Stip. 97. At that time, the parties further stipulated, J.M. ''reported to Respondent that he had difficulty getting OxyContin authorized and wanted to try oxycodone instead.'' Jt. Stip. 98. The parties also stipulated that Respondent checked CURES for J.M. on May 17, 2011. Jt. Stip. 103.a. I find, based on substantial record evidence, that Respondent issued a controlled substance prescription for J.M. on May 17, 2011. GX 22B, at 133 (Roxicodone 30 mg 180 tablets 1 q4–6 prn to a max of 6/day).

I find, based on substantial record evidence including Respondent's medical records for J.M., that the medical office that treated J.M. before Respondent's treatment transmitted a seven-page fax to Respondent on June 14, 2011. GX 22A, at 71–77. I find substantial record evidence that the fax cover sheet states ''[p]lease see attached medical records for . . . [J.M.] per your request.'' *Id.* at 71. I find substantial record evidence that the transmittal includes a letter from the medical practice to J.M. dated June 1, 2011. *Id.* at 72. I find substantial record evidence that the letter states that ''[i]t has been brought to . . . [the] attention'' of the medical office that J.M. ''violated our Controlled Substance Policy by receiving medications from multiple physicians per the DOJ report from 05/31/2011.'' *Id.* I find substantial record evidence that, after stating that the practice has ''nothing further to offer'' J.M. due to the ensuing ''eliminat[ion] of trust,'' the letter states that J.M. ''will receive a 30-day supply of . . . Oxycontin, and Roxicodone today,'' which will be J.M.'s ''final prescriptions filled by . . . [that] office.'' *Id.*

The parties stipulated that Respondent's medical records for J.M.'s June 17, 2011 visit document that J.M.'s mother ''came to the office'' with J.M. Jt. Stip. 99; *see also* Jt. Stip. 100 and GX 22B, at 128 (''Here with mother to plead mercy. Needs a doctor close to home. Wants a second chance.''). I find substantial record evidence that, in the ''Working Treatment Plan'' section of Respondent's medical records for J.M. for the June 17, 2011 visit, Respondent wrote ''One final chance; script for #180 Roxi given.'' GX 22B, at 129; *see also* Jt. Stip. 101–02.

Respondent testified about these initial visits with J.M. Among other things, Respondent admitted in his testimony that J.M. was on a high dose of oxycodone. Tr. 1097. Regarding J.M.'s visit with Respondent on May 17, 2011, Respondent testified that he ''was trying to put the pieces of the puzzle together'' and that he was with J.M. ''for excess of an hour, observing the way . . . [J.M.] walked into the room, observing the way he left the room, [and] observing the way that he remained seated for an excess of an hour.'' *Id.* at 1138. Respondent testified that he ''felt that that was adequate exam for these particular diagnoses'' and that he ''would not expect anything acute on exam'' related to J.M.'s ''long history of compression fractures.'' *Id.*

Regarding J.M.'s June 17, 2011 visit, Respondent testified, defending his issuance of a controlled substance prescription for J.M. without having conducted a physical exam, that ''nothing had changed in these few weeks and there were no acute findings'' and that he ''again, . . . would expect absolutely nothing acute

[54] According to the testimony of Dr. Munzing, ''DP'' means Duragesic Patch, or fentanyl patch. *See, e.g.,* Tr. 208.

[55] According to the record evidence, Respondent failed to document and address, explicitly, negative UDS results for controlled substances that he prescribed ''prn.'' *See, e.g.,* GX 20B, at 67–69 (S.H./methadone). While the analysis of UDS results for controlled substances issued ''prn'' differs from the analysis of UDS results for controlled substances not issued ''prn,'' an analysis would still ensue including, if appropriate, an assessment of whether to issue another prescription for the ''prn'' controlled substance if the controlled substance was not being ingested with the frequency the prescription allowed. The record evidence does not document that Respondent conducted any such analysis; however, I do not consider these matters in this Decision/Order.

[56] I note that Respondent's medical records state that, on June 18, 2012, he issued L.D. refills of Dilaudid, Klonopin, and amphetamine salt and that L.D. would see him again in two months. GX 18B, at 118. Respondent's medical records for L.D. on that date also document that L.D.'s UDS was positive for cocaine. *Id.; see also* Tr. 594 (Dr. Munzing's testimony that a cocaine-positive UDS is ''[s]uper aberrant''). I see nothing in the medical records documenting Respondent's review, consideration, evaluation, assessment, or addressing of L.D.'s cocaine-positive UDS. I find that these medical records are substantial record evidence of Respondent's failure to comply with the applicable standard of care and the usual course of professional practice. *See, e.g.,* MBC Guide to the Laws, at 60–61; *see also* Tr. 584–85, 610–12 (Dr. Munzing's testimony); *but see id.* at 713–14 (Dr. Helm's testimony that the cocaine-positive UDS was ''probably a false positive'' because ''[t]his is not a patient who—one would think would be getting cocaine,'' that he ''would have preferred to see a note in the chart just acknowledging that the finding is there,'' and that he ''think[s] there should have been more steps to confirm'' that the cocaine-positive UDS was a ''false positive'').

on the exam'' because he was ''only treating chronic pain.'' *Id.* at 1139.

Respondent also testified about J.M.'s July 15, 2011 visit with him. According to Respondent, he conducted a comprehensive physical examination of J.M. at that visit ''[b]ecause now the dust had settled,'' ''everything's organized,'' ''we're all in agreement,'' ''[w]e understand everything that's going on,'' ''[t]here was time, and it was time to carry on with this . . . situation,'' and ''[w]e had time to develop a baseline exam and everything like that.'' *Id.* at 1139–40. Respondent also testified that, during the July 15, 2011 visit, J.M. reported experiencing ''an exacerbation of pain,'' ''changes in his range of motion,'' and ''changes in his body movement,'' and ''so then we carry on with the full exam.'' *Id.* at 1140.

Dr. Helm also testified about Respondent's initial visits with J.M.[57] According to Dr. Helm, it is ''acceptable'' to ''defer'' a physical examination for a patient who is already on medications issued by another provider. *Id.* at 733. He testified that the physician is ''deferring the bulk of the exam'' due to being ''so busy . . . collecting the history and determining on the basis of histories or [sic] legitimate medical purpose for the medications'' and ''document[s] why'' the exam is being deferred. *Id.* at 733–34. Dr. Helm testified that he ''understands'' what Respondent's documentation of ''one final chance'' means, ''that . . . [Respondent] is willing to go forward with . . . [J.M.] on a, you know, if you will, a tight leash where he's really got to continue with the meds or continue with compliance and he can't be doing what he just did.'' *Id.* at 806.

Dr. Munzing also testified about Respondent's initial visits with J.M. Regarding J.M.'s May 17, 2011 visit with Respondent, Dr. Munzing testified that Respondent prescribed controlled substances for J.M. even though ''[w]e just don't know . . . [if J.M. was] actually taking all that medication'' based on J.M.'s own documented statement to Respondent that ''he had difficulty getting OxyContin authorized and wanted to try oxycodone instead.'' *Id.* at 548; Jt. Stip. 98; *see also* Tr. 548 (Dr. Munzing's testimony that ''[t]here's no documentation in here regarding urine drug test [sic], regarding prior records at this point, regarding any of that, and so that medication was prescribed strictly based on whether a patient told you without any other investigation, without a detailed review of the patient from what we can see, from what's documented, and without doing any examination of the patient''), *id.* at 547 (Dr. Munzing's testimony that ''[t]here's nothing—it does not appear based on what's documented that actually the Respondent even actually touched the patient, had him do any specific maneuvers . . . none of [what is done during a back exam] existed. None of that was documented.''), *id.* at 563–64 (same).

Regarding J.M.'s June 17, 2011 visit with Respondent, Dr. Munzing testified that ''it's a significant red flag that here [sic] pleading for mercy, one more chance . . . [and] no other significant information is documented. That's a great concern.'' Tr. 267. Dr. Munzing also addressed Respondent's issuance of Roxicodone 30 mg (180 tablets) and oxycodone 30 mg (180 tablets) to J.M. during their initial visits. Dr. Munzing testified that ''here we're three visits into it at least, and we have no exam at all but you're prescribing extremely high dosages of medication,'' that ''here we are just over two weeks later [from when J.M. received controlled substance prescriptions from his prior physician] and you're giving some more . . . [even though h]e should still have . . . at least another couple of weeks left, and so there's no indication to get more,'' and that ''there's a cascade of things that ought to be here,'' specifically listing information about mental health issues and about drug and alcohol current or past history, or use. *Id.* at 267–68.

I credit Dr. Munzing's testimony. *Supra* sections II, III.D., and III.E.

Accordingly, I find substantial record evidence that Respondent acted beneath the applicable standard of care and outside the usual course of professional practice by, for example, issuing J.M. controlled substance prescriptions at J.M.'s first two documented visits. *E.g.,* MBC Guide to the Laws, at 59.

As already discussed, based on these founded violations alone, I find that the Government presented a *prima facie* case. Accordingly, I see no need, and I decline, to discuss and assess the other OSC allegations and the other elements of the Government's case.

IV. Discussion

A. The Controlled Substances Act

Under Section 304 of the CSA, ''[a] registration . . . to . . . distribute[ ] or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined by such section.'' 21 U.S.C. 824(a)(4). In the case of a ''practitioner,'' which is defined in 21 U.S.C. 802(21) to include a ''physician,'' Congress directed the Attorney General to consider the following factors in making the public interest determination:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing . . . controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the . . . distribution[ ] or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f). These factors are considered in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003).

According to Agency decisions, I ''may rely on any one or a combination of factors and may give each factor the weight [I] deem[ ] appropriate in determining whether'' to revoke a registration. *Id.; see also Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018) (citing *Akhtar-Zaidi* v. *Drug Enf't Admin.,* 841 F.3d 707, 711 (6th Cir. 2016); *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *U. S. Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482. ''In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation

[57] While not explicitly addressed in the record evidence, Dr. Helm's testimony appears plausible that J.M. returned to his prior physician's medical practice after seeing Respondent on May 17, 2011, the prior physician's medical practice discovered from CURES that J.M. filled Respondent-issued controlled substance prescriptions, and the prior physician's medical practice dismissed J.M. for violating the policy of receiving medications from only one physician. Tr. 734–35. Dr. Helm's suppositions on these matters are irrelevant to, and therefore do not impact, my Decision/Order.

of a registration. *MacKay,* 664 F.3d at 821.

According to DEA regulations, ''[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied.'' 21 CFR 1301.44(e). In this matter, while I have considered all of the factors, the Government's evidence in support of its prima facie case is confined to Factors Two and Four.[58] Govt Posthearing, at 31. As already discussed, I find that a segment of the Government's case includes sufficient evidence with respect to Factors Two and Four to satisfy its prima facie burden of showing that Respondent's continued registration would be ''inconsistent with the public interest'' without my needing to consider its entire case, some of which is insufficiently developed. 21 U.S.C. 823(f). I further find that Respondent failed to produce sufficient evidence to rebut the Government's prima facie case.

B. Factors Two and/or Four—The Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

Allegation That Respondent's Registrations Are Inconsistent With the Public Interest

According to the CSA's implementing regulations, a lawful prescription for controlled substances is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). The Supreme Court has stated, in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription, that ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006).

Respondent engaged a skillful team and defended himself against all of the OSC's allegations. I read and analyzed every aspect of Respondent's defense including his record evidence. As already discussed, Respondent's evidence and argument are not persuasive on the founded violations. *Supra* section III.F.

Respondent's case admits that some of Respondent's medical recordkeeping is substandard. *See, e.g. supra* section III.F; Tr. 773, 778 (Dr. Helm's testimony about the lack of Respondent's documentation and, in the absence of his documentation, ''[w]e don't know what's going on''). Respondent's case and hearing testimony about the existence, content, and accuracy of his medical records, however, largely excuse his documentation failures. *See, e.g., supra* section III.E.; Tr. 940 (Respondent's testimony that A.A.'s aberrant UDS ''was not of significance to me'' and ''was not of concern to me'' because ''she is my patient,'' ''I'm her doctor,'' and ''I have a relationship with her . . . an understanding with her . . . [a]nd this was not a cause for alarm''); *id.* at 962–63 (Respondent's testimony that his ''record is wrong because I'm so busy talking to the patient . . . [b]ut again, from this chart, that's not a big problem, because it's historically her left knee''); *id.* at 972 (Respondent's testimony that ''a lot of [his medical] records have been read wrong and interpreted wrong [at the hearing] because I'm doing a million things at once, and people are trying to read the exact word''). Respondent's case does not include citation to the applicable standard of care's allowance for such excuses, and I found none. *See supra* section II.

By way of further example, Respondent's case admits that some of Respondent's controlled substance prescription monitoring is substandard. *See, e.g., supra* section III.E; Tr. 1098 (Respondent's testimony that he did not consider a UDS to be aberrant if it is negative for a substance he prescribed, admitting that his ''attorney then, you know, corrected me on that statement''). Respondent testified that he used UDSes to look for the presence of substances that he had not prescribed. Tr. 1098. Yet, despite this testimony, by his own admission he did not follow up on L.D.'s cocaine-positive UDS documented in the medical records until during preparations for this hearing. *Supra* section III.E.

As already discussed, there is substantial record evidence that Respondent issued controlled substance prescriptions before conducting the requisite physical examination and before documenting a diagnosis. *Supra* section III.F. There is substantial record evidence that he prescribed controlled substances as favors or accommodations. *Id.* There is substantial record evidence that Respondent increased the dosages of controlled substances he was prescribing, even controlled substances that are highly abused and diverted and that are a disproportionate cause of death, without the requisite documentation. *Id.* There is even substantial record evidence that Respondent increased the dosage of a controlled substance on the recipient's demand, against his previous medical analysis and medical judgment, and increased the dosage of other controlled substances based on ''ad lib'' self-dosing. *Id.* There is substantial record evidence that Respondent issued controlled substance prescriptions without accurate and complete documentation and based on the representations of others, as opposed to basing it on his independent medical analysis and judgment. *Id.* There is substantial record evidence that Respondent failed correctly to identify aberrant UDSes, to document them, and to resolve them before further prescribing the controlled substance at issue in the aberrancy. *Id.* There is substantial record evidence that Respondent failed to identify and resolve other red flags of abuse and diversion before further prescribing the controlled substance. *Id.*

As already discussed, I find that these unrebutted actions and inactions by Respondent in his controlled-substance related prescribing are violations of the applicable standard of care and are outside the usual course of professional practice and, therefore, are CSA violations. 21 CFR 1306.04(a). Accordingly, I find that it is appropriate to sanction Respondent for these violations.

[58] As to Factor One, the Government does not dispute, and there is no record evidence disputing, Respondent's claims that he has an unblemished medical record and has never had any disciplinary action brought against his license, presumably meaning his medical license. Resp Posthearing, at 2, 21–22; 21 U.S.C. 823(f)(1). State authority to practice medicine is ''a necessary, but not a sufficient condition for registration . . . .'' *Robert A. Leslie, M.D.,* 68 FR at 15230. Therefore, ''[t]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of Respondent's DEA certification is consistent with the public interest.'' *Roni Dreszer, M.D.,* 76 FR 19434, 19444 (2011).

As to Factor Three, there is no evidence in the record that Respondent has a ''conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, as prior Agency decisions have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.,* 75 FR 49956, 49973 (2010), *pet. for rev. denied, MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808 (10th Cir. 2011). Those Agency decisions have therefore concluded that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

The Government's case includes no allegation under Factor Five.

Summary of Factors Two and Four and Imminent Danger

As already discussed, Respondent's case does not successfully rebut the Government's *prima facie* case, established by substantial record evidence, that Respondent issued controlled substance prescriptions beneath the applicable standard of care and outside the usual course of professional practice. Accordingly, I find that Respondent engaged in egregious misconduct which supports the revocation of his registrations. *See Wesley Pope,* 82 FR 14944, 14985 (2017).

For purposes of the imminent danger inquiry, my findings also lead to the conclusion that Respondent ''fail[ed] . . . to maintain effective controls against diversion or otherwise comply with the obligations of a registrant'' under the CSA. 21 U.S.C. 824(d)(2). The substantial record evidence that Respondent issued controlled substance prescriptions beneath the applicable standard of care and outside the usual course of professional practice establishes that there was ''a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance . . . [would] occur in the absence of the immediate suspension'' of Respondent's registrations. *Id.; see, e.g.,* Tr. 1030–32 (Respondent's testimony about his prescribing Duragesic patch when ''you haven't been on it for a while, and you might not even need that much'' and then increasing the dosage based on self-dosing reports); *id.* at 842 (the testimony of Dr. Helm that methadone is a disproportionate cause of death). Thus, I find that, at the time the OSC was issued, there was clear evidence of imminent danger.

V. Sanction

Where, as here, the Government has met its prima facie burden of showing that Respondent's continued registration is inconsistent with the public interest due to his numerous violations pertaining to controlled substance prescribing, the burden shifts to the Respondent to show why he can be entrusted with a new registration. *Garrett Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018) (collecting cases). Moreover, as past performance is the best predictor of future performance, DEA Administrators have required that a registrant who has committed acts inconsistent with the public interest must accept responsibility for those acts and demonstrate that he will not engage in future misconduct. *Id.* A registrant's acceptance of responsibility must be unequivocal. *Id.* In addition, a registrant's candor during the investigation and hearing has been an important factor in determining acceptance of responsibility and the appropriate sanction. *Id.* (collecting cases). In addition, DEA Administrators have found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Id.* DEA Administrators have also considered the need to deter similar acts by the respondent and by the community of registrants. *Id.*

Regarding these matters, I find that Respondent did not take responsibility, let alone unequivocal responsibility, for the founded violations. Tr. 1116 (Respondent's ''I don't'' response during his testimony when asked ''Do you accept responsibility for the prescriptions at issue not being issued in the usual course of professional practice?''). Concerning his medical recordkeeping, while Respondent ''acknowledged'' that it ''could be improved,'' this acknowledgement is not an acceptance of responsibility, let alone an unequivocal acceptance of responsibility. *Id.* at 1133. Further, Respondent's testimony after ''acknowledging'' that his medical recordkeeping could be improved was that ''in retrospect, thinking last night, I could have actually—even with what I have, I could have improved my recordkeeping because it's part of my electronic medical record under treatment plan where you click boxes. . . . [T]here is a section where you can click that the urine drug screens were checked.'' *Id.* at 1133–34. The ALJ followed up with the Respondent on this portion of his testimony, stating that ''these medical records that you have . . . the capability of checking a box that shows that you checked the CURES report or checking a box to show that you had conducted a UDS . . . really is not the problem with this case.'' *Id.* at 1134. ''The problem with this case,'' the ALJ continued, ''is that—it doesn't show that you did anything with it.'' *Id.* When Respondent reacted to the ALJ by stating ''[t]hat I discussed it,'' the ALJ stated ''Yes. So that's not checking a box.'' *Id.* at 1135. I agree with the ALJ. Accordingly, even if it were appropriate to consider Respondent's electronic medical record testimony to be Respondent's proposed remedial measures, I would find Respondent's proposal to be insufficient.

I also note that Respondent testified further about his substandard recordkeeping and the ways he will improve. *Id.* at 1086. Respondent testified that he ''need[s] to learn to type and speak at the same time'' instead of ''spending so much time discussing with the patient's issues.'' *Id.* He also testified that he ''guess[es]'' he could hire a scribe, ''somebody who is sitting there typing while you talk,'' but that he's ''not interested in having someone interfere with . . . [his] relationship with . . . [his] patient.'' *Id.* Respondent further testified that ''the world has changed'' and that he ''now need[s] to think of . . . [his medical records] as not about . . . [him but as a] document [that] is going to be scrutinized by everyone.'' *Id.* at 1087. I reject the suggestion that the applicable standard of care forces a physician to choose between compliance with that standard of care and providing patients medical care that complies with the applicable standard of care within the usual course of professional practice. I find that Respondent's suggestion of this false choice reflects an insufficient appreciation and understanding of medical recordkeeping standards of care and the responsibilities of a registrant.

In sum, I find that the record supports the imposition of a sanction because Respondent did not unequivocally accept responsibility and because Respondent has not convinced me that he can be entrusted with a registration.

The interests of specific and general deterrence weigh in favor of revocation. Respondent explicitly refused to accept responsibility for his substandard controlled substance prescribing. *Id.* at 1116. Respondent has not convinced me that he understands that his controlled substance prescribing fell short of the applicable standard of care and that this substandard controlled substance prescribing has serious negative ramifications for the health, safety, and medical care of individuals who come to him for medical care. As such, it is not reasonable for me to believe that Respondent's future controlled substance prescribing and recordkeeping will comply with legal requirements. Further, given the nature and number of Respondent's violations, a sanction less than revocation would send a message to the existing and prospective registrant community that compliance with the law is not a condition precedent to maintaining a registration.

Accordingly, I shall order the sanctions the Government requested, as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f) and 824(a), I hereby revoke DEA Certificates of Registration BR0869719 and BA7661564 along with DATA-

Waiver No. XR0869719 issued to Craig S. Rosenblum, M.D. I further hereby deny any pending application(s) of Craig S. Rosenblum, M.D., to renew or modify these registrations, as well as any other pending application(s) of Craig S. Rosenblum, M.D., or Aurora Surgery Center LP for registration in California. This Order is effective May 9, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–07727 Filed 4–8–22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Christopher King, C.N.P.; Decision and Order

On December 18, 2019, a former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Christopher C. King, N.P. (hereinafter, Applicant) of Manchester, Maine. Request for Final Agency Action (hereinafter, RFAA), Exhibit (hereinafter, RFAAX) 2 (OSC), at 1. The OSC proposed to deny Applicant's DEA Certificate of Registration application, Number W19022896M, as well as to deny any pending applications for renewal or modification of such registration and any applications for any other registrations pursuant to 21 U.S.C. 824(a)(4) and 823(f), because ''[Applicant's] registration is inconsistent with the public interest.'' *Id.*

The OSC alleged that Applicant had ''exhibited negative experience in handling controlled substances . . . and [had] failed to comply with applicable federal and state laws relating to controlled substances.'' *Id.* at 2. Specifically, the OSC alleged that, while employed at Mercy Hospital from April 10, 2013, to June 13, 2013, Applicant diverted controlled substances on at least two different occasions in violation of federal and state law. *Id.* at 4–6. The OSC also alleged that, while employed at St. Mary's Regional Medical Center (hereinafter, St. Mary's Hospital) from August 25, 2014, until November 1, 2016, Applicant diverted controlled substances on at least five different occasions in violation of federal and state law. *Id.* at 2–3.

The OSC notified Respondent of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 3 (citing 21 CFR 1301.43). The OSC also notified Respondent of the opportunity to submit a corrective action plan. *Id.* at 6–7 (citing 21 U.S.C. 824(c)(2)(C)).

Adequacy of Service

In a Declaration dated August 23, 2021, a Diversion Investigator (hereinafter, the DI) assigned to the Manchester District Office stated that on December 18, 2019, she sent a copy of the OSC to ''both [Applicant's] registered and mailing address via First Class Mail'' and ''sent the [OSC] via certified mail on the following day.'' DI's Declaration, at 2. The DI stated that on December 19, 2019, she ''contacted [Applicant] by phone at the mobile number listed on his application.'' *Id.* According to the DI, she ''explained what an [OSC] was, and requested that [Applicant] contact [her] when he received a copy of the [OSC].'' *Id.* The DI stated that on December 26, 2019, she received an email from Applicant that read, '' 'I have received the hard copy of the [OSC] in the mail. I do not want to pursue this matter and do not feel it is necessary to meet and discuss.' '' *Id.; see also* RFAAX 3 (email from Applicant).

The Government forwarded its RFAA, along with the evidentiary record, to this office on August 26, 2021. In its RFAA, the Government represents that Applicant did not request a hearing. RFAA, at 1. The Government requests that ''the Administrator issue a final order denying the DEA Certificate of Registration application for [Applicant]'' because ''Applicant's [r]egistration is not in the public interest.'' *Id.*

Based on the DI's Declaration, the Government's written representations, and my review of the record, I find that the Government accomplished service of the OSC on Applicant on or before December 26, 2019. I also find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the DI's Declaration, the Government's written representations, and my review of the record, I find that neither Applicant, nor anyone purporting to represent Applicant, requested a hearing, submitted a written statement while waiving Applicant's right to a hearing, or submitted a corrective action plan. Accordingly, I find that Applicant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

I. Findings of Fact

A. Application for DEA Registration

On March 12, 2019, Applicant applied for a DEA Certificate of Registration as a practitioner in Schedules II through V with a proposed registered address of 29 Bowdoin St, Manchester, ME 04351. RFAAX 1, at 1. Applicant's application was assigned Control No. W19022896M. *Id.*

B. Government's Case

The Government's RFAA includes the DI's Declaration and 10 attached Exhibits, including a copy of Applicant's application for DEA registration, various documents pertaining to the drug diversion allegations against Applicant at both St. Mary's Hospital and Mercy Hospital, and a copy of a Consent Agreement between Applicant and the Maine Board of Nursing in which Applicant's license to practice nursing was suspended. *See* RFAAX 1–10.

The DI's Declaration described the investigation into Applicant, including the collection of the Government's Exhibits. DI's Declaration, at 1–3. On June 13, 2013, Mercy Hospital issued a letter to Applicant following an investigation regarding Applicant's ''suspicious behavior'' during his shift on June 4, 2013. RFAAX 9. According to the letter, on June 4, 2013, ''medical waste (wet bloody paper towel, open syringe wrapper, syringe cap, open band aid wrapper, and an open alcohol wipe wrapper) was found in the bathroom in the staff break room.'' *Id.* Applicant's nurse manager ''had noted that [Applicant] had recently come into the area and had been in the bathroom.'' *Id.* According to the letter, video footage of the Emergency Department area prior to the medical waste being found was reviewed, and Applicant was observed pulling Dilaudid from the Pyxis machine and then entering the patient area for several minutes. *Id.* The video footage showed Applicant going to a supply cart and putting supplies in his pants pocket, then exiting the Emergency Department and entering the staff break room around the same time that Applicant's nurse manager had seen Applicant enter the bathroom. *Id.* The video footage showed Applicant returning to the Emergency Department several minutes later and going immediately to a sharps disposal container, where he pulled something from his pants pocket to dispose of in that container. *Id.* Finally, the video footage showed Applicant requesting an

additional dose of Dilaudid from the ordering physician for the patient. *Id.*

According to the letter, after review of Applicant's other worked shifts since his start at Mercy Hospital, there was ''further concern that similar behavior occurred on another shift.'' *Id.* During a meeting with Applicant on June 4, 2013, Applicant ''indicated that the patient did receive both doses of Dilaudid on that day; however, [Applicant was] unable to provide a clear answer as to why [he] had put a sharp in [his] pocket and later disposed of it [ ] when there are sharps containers in every patient bay[ ].'' *Id.* Moreover, during a phone conversation on June 12, 2013, Applicant ''declined to return to Mercy [Hospital] to participate in a follow-up conversation to [the] investigation.'' *Id.* According to the letter, Applicant was told that because of his behavior, Mercy Hospital had concerns that he may have been diverting medication, and consequently, Applicant's employment at Mercy Hospital was terminated effective June 13, 2013. *Id.*

On November 1, 2016, a Risk Manager at St. Mary's Hospital issued a Memorandum to the HR department regarding an ''Investigation of Suspicion of Drug Diversion.'' RFAAX 6, at 1. According to the Memorandum, on September 24, 2016, Applicant ''was found to have pulled a medication for another Emergency Department nurse's patient.'' *Id.* Further, chart documentation ''notes the medication as 'contaminated' and another vial was pulled and given to the patient by the nurse assigned to that patient.'' *Id.* The medication pulled was ''Hydromorphone 1 mg/1 mL Syringe.'' *Id.* According to the Memorandum, ''[w]hen handed to the other nurse, she noticed that the vial had been accessed and reported it to the nursing supervisor who then contacted the Director of the Emergency Department.'' *Id.* Staff was then instructed to safeguard the vial so that it could be sent for testing, with the results of the testing showing that the vial was at half concentration, indicating that it had been tampered with. *Id.; see also* RFAAX 7.

According to the Memorandum, there had been other suspicious incidents involving Applicant and several sharps containers in the Emergency Department. RFAAX 6, at 1. ''On one occasion, [Applicant] lost his ring in a sharps container in the [Emergency Department].'' *Id.* ''On another occasion, [Applicant] was found to be bleeding from his hand,'' and although he told staff he had cut himself on the sink, ''no blood was found on the sink but blood was noted on the sharps container located in that area.'' *Id.* The Memorandum notes that ''[t]here was no confirmation that [Applicant] accessed this sharps container.'' *Id.*

The Memorandum further states that ''[a] chart audit was performed to determine Pyxis access by [Applicant]'' and ''[a] report of [Applicant's] Pyxis access from August 25, 2016 to September 24, 2016 was run and reviewed against patient charts for that time period.'' *Id.* Further, ''[i]t was also reviewed against a full Pyxis report for all users for the same time period.'' The Memorandum states that ''[s]everal missing waste documentation was found from this initial chart audit.'' *Id.* On September 3, 2016, a 1 mg/1 mL syringe of Hydromorphone was removed, but only 0.5 mg was documented to be given to the patient, with no waste documented for the excess controlled substance. *Id.* On September 5, 2016, a 100 mcg/2 mL vial of Fentanyl Citrate for another nurse's patient was removed, but only 50 mcg was documented to be given to the patient, with no waste documented for the excess medication. *Id.* at 2. On September 10, 2016, a 2 mg/1 mL vial of Lorazepam was removed, but only 0.5 mg was ordered and documented to be given to the patient, with no waste documented for the excess controlled substance. *Id.* Finally, on September 11, 2016, a 100 mcg/2 mL vial of Fentanyl Citrate was removed, but only 50 mcg was ordered and documented to be given to the patient, with no waste documented for the excess controlled substance. *Id.*

On November 1, 2016, St. Mary's Hospital issued a letter to Applicant notifying him of his immediate dismissal from employment. RFAAX 5. In addition to the incidents of potential drug diversion previously identified in the above-described Memorandum, the letter also stated that Applicant ''falsified and omitted pertinent facts from [his] St. Mary's [Hospital] Employment Application by indicating that [his] prior employment at CMMC was still 'present' and for omitting pertinent employment information for [his] work and termination from Mercy Hospital in 2013.'' *Id.*

On October 16, 2017, Applicant signed a Consent Agreement for Reprimand, Suspension, and Probation (hereinafter, Consent Agreement) issued by the State of Maine Board of Nursing (hereinafter, the Board). RFAAX 10, at 1 and 5. The Consent Agreement includes facts pertaining to Applicant's alleged diversion while employed at St. Mary's Hospital, along with additional facts, such as that Applicant ''has a March 31, 2014 letter of concern on file with the Board in which the Board communicates its concern regarding 'the importance of the proper administration, waste and disposal of scheduled drugs in any employment setting.' '' *Id.* at 1–2. By signing the Consent Agreement, Applicant agreed to accept a Reprimand and agreed that his license would be suspended for one year followed by at least two years of probation. *Id.* at 2–3. Applicant also agreed that during the period of suspension, he would not ''work in any capacity requiring a nursing license'' and that he would continue to participate in the Maine Medical Professionals Health Program (hereinafter, MPHP) and ''remain in compliance with all the terms of his current MPHP monitoring agreement.'' *Id.* at 2.

II. Discussion

A. 21 U.S.C. 823(f): The Five Public Interest Factors

Pursuant to section 303(f) of the CSA, ''[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Section 303(f) further provides that an application for a practitioner's registration may be denied upon a determination that ''the issuance of such registration . . . would be inconsistent with the public interest.'' *Id.* In making the public interest determination, the CSA requires consideration of the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f).

The DEA considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993). Thus, there is no need to enter findings on each of the factors. *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Furthermore, there is no

requirement to consider a factor in any given level of detail. *Trawick* v. *Drug Enf't Admin.,* 861 F.2d 72, 76–77 (4th Cir. 1988). The balancing of the public interest factors ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest . . . .'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009). When deciding whether registration is in the public interest, the DEA must consider the totality of the circumstances. *See generally Joseph Gaudio, M.D.,* 74 FR 10083, 10094–95 (2009) (basing sanction on all evidence on record).

The Government does not dispute that Applicant holds a valid state nursing license and is authorized to dispense controlled substances in the State of Maine where he practices. *See* OSC, at 2. While I have considered all of the public interest factors [1] in 21 U.S.C. 823(f), the public interest factors that are most relevant to the Government's case for denial of Applicant's application are Public Interest Factors One, Two, and Four. *See* RFAA, at 5–6. Moreover, the Government has the burden of proof in this proceeding. 21 CFR 1301.44. I find that the Government's evidence with respect to Factors Two, and Four satisfies its *prima facie* burden of showing that Applicant's registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(f). Specifically, I find that the record contains substantial evidence that Applicant violated both Maine law and federal law when he diverted controlled substances from Mercy Hospital and St. Mary's Hospital. I further find that Applicant failed to provide evidence to rebut the Government's *prima facie* case.

1. Factor One

In determining the public interest under Factor One, the ''recommendation of the appropriate State licensing board or professional disciplinary authority'' shall be considered. 21 U.S.C. 823(f)(1). ''Two forms of recommendations appear in Agency decisions: (1) A recommendation to DEA directly from a state licensing board or professional disciplinary authority (hereinafter, appropriate state entity), which explicitly addresses the granting or retention of a DEA COR; and (2) the appropriate state entity's action regarding the licensure under its jurisdiction on the same matter that is the basis for the DEA OSC.'' *John O. Dimowo,* 85 FR 15800, 15809 (2020); see also *Vincent J. Scolaro,* D.O., 67 FR 42060, 42065 (2002) (''While the State Board did not affirmatively state that the Respondent could apply for a DEA registration, [the ALJ] found that the State Board by implication acquiesced to the Respondent's application because the State Board has given state authority to the Respondent to prescribe controlled substances.'').

As previously discussed, on October 16, 2017, Applicant entered into a Consent Agreement issued by the Board. RFAAX 10, at 1 and 5. The Board's Consent Agreement includes some of the allegations against Applicant that were addressed in the OSC and RFAA—namely, those pertaining to Applicant's alleged diversion while employed at St. Mary's Hospital. *Id.* at 1–2. Further, the Consent Agreement includes additional facts related to Applicant's alleged history of diversion such as that Applicant ''has a March 31, 2014 letter of concern on file with the Board in which the Board communicates its concern regarding 'the importance of the proper administration, waste and disposal of scheduled drugs in any employment setting.' '' *Id.* at 2. The Consent Agreement suspends Applicant's license for one year followed by at least two years of probation. *Id.* at 2–3. The Consent Agreement also prohibited Applicant from ''work[ing] in any capacity requiring a nursing license'' during the suspension and required him to ''continue to participate in the MPHP and remain in compliance with all the terms of his current MPHP monitoring agreement.'' *Id.* at 2.

While the Board's Consent Agreement is not a ''direct recommendation'' for purposes of Factor One, it does indicate a recommendation by the appropriate state entity regarding a large portion of the allegations and evidence before me. *John O. Dimowo,* 85 FR at 15180. The Consent Order makes clear that the Board was aware of Applicant's alleged diversion incidents from his time as an employee at St. Mary's Hospital. The Consent Order also makes clear that the Board was aware that Applicant had a history of diversion allegations against him by including in its factual findings that, in March 2014, Applicant received a letter of concern from the Board that alluded to possible diversion in an employment setting. The Consent Order does not, however, make clear whether the Board was aware of Applicant's alleged diversion incidents from his time as an employee at Mercy Hospital nor whether the 2014 letter of concern was in reference to those allegations or something else. Additionally, the Board implemented a multi-year disciplinary action that included a year of total suspension from practice followed by a probationary period in which Applicant's practice would be ''restricted to structured settings with on-site supervision.'' RFAAX 10, at 3. The Board also required that Applicant ''sign a monitoring agreement with the MPHP, to remain in effect for at least two (2) years of [his] employment in the practice of nursing.'' *Id.*

The Board's Consent Agreement is not dispositive of the public interest inquiry in this case. The Board's suspension of Applicant's nursing license, as well as its probationary conditions, do not indicate a substantial amount of trust in Applicant. Ultimately, I find the Board's Consent Agreement to weigh slightly in favor of Applicant, but its weight is also minimized by the ambiguity regarding the Board's awareness of the full extent of Applicant's history of diversion allegations, the sanctions imposed by the Board, and the fact that I have no information from Applicant to mitigate the circumstances. *See John O. Dimowo,* 85 FR 15810–11 (citing *Brian Thomas Nichol, M.D.,* 83 FR 47352, 47362–63 (2018)).

2. Factors Two and Four

The unrebutted record evidence demonstrates that Applicant has a history of diversion, which comprises multiple documented incidents from at least two different places of employment. Although Applicant has denied at least some of the allegations from his time as an employee at St. Mary's Hospital, (RFAAX 10, at 1–2), Applicant nonetheless signed the Board's Consent Agreement in which he agreed that there was ''sufficient admissible evidence for the Board to find that it [was] more likely than not'' that he engaged in the conduct described in the allegations. *Id.* at 2. Furthermore, Applicant provided no contrary evidence on the record. Accordingly, I find that Applicant's history of diverting controlled substances constitutes negative dispensing experience and weighs

[1] As to Factor Three, there is no evidence in the record that Applicant has been convicted of an offense under either federal or state law ''relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, as Agency cases have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.,* 75 FR 49956, 49973 (2010). Agency cases have therefore found that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

As to Factor Five, the Government's evidence fits squarely within the parameters of Factors One, Two, and Four and does not raise ''other conduct which may threaten the public health and safety.'' 21 U.S.C. 823(f)(5). Accordingly, Factor Five does not weigh for or against Applicant.

against granting Applicant's application for a registration.

Furthermore, the Government alleges that Applicant repeatedly violated state and federal laws related to controlled substances by diverting controlled substances on at least two different occasions while employed at Mercy Hospital and on at least five different occasions while employed at St. Mary's Hospital. OSC, at 2 and 4 (citing 21 U.S.C. 843(a)(3); 21 CFR 1301.22(c); 17–A Me. Rev. Stat. § 1107–A; 32 Me. Rev. Stat. § 2105–A(2)(F) and (H); and Maine State Board of Nursing Rule Ch. 4 § 3(P)).

According to Maine law, ''a person is guilty of unlawful possession of a scheduled drug if the person intentionally or knowingly possesses what that person knows or believes to be a scheduled drug, which is in fact a scheduled drug'' [2] unless ''the person possessed a valid prescription for the scheduled drug or controlled substance that is the basis for the charge and[ ], at all times, the person intended the drug to be used only for legitimate medical use in conformity with the instructions provided by the prescriber and dispenser.'' Me. Rev. Stat. Ann. tit. 17–A, §§ 1107–A(1) and (4) (Westlaw, current with legislation through the 2021 First Regular Session and Second Special Session of the 130th Legislature). Further, Maine regulation states that nurses are prohibited from engaging in unprofessional conduct as well as from violating Board rules, including, ''[d]iverting drugs, supplies or property of patients or health care provider[s].'' 02–380 Me. Code R. Ch. 4, § 3(P) (Westlaw, current through the June 16, 2021 Maine Weekly Rule Notice).

Under federal law, it is unlawful ''to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.'' 21 U.S.C. 843(a)(3). Federal law also states that ''[a]n individual practitioner who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself, provided that . . . [s]uch dispensing, administering or prescribing is done in the usual course of his/her professional practice.'' 21 CFR 1301.22(c). Federal law defines an individual practitioner as an ''individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice.'' 21 CFR 1300.01.

In this case, the evidence supports a finding that Applicant diverted controlled substances on at least two different occasions while employed at Mercy Hospital and on at least five different occasions while employed at St. Mary's Hospital. In doing so, he clearly acted outside of the usual course of his professional practice and dispensed controlled substances in violation of state and federal law. Given the repeated nature of Applicant's violations of federal and state regulations related to controlled substances, I find that Factors Two and Four strongly weigh against Applicant's registration and I find Applicant's registration to be inconsistent with the public interest in balancing the factors in 21 U.S.C. 823(f).

III. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that grounds for denial exist, the burden shifts to the Applicant to show why he can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18882, 18910 (2018) (collecting cases). In this case, Applicant did not request a hearing and did not avail himself of the opportunity to refute the Government's case. *See* RFAA, at 1 and RFAAX 3. As such, Applicant has not expressed any remorse nor provided any assurances that he would implement remedial measures to ensure his misconduct is not repeated, and such silence weighs against his registration. *Zvi H. Perper, M.D.,* 77 FR 64131, 64142 (2012) (citing *Medicine Shoppe-Jonesborough,* 73 FR 363, 387 (2008)); *see also Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007). Further, due to the lack of a statement or testimony from Applicant, it is unclear whether Applicant can be entrusted with a DEA registration. Therefore, I find that sanction is appropriate to protect the public from a recurrence of Applicant's unlawful actions. *See Leo R. Miller, M.D.,* 53 FR 21931, 21932 (1988). Accordingly, I shall order the sanctions requested by the Government, contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f) and 21 U.S.C. 824(a), I hereby deny the pending application for a Certificate of Registration, Control Number W19022896M, submitted by Christopher C. King, N.P., as well as any other pending application of Christopher C. King, N.P. for additional registration in Maine. This Order is effective May 9, 2022.

Anne Milgram,

Administrator.

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[2] I am not including a finding on this particular state law, because the Government failed to provide any arguments related to these allegations in the RFAA or further information related to the Maine schedules. It is clear to me that Applicant's registration is not in the public interest due to his diversion in spite of the limited arguments in the RFAA.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Crosby Pharmacy and Wellness; Decision and Order

I. Introduction

On October 23, 2021, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Crosby Pharmacy and Wellness (hereinafter, Applicant) of Montgomery, Texas. OSC, at 1. The OSC proposes the denial of Applicant's registration application, Control No. W20008908A (hereinafter, registration application). It alleges that Applicant materially falsified its registration application and that Applicant's registration would be ''inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).'' *Id.*

Specifically, the OSC alleges that, during an onsite visit when Applicant was a registrant, the Government discovered ''serious recordkeeping violations,'' including not maintaining an initial inventory, not maintaining a biennial inventory, and not maintaining accurate records of all controlled substances received and sold. *Id.* at 1–2 (citing 21 CFR 1304.11(b), 1304.11(c), 1304.21(a)). The OSC also alleges that Applicant materially falsified its registration application by answering ''no'' to the question of whether it had ''ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted, or denied, or is any such action pending.'' *Id.* at 2.

The OSC notifies Applicant of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing; the procedures for electing each option; and the consequences for failing to elect either option. *Id.* at 3 (citing 21 CFR 1301.43). The OSC also notifies

Applicant of the opportunity to submit a corrective action plan. *Id.* at 3–4 (citing 21 U.S.C. 824(c)(2)(C)).

II. Adequacy of Service

In a sworn Declaration dated August 20, 2021 (hereinafter, Declaration), a Diversion Investigator (hereinafter, DI) assigned to the Houston Division Office in Houston, Texas, stated that she ''caused a copy of the . . . [OSC] to be sent to . . . [Applicant] at . . . [its] proposed registered address via First Class Mail and Certified Mail.'' DI Declaration, at 3. She stated that ''[b]oth of these mailings were returned to DEA.'' *Id.* The DI also stated that, on November 12, 2020, she ''caused a copy of the . . . [OSC] to be emailed'' to Applicant at the ''email address . . . given to DEA by . . . [Applicant] in . . . [its registration a]pplication.'' *Id.* According to the DI's sworn Declaration, she ''did not receive any notification that the message was not delivered.'' *Id.*

The Government forwarded its Request for Final Agency Action (hereinafter, RFAA), along with the evidentiary record, to this office on August 24, 2021. In its RFAA, the Government represented that ''Applicant did not request a hearing'' and requested that I ''enter an order denying Applicant's application.'' RFAA, at 1.

Based on the DI's Declaration, the Government's written representations, and my review of the record, I find that the Government accomplished service of the OSC on Applicant on or about November 12, 2020. I also find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the Government's written representations, I find that neither Applicant, nor anyone purporting to represent Applicant, requested a hearing, submitted a written statement while waiving Applicant's right to a hearing, or submitted a corrective action plan. Accordingly, I find that Applicant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21 CFR 1301.43(d); 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

III. Findings of Fact

A. Applicant's Registration History

I find there is substantial uncontroverted record evidence that Applicant previously held registration No. FC7640623. RFAA Exhibit (hereinafter, RFAAX) 3, at 1. I find there is substantial uncontroverted record evidence that Applicant surrendered that registration for cause by signing a DEA–104, ''Surrender for Cause of DEA Certificate of Registration'' on January 8, 2020. RFAAX 4, at 1. Further, I find there is substantial uncontroverted record evidence that, on or around January 29, 2020, Applicant submitted the registration application. DI Declaration, at 2; RFAAX 2, at 1–3. I find clear, unequivocal, convincing, and unrebutted record evidence that, on the registration application, Applicant certified that it had never ''surrendered (for cause) . . . a federal controlled substance registration.'' RFAAX 2, at 1. I find there is substantial uncontroverted record evidence that DEA issued this OSC about the registration application. OSC, at 1; RFAAX 4, at 2.

B. Investigation of Applicant

I find there is substantial uncontroverted record evidence that DI and other DEA employees ''conducted an onsite visit'' of Applicant on January 8, 2020. DI Declaration, at 1. I find there is substantial uncontroverted record evidence that, during this visit, the DEA team ''discovered a number of problems with . . . [Applicant's controlled-substance-related] recordkeeping.'' *Id.* I further find there is substantial uncontroverted record evidence that DI ''confronted'' a representative of Applicant about ''some'' of the recordkeeping problems. *Id.* at 2. I find there is substantial uncontroverted record evidence that, ''[i]n response,'' a representative of Applicant ''agreed to surrender'' Applicant's registration and signed a DEA–104 stating that Applicant was ''surrender[ing its registration] for cause.'' *Id.;* RFAAX 4, at 1. I find there is substantial uncontroverted record evidence that DEA sent Applicant a letter, dated January 24, 2020, ''confirming the surrender of . . . [its] registration privileges in Schedules II through V on January 8, 2020,'' and stating that, ''[c]oncurrent with the surrender,'' Applicant is ''no longer authorized to order, distribute, possess, dispense, administer, prescribe, or engage in any activities with controlled substances under DEA Registration Number FC7640623.'' RFAAX 7, at 1. I find there is substantial uncontroverted record evidence that DEA directed the January 24, 2020 letter to Applicant at the physical address Applicant submitted in the registration application. RFAAX 7, at 1; RFAAX 2, at 1.

I find there is substantial uncontroverted record evidence that DI continued the investigation of Applicant after its voluntary registration surrender for cause by issuing an administrative subpoena to Applicant's distributor. RFAAX 5, at 1; DI Declaration, at 2. I find there is substantial uncontroverted record evidence that, pursuant to the administrative subpoena, Applicant's distributor provided DI with DEA Form 222s and invoices. DI Declaration, at 2. I find there is substantial uncontroverted record evidence that these distributor documents show that the distributor provided Applicant with more than 18,000 tablets of oxycodone 30 mg, more than 16,000 tablets of hydrocodone/acetaminophen 10/325 mg, more than 13,000 tablets of alprazolam 2 mg, more than 20,000 tablets of carisoprodol 350 mg, and 120 bottles of 473 ml promethazine with codeine. *Id.; see also* RFAAX 6. I find there is substantial uncontroverted record evidence that the distributor shipped controlled substances to Applicant. DI Declaration, at 2; RFAAX 6. I find there is substantial uncontroverted record evidence that Applicant did not produce for the DEA team an initial inventory of the controlled substances, ''any records of dispensing any controlled substances,'' and ''any controlled substances.'' DI Declaration, at 1.

III. Discussion

A. The Controlled Substances Act and the Public Interest Factors

Pursuant to the Controlled Substances Act (hereinafter, CSA), ''[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). The CSA further provides that an application for a practitioner's registration may be denied upon a determination that ''the issuance of such registration . . . would be inconsistent with the public interest.'' *Id.* In making the public interest determination, the CSA requires consideration of the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing . . . controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Id.

These factors are considered in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). I ''may rely on any one or a combination of factors and may give each factor the weight [I] deem[ ] appropriate in determining whether . . . an application for registration [should be] denied.'' *Id.* Moreover, while I am required to consider each factor, I ''need not make explicit findings as to each one,'' and I ''can give each factor the weight . . . [I] determine[ ] is appropriate.'' *Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018) (quoting *Akhtar-Zaidi* v. *Drug Enf't Admin.,* 841 F.3d 707, 711 (6th Cir. 2016)); *see also MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman* v. *Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009) (quoting *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005))). In other words, the public interest determination ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Peter A. Ahles, M.D.,* 71 FR 50097, 50098–99 (2006).

The OSC in this matter, as already discussed, alleges that Applicant's registration application should be denied because it would be inconsistent with the public interest for Applicant to have a registration and because Applicant's registration application contains a materially false response to a liability question. OSC, at 1–3; 21 U.S.C. 823(f), 824(a)(1); *supra* section II. A determination that the issuance of a registration ''would be inconsistent with the public interest'' is a basis for the denial of a registration application. 21 U.S.C. 823(f). The CSA, however, places the provision addressing the ramification of a material falsification with the bases for revocation or suspension of a registration. 21 U.S.C. 824(a).

Prior Agency decisions have addressed whether it is appropriate to consider a material falsification and other bases for revocation or suspension described in 21 U.S.C. 824(a) when determining whether or not to grant a practitioner registration application.[1] For over forty-five years, and as recently as late last year, Agency decisions have concluded that it is. *See, e.g., Lisa M. Jones, N.P.,* 86 FR 52196 (2021); *Robert Wayne Locklear,* 86 FR 33738 (2021) (collecting Agency decisions). These decisions offer multiple bases and analyses for that conclusion. 86 FR at 33744–45. For example, a prior decision noted that ''[t]o hold otherwise would mean that applications would have to be granted [under 21 U.S.C. 823(f)] only to be revoked the next day'' under 21 U.S.C. 824(a). *Id.* at 33744 (quoting *John R. Amato, M.D.,* 40 FR 22852 (1975)). I reaffirm my decision in *Lisa M. Jones, N.P.* that a basis for revocation or suspension described in a provision of 21 U.S.C. 824(a) may be the basis for the denial of a practitioner registration application.

B. Allegation That Applicant Submitted a Materially False Registration Application

Having read and analyzed all of the record evidence, I find from clear, unequivocal, convincing, and unrebutted record evidence that Applicant surrendered (for cause) its DEA registration on January 8, 2020. *Supra* section II.A, section II.B; RFAAX 4. Having read and analyzed all of the record evidence, I find from clear, unequivocal, convincing, and unrebutted record evidence that Applicant answered ''no'' to the second liability question in the registration application—whether Applicant ''ever surrendered (for cause) . . . a federal controlled substance registration.'' *Supra* section II.A. Applicant's false answer to the second liability question in the registration application implicates two of the public interest factors that the CSA requires me to consider: Applicant's experience in dispensing controlled substances, and Applicant's compliance with applicable federal laws relating to controlled substances. 21 U.S.C. 823(f)(2), (4); *Frank Joseph Stirlacci, M.D.,* 85 FR 45229, 45234 (2020). As such, Applicant's false response to the second liability question in the registration application was ''predictably capable of affecting, *i.e.,* had a natural tendency to affect'' my official decision on its registration application. *Frank Joseph Stirlacci, M.D.,* 85 FR at 45238. Accordingly, I find from clear, unequivocal, convincing, and unrebutted record evidence that the registration application contains a material falsification, an independent basis for the denial of the registration application.

C. Allegation That Issuing a Registration to Applicant Would Be Inconsistent With the Public Interest

As already discussed, the OSC includes three allegations that Applicant failed to maintain required ''controlled substances records.'' OSC, at 2. First, the OSC alleges that Applicant ''failed to maintain an initial inventory, in violation of 21 CFR 1304.11(b).'' *Id.* As already discussed, based on substantial uncontroverted record evidence that the distributor shipped controlled substances to Applicant, I find there is substantial uncontroverted record evidence that Applicant did not produce for the DEA team an initial inventory of the controlled substances, ''any records of dispensing any controlled substances,'' and ''any controlled substances.'' *Supra* section II.B. Accordingly, I find that Applicant violated the CSA by failing to maintain an initial inventory, implicating 21 U.S.C. 823(f)(2) and (4). 21 CFR 1304.11(b).

Second, the OSC alleges that Applicant ''failed to maintain a biennial inventory, in violation of 21 CFR 1304.11(c).'' OSC, at 2. There is no evidence in the record that supports this allegation. Accordingly, I find that this OSC allegation is not founded.

Third, the OSC alleges that Applicant ''failed to maintain accurate records of all controlled substances received and sold, in violation of 21 CFR 1304.21(a).'' *Id.* As already discussed, based on substantial uncontroverted record evidence that the distributor shipped controlled substances to Applicant, I find there is substantial uncontroverted record evidence that Applicant did not produce for the DEA team ''any records of dispensing any controlled substances'' and ''any controlled substances.'' *Supra* section II.B. Accordingly, I find that Applicant violated the CSA by failing to maintain accurate records of all controlled substances received and sold, implicating 21 U.S.C. 823(f)(2) and (4). 21 CFR 1304.21(a).

The Government has the burden of proof in this proceeding. 21 CFR 1301.44(d). I carefully considered all of the record evidence relevant to the material falsification allegation, the recordkeeping allegations, and the public interest factors of 21 U.S.C. 823(f)(2) and (4). For the above-stated reasons, I find that the Government met its burden on the OSC's material falsification allegation and on two of the OSC's three recordkeeping violation allegations. I further find that Applicant did not submit any evidence, let alone evidence that rebuts the Government's *prima facie* case, on these founded OSC allegations. Accordingly, I conclude that it would be ''inconsistent with the public interest'' for me to grant the registration application. 21 U.S.C. 823(f).

[1] A pharmacy is a ''practitioner.'' 21 U.S.C. 802(21).

IV. Sanction

Where, as here, the Government presented a *prima facie* case that it would be ''inconsistent with the public interest'' to grant the registration application, and Applicant did not rebut the Government's *prima facie* case, the ''burden of proof shifts'' to Applicant ''to show why it can be trusted with a registration.'' *Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d at 830; *see also Samuel Mintlow, M.D.,* 80 FR 3630, 3652 (2015) (''[S]ufficient mitigating evidence'' must be presented ''to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.''); *Cleveland J. Enmon Jr., M.D.,* 77 FR 57116, 57126 (2012) (same); *Robert M. Golden, M.D.,* 61 FR 24808, 24812 (1996) (same). Further, past performance is the best predictor of future performance and, when an applicant has ''failed to comply with its responsibilities in the past, it makes sense for the agency to consider whether the pharmacy will change its behavior in the future.'' *Pharmacy Doctors Enterprises, Inc.* v. *Drug Enf't Admin.,* 789 F. App'x at 733 (citing *Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d at 831 (citing *MacKay* v. *Drug Enf't Admin.,* 664 F.3d at 820 (''[T]hat consideration is vital to whether continued registration is in the public interest.'') and *Alra Labs., Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995) (''An agency rationally may conclude that past performance is the best predictor of future performance.''))).

Additionally, in evaluating whether a practitioner should be entrusted with a registration, the Agency considers whether the practitioner has accepted responsibility for any misconduct; circuit courts have approved the Agency's acceptance of responsibility requirement. *Pharmacy Doctors Enterprises, Inc.* v. *Drug Enf't Admin.,* 789 F. App'x at 732; *Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d at 830 (citing *MacKay* v. *Drug Enf't Admin.,* 664 F.3d at 820 (''The DEA may properly consider whether a physician admits fault in determining if the physician's registration should be revoked.'')); *see also Jeffrey Stein, M.D.,* 84 FR 46968, 46972–73 (2019) (unequivocal acceptance of responsibility); *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 463 (2009) (collecting cases).

The Agency also has decided that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Garrett Howard Smith, M.D.,* 83 FR 18882, 18910 (2018) (collecting cases); *Samuel Mintlow, M.D.,* 80 FR at 3652 (''Obviously, the egregiousness and extent of a registrant's misconduct are significant factors in determining the appropriate sanction.''). The Agency has also considered the need to deter similar acts by Applicant and by the community of registrants and potential registrants. *Id.*

In terms of egregiousness, the violations that the record evidence shows Applicant committed go to the heart of the CSA—not complying with required controlled substance recordkeeping and submitting a registration application that includes a material falsification.

Applicant did not take responsibility for the founded violations. Accordingly, it is not reasonable to believe that Applicant's future controlled substance dispensing will comply with legal requirements.[2]

For all of these reasons, I find that it would be inconsistent with the public interest for me to entrust Applicant with a registration. Accordingly, I shall order the denial of Applicant's registration application, Control No. W20008908A.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny the registration application submitted by Crosby Pharmacy and Wellness, Control No. W20008908A, seeking registration in Texas as a practitioner, and I hereby deny any other pending application submitted by Crosby Pharmacy and Wellness for a DEA registration in the State of Texas. This Order is effective May 11, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–07687 Filed 4–8–22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 22–7]

Adam T. Rodman, P.A.; Decision and Order

On November 8, 2021, a former Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Adam T. Rodman, P.A. (hereinafter, Respondent) of Dedham, Massachusetts. OSC, at 1 and 3. The OSC proposed the revocation of Respondent's Certificate of Registration No. MR0956586. *Id.* at 1. It alleged that Respondent ''[does] not have authority to dispense or prescribe controlled substances in the Commonwealth of Massachusetts, the state in which [he is] registered with the DEA.'' *Id.* (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that on or about June 30, 2021, the Massachusetts Drug Control Program accepted Respondent's voluntary surrender of his state controlled substances registration for schedules II through V. *Id.* at 2. According to the OSC, Respondent retained authority in schedule VI, which does not include federally-scheduled drugs. *Id.* (citing Mass. Gen. Laws ch. 94C, § 2).

The OSC notified Respondent of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 2–3 (citing 21 CFR 1301.43). The OSC also notified Respondent of the opportunity to submit a corrective action plan. *Id.* at 3 (citing 21 U.S.C. 824(c)(2)(C)).

By letter dated December 1, 2021, Respondent timely requested a hearing.[1] Request for Hearing, at 1. In his Request for Hearing, Respondent objected to the revocation of his DEA registration and stated: ''The basis for my objection is, in part, that my Massachusetts Controlled Substance Registration has not been suspended, revoked, or denied, and therefore 21 U.S.C. 824(a)(3) is not applicable.'' *Id.*

The Office of Administrative Law Judges put the matter on the docket and assigned it to Administrative Law Judge Teresa A. Wallbaum (hereinafter, the ALJ). On December 2, 2021, the ALJ issued an Order Directing the Government to File Evidence Regarding Its Lack of State Authority Allegation and Briefing Schedule (hereinafter, Briefing Schedule). On December 15, 2021, the Government timely filed its Notice of Filing of Evidence and Motion for Summary Disposition (hereinafter, Government's Motion). Order Granting the Government's Motion for Summary Disposition, and Recommended Rulings, Findings of Fact, Conclusions

[2] I do not consider remedial measures when an applicant does not unequivocally accept responsibility. In this matter, Applicant did not accept responsibility or propose remedial measures.

[1] The Request for Hearing was filed on December 1, 2021. Order Directing the Government to File Evidence Regarding Its Lack of State Authority Allegation and Briefing Schedule dated December 2, 2021, at 1. I find that the Government's service of the OSC was adequate and that the Request for Hearing was timely filed on December 1, 2021.

of Law, and Decision of the Administrative Law Judge dated January 27, 2022 (hereinafter, Recommended Decision or RD), at 2. In its Motion, the Government argued that because Respondent lacks authority to handle controlled substances in Massachusetts, the state in which he is registered with the DEA, his DEA registration should be revoked. Government's Motion, at 2–3. On January 18, 2022, Respondent timely [2] filed his Opposition to Government's Motion for Summary Disposition (hereinafter, Respondent's Opposition). RD, at 2. In his Opposition, Respondent argued that the plain language of 21 U.S.C. 824(a)(3) does not apply to him and that his DEA registration should not be revoked because his Massachusetts Controlled Substance Registration was not suspended, revoked, or denied, but instead voluntarily surrendered. Respondent's Opposition, at 2–4.

On January 27, 2022, the ALJ granted the Government's Motion, finding that ''[t]here is no genuine issue of material fact in this case.'' RD, at 6. Further, the ALJ found that Respondent's argument regarding the plain language of 21 U.S.C. 824(a)(3) was ''at odds with clear Agency precedent on the issue and must therefore fail,'' because ''regardless of how or why [Respondent] lost his authority to handle controlled substances under state law, he has lost it.'' *Id.* at 7. Accordingly, the ALJ recommended that Respondent's DEA registration be revoked and that any application to renew or modify his registration, or any applications for any other DEA registrations in Massachusetts, be denied based on Respondent's lack of state authority to handle controlled substances. *Id.* at 8. By letter dated February 22, 2022, the ALJ certified and transmitted the record to me for final Agency action and advised that neither party filed exceptions.

I issue this Decision and Order based on the entire record before me. 21 CFR 1301.43(e). I make the following findings of fact.

Findings of Fact

Respondent's DEA Registration

Respondent is the holder of DEA Certificate of Registration No. MR0956586 at the registered address of 983 Providence Highway, Dedham, Massachusetts 02026. Government's Motion, Declaration of [Diversion Investigator (DI)], at 1. Pursuant to this DEA registration, Respondent is authorized to dispense controlled substances in schedules II through V as a mid-level practitioner. *Id.* Respondent's registration expires on April 30, 2024. *Id.*

The Status of Respondent's State License

On June 30, 2021, the Massachusetts Drug Control Program accepted Respondent's voluntary surrender of his Massachusetts controlled substances registration for Massachusetts drug schedules II through V and stated that Respondent was ''no longer authorized to prescribe, distribute, possess, dispense or administer controlled substances from schedules II through V in the Commonwealth of Massachusetts.'' Government's Motion, Declaration of DI, Exhibit (hereinafter GX) A. The Massachusetts Drug Control Program also clarified that Respondent's Massachusetts controlled substances registration would retain authorization for schedule VI medications only. *Id.*

On August 30, 2021, the Massachusetts Board of Registration of Physician Assistants (hereinafter, the Board) entered into a Consent Agreement for Probation (hereinafter, Consent Agreement) with Respondent regarding Respondent's Massachusetts Physician Assistant license. Respondent's Opposition, Exhibit (hereinafter, RX) A, at 1–2. By signing the Consent Agreement, Respondent admitted that on various dates between October 4, 2018, and September 30, 2019, he had diverted controlled substances. *Id.* at 2. Specifically, Respondent admitted that for multiple patients, he had examined them, written them prescriptions for controlled substances, and asked them to bring him the filled prescriptions. *Id.* The Consent Agreement placed Respondent's Massachusetts Physician Assistant license on probation for two years subject to various requirements and conditions. *Id.* at 2–8.

According to online records for Massachusetts, of which I take official notice, Respondent's Massachusetts controlled substances registration is current, but authorized only for drug schedule VI.[3] Massachusetts Health Professions License Verification Site, *https://madph.mylicense.com/verification* (last visited date of signature of this Order). Further, online records for Massachusetts list Respondent's Massachusetts Physician Assistant license as on probation. *Id.*

Accordingly, I find that Respondent is not currently licensed to dispense controlled substances in schedules II through V in Massachusetts, the state in which he is registered with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) ''upon a finding that the registrant . . . has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' [4] With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71371 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27616, 27617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress

[2] Respondent was granted an extension of time to file a reply to the Government's Motion. *See* Order Amending Briefing Schedule dated December 23, 2021.

[3] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Respondent may dispute my finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.usdoj.gov.*

[4] Respondent argues that 21 U.S.C. 824(a)(3) only refers to revocation, suspension, or denial; however, the Agency has consistently stated that the central issue is whether or not the registrant is ''currently authorized to handle controlled substances in the state,'' *James Hooper,* 76 FR 71371 (2011) (quoting *Anne Lazar Thorn,* 62 FR 12847, 12848 (1997)); thus, it is of no consequence whether the registrant's state license was revoked or suspended, has expired, or was voluntarily surrendered. *See, e.g., Alex E. Torres, M.D.,* 87 FR 3352 (2022) (voluntary surrender of medical license); *Tel-Pharmacy,* 87 FR 2904 (2022) (state pharmacy license expired); *Humberto A. Florian, M.D.,* 86 FR 52203 (2021) (state medical license revoked); *Javaid A. Perwaiz, M.D.,* 86 FR 20732 (2021) (state medical license expired); *Michael Thomas Watkins, M.D.,* 85 FR 27246 (2020) (voluntary agreement to cease practicing medicine in Massachusetts). What is of consequence is the fact that Respondent is no longer authorized to handle controlled substances in the Commonwealth of Massachusetts, where he is registered with the DEA. Furthermore, the letter of acceptance of the consent agreement from the Massachusetts Drug Control Program implies that Respondent may only re-apply for such a registration in September 2023. *See* GX A, at 1.

defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51104, 51105 (1993); *Bobby Watts, M.D.,* 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton,* 43 FR at 27617.

According to the Massachusetts Controlled Substances Act, ''every person who . . . dispenses . . . any controlled substance within the commonwealth shall . . . register with the commissioner of public health, in accordance with his regulations.'' Mass. Gen. Laws ch. 94C, § 7(a) (Westlaw, current through Chapter 14 of the 2022 2nd Annual Session). Further, ''[a] prescription for a controlled substance may be issued only by a practitioner who is (1) authorized to prescribe controlled substances; and (2) registered pursuant to the provisions of [the Massachusetts Controlled Substances Act].'' *Id.* at § 18(a).

Here, the undisputed evidence in the record is that Respondent is not authorized to dispense controlled substances in schedules II through V in Massachusetts.[5] Further, I agree with the ALJ that it is of no consequence that Respondent's Massachusetts controlled substances registration for drug schedules II through V was voluntarily surrendered rather than revoked or suspended. Thus, because Respondent is not authorized to prescribe controlled substances in schedules II through V in Massachusetts, Respondent is not eligible to maintain a DEA registration. Accordingly, I will order that Respondent's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. MR0956586 issued to Adam T. Rodman, P.A. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Adam T. Rodman, P.A. to renew or modify this registration, as well as any other pending application of Adam T. Rodman, P.A. for additional registration in Massachusetts. This Order is effective May 11, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–07726 Filed 4–8–22; 8:45 am]

BILLING CODE 4410–09–P

[5] As previously discussed, Respondent is only authorized to dispense controlled substances in schedule VI in Massachusetts. *See supra.* According to the Massachusetts Controlled Substances Act, schedules I through V incorporate the five schedules of controlled substances under the CSA, with schedule VI consisting of ''all prescription drugs not included in the first five schedules.'' Mass. Gen. Laws ch. 94C, § 2(a) (Westlaw, current through Chapter 14 of the 2022 2nd Annual Session). As such, Respondent does not have state authority to dispense CSA controlled substances in Massachusetts.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 22–12]

Lezlie McKenzie, N.P.; Decision and Order

On December 10, 2021, a former Acting Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Lezlie McKenzie, N.P. (hereinafter, Respondent) of Missoula, Montana. OSC, at 1. The OSC proposed the revocation of Respondent's Certificate of Registration Number MM0938261 (hereinafter, registration or COR). *Id.* It alleged that Respondent ''[is] currently without authority to handle controlled substances in Montana, the state in which [she is] registered with DEA.'' *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that on July 26, 2021, the Montana Board of Nursing entered a Final Order that outlined ''conditions [Respondent was] required to meet in order to maintain [her] Montana nursing license.'' *Id.* The OSC further alleged that on October 26, 2021, the Montana Board of Nursing ''indefinitely suspended [Respondent's] Montana nursing licenses for failure to abide by the terms'' of the July 26, 2021 Order. *Id.*

The OSC notified Respondent of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* (citing 21 CFR 1301.43). The OSC also notified Respondent of the opportunity to submit a corrective action plan. *Id.* at 3 (citing 21 U.S.C. 824(c)(2)(C)).

By letter dated January 6, 2022, Respondent timely requested a hearing.[1] Request for Hearing, at 1. In her Request for Hearing, Respondent stated that she ''wish[es] to not relinquish any rights in regards to this matter and intend[s] to comply fully with any regulations of the DEA.'' *Id.*

The Office of Administrative Law Judges put the matter on the docket and assigned it to Chief Administrative Law Judge John J. Mulrooney II (hereinafter, the Chief ALJ). On January 10, 2022, the Chief ALJ issued an Order Directing the Filing of Government Evidence Regarding Its Lack of State Authority Allegation and Briefing Schedule (hereinafter, Briefing Schedule). On January 24, 2022, the Government timely filed its Submission of Evidence and Motion for Summary Disposition (hereinafter, Government's Motion). In its Motion, the Government argued that because Respondent lacks authority to handle controlled substances in Montana, the state in which she is registered with the DEA, her DEA registration should be revoked. Government's Motion, at 2–5. Respondent did not file any answer to the Government's Motion. Order Granting the Government's Motion for Summary Disposition, and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge dated February 8, 2022 (hereinafter, Recommended Decision or RD), at 2.

On February 8, 2022, the Chief ALJ granted the Government's Motion, finding that ''[s]ince the Respondent does not have authority as a practitioner in Montana, and this fact is not challenged by the Respondent, there is no other fact of consequence for this tribunal to decide in order to determine whether or not she is entitled to hold a COR.'' RD, at 5. Accordingly, the Chief

[1] The Request for Hearing was filed on January 6, 2022. Order Directing the Filing of Government Evidence Regarding Its Lack of State Authority Allegation and Briefing Schedule dated January 10, 2022, at 1. I find that the Government's service of the OSC was adequate and that the Request for Hearing was timely filed on January 6, 2022.

ALJ recommended that Respondent's DEA registration be revoked based on Respondent's lack of state authority to handle controlled substances. *Id.* By letter dated March 7, 2022, the Chief ALJ certified and transmitted the record to me for final Agency action and advised that neither party filed exceptions.

I issue this Decision and Order based on the entire record before me. 21 CFR 1301.43(e). I make the following findings of fact.

Findings of Fact

Respondent's DEA Registration

Respondent is the holder of DEA registration MM0938261 at the registered address of 715A Skyla Ct., Missoula, Montana 59801–1480. Government's Motion, Exhibit (hereinafter, GX) D (Declaration of [Diversion Investigator (DI)]), at 1. Pursuant to this DEA registration, Respondent is authorized to prescribe controlled substances in schedules II through V as a mid-level practitioner. GX A (Printout of Respondent's registration information from DEA's Registrant Information Consolidated System). Respondent's registration expires on January 31, 2024. *Id.*

The Status of Respondent's State License

On July 26, 2021, the Montana Board of Nursing (hereinafter, MBN) entered a Final Order regarding Respondent's nursing licenses (hereinafter, MBN Order or Order). GX B. The Order stated that Respondent held licenses in Montana as a registered nurse (hereinafter, RN) and an advanced practice RN (hereinafter, APRN), and that Respondent possessed prescriptive authority under her APRN license. *Id.* at 2. The Order further stated that Respondent had engaged in unprofessional conduct under Montana law, and provided conditions that Respondent was required to meet in order to maintain her state prescribing privileges. *Id.*

According to the DI's declaration, DEA learned on October 26, 2021, that the MBN had indefinitely suspended Respondent's state nursing licenses ''for failure to abide by the terms'' of the conditions set forth in the July 26, 2021 MBN Order. GX D, at 2. DI represented that Respondent's license remained suspended as of January 13, 2022, and submitted a printout of the Montana Department of Labor and Industry's online licensing verification page confirming the suspension of Respondent's APRN license. *Id.* at 3; GX C

According to online records for Montana, of which I take official notice, Respondent's Montana APRN license is suspended and expired.[2] Montana Department of Labor and Industry, *https://ebizws.mt.gov/PUBLICPORTAL/searchform?mylist=licenses&pk_vid=d831a8116efb756d16474448085e834e* (last visited date of signature of this Order). Accordingly, I find that Respondent is not currently licensed to dispense controlled substances in schedules II through V in Montana, the state in which she is registered with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) ''upon a finding that the registrant . . . has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71371 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27616, 27617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51104, 51105 (1993); *Bobby Watts, M.D.,* 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton,* 43 FR at 27617.

According to the Montana Administrative Code, ''[o]nly an APRN granted prescriptive authority by the board may prescribe, procure, administer, and dispense . . . controlled substances pursuant to applicable state and federal laws and within the APRN's role and population focus.'' Mont. Admin. R. 24.159.1461 (2013) (Westlaw, current through Issue 4 of the 2022 Montana Administrative Register). Further, according to the Montana Controlled Substances Act, ''dangerous drug[s]'' [3] in schedules II through IV may only be dispensed with a ''prescription by a practitioner.'' [4] Mont. Code Ann. § 50–32–208 (West 2015) (Westlaw, current through the 2021 session of the Montana Legislature). A ''practitioner'' is defined as a ''physician, dentist, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, or conduct research with respect to or to administer a dangerous drug in the course of professional practice or research in this state.'' Mont. Code Ann. § 50–32–101(24)(a) (West 2013) (Westlaw, current through the 2021 session of the Montana Legislature).

Here, the undisputed evidence in the record is that Respondent is not authorized to dispense controlled substances in schedules II through V in Montana. Thus, because Respondent is

[2] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Respondent may dispute my finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.usdoj.gov.*

[3] The state's criteria for labeling drugs as ''dangerous drugs'' are similar to the CSA's criteria for labeling drugs as controlled substances. *See generally id.* at § 50–32–201 through § 50–32–233.

[4] ''[A] dangerous drug included in Schedule V may not be distributed or dispensed other than for a medical purpose.'' Mont. Code Ann. § 50–32–208(3) (West 2015).

not authorized to prescribe controlled substances in schedules II through V in Montana, Respondent is not eligible to maintain a DEA registration. Accordingly, I will order that Respondent's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. MM0938261 issued to Lezlie McKenzie, N.P. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Lezlie McKenzie, N.P., to renew or modify this registration, as well as any other pending application of Lezlie McKenzie, N.P., for additional registration in Montana. This Order is effective May 11, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–07723 Filed 4–8–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; International Training Application

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Bureau of Labor Statistics (BLS)-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 May 11, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) 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; (4) ways to enhance the quality, utility and clarity of the information collection; 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.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202–693–8538, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The BLS is given broad authority under Title 29 of the U.S. Code ''to acquire and diffuse among the people of the United States useful information on subjects connected with labor, in the most general and comprehensive sense of that word.'' The BLS has provided international training in labor market information and price indexes since 1945. Each year, the BLS conducts training programs of 1 to 2 weeks duration at its training facilities in Washington, DC. This information collection request allows the BLS to collect the information needed to register trainees for the international training programs. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on January 21, 2022 (87 FR 3355).

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–BLS.

Title of Collection: International Training Application.

OMB Control Number: 1220–0179.

Affected Public: Individuals or Households.

Total Estimated Number of Respondents: 100.

Total Estimated Number of Responses: 100.

Total Estimated Annual Time Burden: 34 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Dated: April 4, 2022.

Mara Blumenthal,

Senior PRA Analyst.

[FR Doc. 2022–07651 Filed 4–8–22; 8:45 am]

BILLING CODE 4510–24–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petition for Modification of Application of Existing Mandatory Safety Standards

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: This notice is a summary of a petition for modification submitted to the Mine Safety and Health Administration (MSHA) by the party listed below.

DATES: All comments on the petition must be received by MSHA's Office of Standards, Regulations, and Variances on or before May 11, 2022.

ADDRESSES: You may submit comments identified by Docket No. MSHA–2022–0018 by any of the following methods:

1. *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments for MSHA–2022–0018.
2. *Fax:* 202–693–9441.
3. *Email: petitioncomments@dol.gov.*
4. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452,

Attention: S. Aromie Noe, Acting Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect copies of the petition and comments during normal business hours at the address listed above. Before visiting MSHA in person, call 202–693–9455 to make an appointment, in keeping with the Department of Labor's COVID–19 policy. Special health precautions may be required.

FOR FURTHER INFORMATION CONTACT: S. Aromie Noe, Office of Standards, Regulations, and Variances at 202–693–9440 (voice), *Petitionsformodification@dol.gov* (email), or 202–693–9441 (fax). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations (CFR) part 44 govern the application, processing, and disposition of petitions for modification.

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

2. The application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, sections 44.10 and 44.11 of 30 CFR establish the requirements for filing petitions for modification.

II. Petition for Modification

Docket Number: M–2022–009–M.

Petitioner: TATA Chemicals Soda Ash Partners, P.O. Box 551, Green River, Wyoming 82935.

Mine: TATA Chemicals Mine, MSHA ID No. 48–00155, located in Sweetwater County, Wyoming.

Regulation Affected: 30 CFR 57.22305, Approved equipment (III mines).

Modification Request: The petitioner requests a modification of 30 CFR 57.22305 to permit the use of non-MSHA approved electronic total stations/theodolites in or beyond the last open crosscut and where methane may enter the air current.

The petitioner states that:

(a) A Wild/Leica T16 theodolite is used to perform all surveying work in the return and past the last open crosscut. This instrument is becoming obsolete, according to the petitioner's surveying equipment supplier.

(b) There are no MSHA-approved electronic total stations or theodolites.

(c) Electronic total stations allow surveying personnel to measure distances without entering an area. A built-in electronic distance meter allows remote measurement by reflecting light off an object, such as the face, with no reflector. Use of the electronic total stations eliminates miner travel through areas with poor roof or rib conditions and allows measurement in unbolted areas. Station use also significantly reduces surveying personnel's exposure to poor ground conditions.

(d) Nineteen of the 21 electronic total stations/theodolites listed in the petitioner's proposal have an IP (Ingress Progression) 66 rating; two have an IP 65 rating.

(e) The lithium batteries used for the instruments listed in the petitioner's proposal meet the UL 1642 standard or IEC (International Electrotechnical Commission) 62133 standard.

(f) Using the instruments listed in the petitioner's proposal will provide the most accurate and safest means of surveying in methane-containing air and will improve the quality and accuracy of surveys, which will improve the safety of the mining operation.

The petitioner proposes the following alternative method:

(a) Use the following non-MSHA approved electronic total stations/theodolites under normal mining conditions in or beyond the last open crosscut and where methane may enter the air current:

(1) Sokkia Electronic Total Station Model SET350RX–3
(2) Sokkia Electronic Total Station Model SET350R
(3) Sokkia Electronic Total Station Model SET50RX
(4) Sokkia Electronic Total Station Model SET300
(5) Sokkia Intelligent Measurement Total Station Model iM–100
(6) Sokkia Intelligent Measurement Total Station Model iM–50
(7) Sokkia Compact X-ellence Station CX
(8) Sokkia Compact X-ellence Station CX–60
(9) Topcon Electronic Total Station Model GTS–225
(10) Topcon Electronic Total Station Model GTS–300W
(11) Topcon Digital Theodolite Model DT–270L
(12) Topcon Digital Theodolite Model DT–209L
(13) Topcon Electronic Total Station Model GTS–301D
(14) Topcon Electronic Total Station Model GTS–235W
(15) Topcon Electronic Total Station Model GM–50
(16) Topcon Electronic Total Station Model GM–100
(17) Leica Flexline Total Station Model TS03
(18) Leica Flexline Total Station Model TS07
(19) Leica Flexline Total Station Model TS10
(20) Leica Nova TM60 Monitoring Total Station (IP 65)
(21) Leica Nova TS60 Robotic Total Station (IP 65)

(b) While not in operation, the electronic total station/theodolite will be charged out-by the last open crosscut utilizing the manufacturer's approved battery charger.

(c) The mine surveyor will follow manufacturer's instruction on how to properly inspect the unit to ensure it is in proper working order before using it past the last open crosscut or where methane may enter the air current.

(d) If 1.0 percent or more methane is detected, the procedures in 30 CFR 57.22234 will be followed.

The petitioner asserts that the alternative method proposed will at all times guarantee no less than the same measure of protection afforded the miners under the mandatory standard.

Song-ae Aromie Noe,

Acting Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2022–07650 Filed 4–8–22; 8:45 am]

BILLING CODE 4520–43–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2022–037]

National Industrial Security Program Policy Advisory Committee (NISPPAC); Meeting

AGENCY: Information Security Oversight Office (ISOO), National Archives and Records Administration (NARA).

ACTION: Notice of federal advisory committee meeting.

SUMMARY: We are announcing an upcoming National Industrial Security Program Policy Advisory Committee (NISPPAC) meeting in accordance with the Federal Advisory Committee Act and implementing regulations.

DATES: The meeting will be on April 27, 2022, from 10:00 a.m. to 12:00 p.m. EDT.

ADDRESSES: This meeting will be a virtual meeting. See supplementary procedures below.

FOR FURTHER INFORMATION CONTACT: Heather Harris Pagán, ISOO Senior Program Analyst, by telephone at 202.357.5351 or by email at *NISPPAC@nara.gov.* Contact ISOO at *ISOO@nara.gov* and the NISPPAC at *NISPPAC@nara.gov.*

SUPPLEMENTARY INFORMATION: This virtual meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. app 2) and implementing regulations at 41 CFR 101–6. The Committee will discuss National Industrial Security Program policy matters.

Procedures: Members of the public must register in advance through the

Event Services link *https://ems8.intellor.com/?do=register&t=1&p=841483* if you wish to attend. NISPPAC members, ISOO employees, and speakers should send an email to *NISPPAC@nara.gov* for the appropriate registration information instead of registering with the above link.

Tasha Ford,

Committee Management Officer.

[FR Doc. 2022–07681 Filed 4–8–22; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Biological Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Advisory Committee for Biological Sciences (#1110).

Date and Time: May 11, 2022, 10 a.m.–5 p.m. Eastern, May 12, 2022, 10 a.m.–1 p.m. Eastern.

Place: NSF, 2415 Eisenhower Avenue, Alexandria, VA 22314 (Virtual).

The meeting will be held virtually among the Advisory Committee members. Livestreaming will be accessible through the following pages: May 11th—*https://youtu.be/eDt3J_4i0Ws* and May 12th—*https://youtu.be/Hr53MPB5fZw.*

Type of Meeting: Open.

Contact Persons: Montona Futrell-Griggs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; Telephone: (703) 292–7162.

Summary of Minutes: Minutes will be available on the BIO Advisory Committee website at *https://www.nsf.gov/bio/advisory.jsp* or can be obtained from the contact person listed above.

Purpose of Meeting: The Advisory Committee for the Directorate for Biological Sciences (BIO) provides advice and recommendations concerning major program emphases, directions, and goals for the research-related activities of the divisions that make up BIO.

Agenda: Agenda items will include: A directorate business update; an overview of BIO's portfolio and standard metrics; discussion of use-inspired research in context of the Convergence Accelerator program, workforce development programs in the Directorate of Education and Human Resources, industry partnership opportunities, and BIO's support for climate-related research; updates from the Committee on Equal Opportunities in Science and Engineering and the AC for Environmental Research and Education; discussion with the NSF Chief Operating Officer; and other directorate matters.

Dated: April 5, 2022.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2022–07649 Filed 4–8–22; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0083]

Qualification of Class 1E Connection Assemblies for Production and Utilization Facilities

AGENCY: Nuclear Regulatory Commission

ACTION: Draft regulatory guide; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft regulatory guide (DG), DG–1400, ''Qualification of Class 1E Connection Assemblies for Production and Utilization Facilities.'' This DG is the proposed Revision 2 to Regulatory Guide (RG) 1.156. Methods described in RG 1.156 are acceptable to the NRC staff pertaining to the environmental qualification of connectors, terminations, and environmental seals in combination with cables or wires as assemblies for service in nuclear power plants to ensure that the connection assemblies can perform their safety functions.

DATES: Submit comments by May 11, 2022. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0083. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov*. For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: James Steckel, Office of Nuclear Regulatory Research, telephone: 301–415–1026, email: *James.Steckel@nrc.gov*; and Sheila Ray, Office of Nuclear Reactor Regulation, telephone: 301–415–3653, email: *Sheila.Ray@nrc.gov*. Both are staff members of the U.S. Nuclear Regulatory Commission, Washington DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2022–0083 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0083.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov*. DG–1400, ''Qualification of Class 1E Connection Assemblies for Production and Utilization Facilities,'' is available in ADAMS under Accession No. ML21288A562. The staff is also issuing for public comment a draft regulatory analysis for DG–1400 under ADAMS Accession No. ML21288A561.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2022–0083 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Additional Information

The NRC is issuing for public comment a DG in the NRC's ''Regulatory Guide'' series. This series was developed to describe methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific issues or postulated events, and to describe information that the staff needs in its review of applications for permits and licenses.

The DG, entitled ''Qualification of Class 1E Connection Assemblies for Production and Utilization Facilities,'' is temporarily identified by its task number, DG–1400.

Production and utilization facilities licensed under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities'' and 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants'' are required to demonstrate and document for Class 1E electrical connection assemblies and environmental seals in combination with cables or wires as assemblies for the ability of this equipment to perform safety functions under applicable service conditions, including design-basis events. Proposed Revision 2 provides updated information on state-of-the-art environmental qualification methodologies for production and utilization facilities.

The staff is also issuing for public comment a draft regulatory analysis (ADAMS Accession No. ML21288A561). The staff developed a regulatory analysis to assess the value of issuing or revising a regulatory guide as well as alternative courses of action.

III. Backfitting, Forward Fitting, and Issue Finality

Issuance of DG–1400, if finalized, would not constitute backfitting as that term is defined in 10 CFR 50.109, ''Backfitting,'' and as described in NRC Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; would not constitute forward fitting as that term is defined and described in MD 8.4; and would not affect issue finality of any approval issued under 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants.'' As explained in DG–1400, applicants and licensees are not required to comply with the positions set forth in DG–1400.

IV. Submitting Suggestions for Improvement of Regulatory Guides

A member of the public may, at any time, submit suggestions to the NRC for improvement of existing RGs or for the development of new RGs. Suggestions can be submitted on the NRC's public website at *https://www.nrc.gov/reading-rm/doc-collections/reg-guides/contactus.html.* Suggestions will be considered in future updates and enhancements to the ''Regulatory Guide'' series.

Dated: April 5, 2022.

For the Nuclear Regulatory Commission.

Meraj Rahimi,

Chief, Regulatory Guide and Projects Management Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2022–07654 Filed 4–8–22; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2022–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of April 11, 18, 25, May 2, 9, 16, 2022. All listed meeting times (see **MATTERS TO BE CONSIDERED**) are local to the meeting location. The schedule for Commission meetings is subject to change on short notice. The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

PLACE: Multiple locations (see **MATTERS TO BE CONSIDERED**). The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

STATUS: Public.

Members of the public may request to receive the information in these notices electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Wendy.Moore@nrc.gov* or *Betty.Thweatt@nrc.gov.*

MATTERS TO BE CONSIDERED:

Week of April 11, 2022

There are no meetings scheduled for the week of April 11, 2022.

Week of April 18, 2022—Tentative

Friday, April 22, 2022

2:30 p.m. Meeting with the Navajo Tribal Community Members of the Red Water Pond Road (Contact: Wesley Held: 301–287–3591)

Additional Information: The meeting will be held at the Red Water Pond Road Cha'a'oh (''Shade House''), New Mexico. The GPS coordinates for the meeting location are 35.68485338436599, –108.5433161361636. From Church Rock on State Route 566, head northeast for eleven miles. After driving past mile marker eleven and Pipeline Road, the road bends to the left. Shortly after, you will soon see the Red Water Pond Road sign. Take a right hand turn off State Route 566 onto Red Water Pond Road, which is an all-dirt road. The meeting location is about a quarter mile on the right. Pursuant to Navajo Public Health Order 2022–05, reopening status is currently set at ''yellow'' (moderate transmission of COVID–19) and the Red Water Pond Road Community Meeting facility will be allowed to seat up to 50 persons. The grounds surrounding the facility will be set up for additional participants in a ''drive-in'' setting where participants remain in their vehicles during the broadcast of the meeting via public address/sound

system. The maximum number of vehicles allowed onto the grounds of the facility will be set at 100 vehicles at six feet apart. In addition, all individuals 2 years of age and older shall wear masks while in public where the individual could come within 6 feet of someone who is not from the individual's household.

6:30 p.m. Discussion of the Ten-Year Plan to Address Impacts of Uranium Contamination on the Navajo Nation and Lessons Learned from the Remediation of Former Uranium Mill Sites (Contact: Wesley Held: 301–287–3591)

Additional Information: On April 1 and April 4, 2022, the Commission voted to approve changing the start time of the meeting from 6:00 p.m. to 6:30 p.m. The meeting will be held at the Hilton Garden Inn, 1530 W Maloney Ave., Gallup, New Mexico. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/* or by teleconference (Dial-in number: 800–369–2047; Passcode: 6097034).

Week of April 25, 2022—Tentative

There are no meetings scheduled for the week of April 25, 2022.

Week of May 2, 2022—Tentative

There are no meetings scheduled for the week of May 2, 2022.

Week of May 9, 2022—Tentative

Tuesday, May 10, 2022

9:00 a.m. Strategic Programmatic Overview of the Fuel Facilities and the Spent Fuel Storage and Transportation Business Lines (Contact: Jenny Weil: 301–415–1024)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/*.

Thursday, May 12, 2022

10:00 a.m. Briefing on Advanced Reactors Activities with Federal Partners (Contact: Caty Nolan: 301–287–1535)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/*.

Week of May 16, 2022—Tentative

There are no meetings scheduled for the week of May 16, 2022.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: April 7, 2022.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator Office of the Secretary.

[FR Doc. 2022–07771 Filed 4–7–22; 11:15 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94606; File No. SR–ICEEU–2022–003]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Immediate Effectiveness of Proposed Rule Change, as Modified by Amendment No. 1, Relating to Amendments to the ICE Clear Europe Futures & Options Guaranty Fund Policy

April 5, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 28, 2022, ICE Clear Europe Limited (''ICE Clear Europe'' or the ''Clearing House'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II, and III below, which Items have been prepared primarily by ICE Clear Europe. ICE Clear Europe filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(4)(ii) thereunder,[4] such that the proposed rule change was immediately effective upon filing with the Commission. On April 4, 2022, ICE Clear Europe filed Amendment No. 1 to the proposed rule change to make certain changes to Exhibit 1A and the confidential Exhibit 5.[5] The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 1 (hereafter the ''proposed rule change''), from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

ICE Clear Europe Limited (''ICE Clear Europe'' or the ''Clearing House'') submits this partial amendment (''Amendment No. 1'') to its previously submitted rule changes (the ''Initial Filing'') to amend its Futures & Options Guaranty Fund Policy (''F&O Guaranty Fund Policy'' or ''Policy'').[6] Amendment No. 1 is intended to make an update to (i) Exhibit 1A of the Initial Filing to include a statement by the Clearing House on the burden on competition and (ii) the confidential Exhibit 5 as set out in the Initial Filing to include a filing number on page 25 thereof. The proposed rule changes as set out in the Initial Filing are otherwise unchanged.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe 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. ICE Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

The purpose of Amendment No. 1 is to add Section IIB (which is a statement of the Clearing House on the burden of competition) to Exhibit 1A of the Initial Filing and to add the filing number SR–ICEEU–2022–003 to the header in page 25 of confidential Exhibit 5 as set out in the Initial Filing. The Clearing House's statement on the burden of competition was already described in Form 19b–4 of the Initial Filing but omitted from Exhibit 1A of the Initial Filing.

(b) Statutory Basis

The description of the statutory basis for the amendments set forth in the Initial Filing, as amended hereby, is unchanged.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(4)(ii).

[5] In Amendment No. 1, ICEEU revised Exhibit 1A to include a statement on the burden on competition and revised confidential Exhibit 5 to include a filing number on page 25 thereof; however, the substance of the proposal is unchanged.

[6] Capitalized terms used but not defined herein have the meanings specified in the ICE Clear Europe Clearing Rules and the F&O Guaranty Fund Policy.

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed amendments would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The amendments are being adopted to update and clarify the Clearing House's F&O Guaranty Fund Policy, which relates to the Clearing House's internal processes for determining and reviewing the F&O Fund level in accordance with the Rules. ICE Clear Europe does not believe the amendments will result in any immediate change to the F&O Fund level. Further, ICE Clear Europe does not believe the amendments would affect the costs of clearing, the ability of market participants to access clearing, or the market for clearing services generally. Therefore, ICE Clear Europe does not believe the proposed rule change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

The statement on comments on the proposed rule change in the Initial Filing, as set forth in the Initial Filing, as amended hereby, is unchanged.

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) of the Act[7] and paragraph (f) of Rule 19b–4[8] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICEEU–2022–003 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–ICEEU–2022–003 Amendment No. 1. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change, that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at *https://www.theice.com/clear-europe/regulation.*

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICEEU–2022–003 and should be submitted on or before May 2, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–07622 Filed 4–8–22; 8:45 am]

BILLING CODE 8011–01–P

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, April 14, 2022.

PLACE: The meeting will be held via remote means and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.sec.gov.*

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

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: April 7, 2022.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2022–07814 Filed 4–7–22; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94610; File No. SR–NASDAQ–2022–028]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Expiration Date of the Temporary Amendments Concerning Video Conference Hearings

April 5, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 23, 2022, The Nasdaq Stock Market LLC (''Nasdaq'' 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 Exchange has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. 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 extend the expiration date of the temporary amendments in SR–NASDAQ–2020–076 from March 31, 2022, to July 31, 2022.[4] The proposed rule change would not make any changes to the text of the Exchange rules.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/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 Exchange proposes to continue to harmonize Exchange Rules 1015, 9261, 9524 and 9830 with recent changes by the Financial Industry Regulatory Authority, Inc. (''FINRA'') to its Rules 1015, 9261, 9524 and 9830 in response to the COVID–19 global health crisis and the corresponding need to restrict in-person activities. The Exchange originally filed proposed rule change SR–NASDAQ–2020–076, which allows the Exchange's Office of Hearing Officers (''OHO'') and the Exchange Review Council (''ERC'') to conduct hearings, on a temporary basis, by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing. In December 2021, the Exchange filed a proposed rule change, SR–NASDAQ–2021–104, to extend the expiration date of the temporary amendments in SR-NASDAQ–2020–076 from December 31, 2021, to March 31, 2022.[5]

While there are material signs of improvement, uncertainty still remains for the coming months. The continued presence of COVID–19 variants, dissimilar vaccination rates throughout the United States, and the current medium to high COVID–19 community levels in many states indicate that COVID–19 remains an active and real public health concern.[6] Due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions,[7] the Exchange believes that there is a continued need for temporary relief beyond March 31, 2022. Accordingly, the Exchange proposes to extend the expiration date of the temporary rule amendments in SR–NASDAQ–2020–076 from March 31, 2022, to July 31, 2022.

On November 5, 2020, the Exchange filed, and subsequently extended to March 31, 2022, SR–NASDAQ–2020–076, to temporarily amend Exchange Rules 1015, 9261, 9524 and 9830 to grant OHO and the ERC authority[8] to conduct hearings in connection with appeals of Membership Application Program decisions, disciplinary actions, eligibility proceedings and temporary and permanent cease and desist orders by video conference, if warranted by the COVID–19-related public health risks posed by an in-person hearing.[9]

As set forth in the previous filings, the Exchange also relies on COVID–19 data and the guidance issued by public health authorities to determine whether the current public health risks presented by an in-person hearing may warrant a hearing by video conference.[10] Based on that data and guidance, the Exchange does not believe the COVID–19-related health concerns necessitating this relief will meaningfully subside by March 31, 2022, and believes that there will be a continued need for this temporary relief

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

[4] If the Exchange seeks to provide additional temporary relief from the rule requirements identified in this proposed rule change beyond July 31, 2022, the Exchange will submit a separate rule filing to further extend the temporary extension of time. The amended Exchange rules will revert to their original form at the conclusion of the temporary relief period and any extension thereof.

[5] *See* Securities Exchange Act Release No. 93852 (December 22, 2021), 86 FR 74201 (December 29, 2021) (Notice of Filing and Immediate Effectiveness of File No. SR–NASDAQ–2021–104).

[6] For example, on February 18, 2022, President Joe Biden continued the national emergency concerning COVID–19 beyond March 1, 2022, because COVID–19 ''continues to cause significant risk to the public health and safety'' of the United States. *See* Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID–19) Pandemic, 87 FR 10289 (February 23, 2022).

[7] For instance, the Centers for Disease Control (''CDC'') recommends that people wear a mask in public indoor settings in areas with a high COVID–19 community level regardless of vaccination status or individual risk. *See https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html.* Furthermore, numerous states currently have COVID–19 restrictions in place. Hawaii requires most people to wear masks in indoor public places regardless of vaccination status and several other states have mask mandates in certain settings, such as healthcare and correctional facilities.

[8] For OHO hearings under Exchange Rules 9261 and 9830, the proposed rule change temporarily grants authority to the Chief or Deputy Chief Hearing Officer to order that a hearing be conducted by video conference. For ERC hearings under Exchange Rules 1015 and 9524, this temporary authority is granted to the ERC or relevant Subcommittee.

[9] *See* Securities Exchange Act Release No. 90390 (November 10, 2020), 85 FR 73302 (November 17, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–NASDAQ–2020–076); *see also* Securities Exchange Act Release No. 90774 (December 22, 2020), 85 FR 86614 (December 30, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–NASDAQ–2020–092); Securities Exchange Act Release No. 91763 (May 4, 2021), 86 FR 25055 (May 10, 2021) (Notice of Filing and Immediate Effectiveness of File No. SR–NASDAQ–2021–033); Securities Exchange Act Release No. 92911 (September 9, 2021), 86 FR 51395 (September 15, 2021) (Notice of Filing and Immediate Effectiveness of File No. SR–NASDAQ–2021–067); *supra* note 5.

[10] As noted in SR–NASDAQ–2020–076, the temporary proposed rule change grants discretion to OHO and the ERC to order a video conference hearing. In deciding whether to schedule a hearing by video conference, OHO and the ERC may consider a variety of other factors in addition to COVID–19 trends.

beyond that date. Accordingly, the Exchange proposes to extend the expiration date of the temporary rule amendments originally set forth in SR–NASDAQ–2020–076 from March 31, 2022, to July 31, 2022. The extension of these temporary amendments allowing for specified OHO and ERC hearings to proceed by video conference will allow the Exchange's critical adjudicatory functions to continue to operate effectively in these extraordinary circumstances—enabling the Exchange to fulfill its statutory obligations to protect investors and maintain fair and orderly markets—while also protecting the health and safety of hearing participants.

The Exchange has filed the proposed rule change for immediate effectiveness and has requested that the SEC waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so the Exchange can implement the proposed rule change immediately.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Section 6(b)(5) of the Act,[12] in particular, in that it is designed to promote just and equitable principles of trade, 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, by continuing to provide greater harmonization between the Exchange rules and FINRA rules of similar purpose,[13] resulting in less burdensome and more efficient regulatory compliance.

The proposed rule change, which extends the expiration date of the temporary amendments to the Exchange rules set forth in SR–NASDAQ–2020–076, will continue to aid the Exchange's efforts to timely conduct hearings in connection with its core adjudicatory functions. Given the current and frequently changing COVID–19 conditions and the uncertainty around when those conditions will see meaningful, widespread, and sustained improvement, without this relief allowing OHO and ERC hearings to proceed by video conference, the Exchange might be required to postpone some or almost all hearings indefinitely. The Exchange must be able to perform its critical adjudicatory functions to fulfill its statutory obligations to protect investors and maintain fair and orderly markets. As such, this relief is essential to the Exchange's ability to fulfill its statutory obligations and allows hearing participants to avoid the serious COVID–19-related health and safety risks associated with in-person hearings.

Among other things, this relief will allow OHO to conduct temporary cease and desist proceedings by video conference so that the Exchange can take immediate action to stop ongoing customer harm and will allow the ERC to timely provide members, disqualified individuals and other applicants an approval or denial of their applications. As set forth in detail in SR–NASDAQ–2020–076, this temporary relief allowing OHO and ERC hearings to proceed by video conference accounts for fair process considerations and will continue to provide fair process while avoiding the COVID–19-related public health risks for hearing participants. Accordingly, the proposed rule change extending this temporary relief is in the public interest and consistent with the Act's purpose.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the temporary proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. As set forth in SR–NASDAQ–2020–076, the proposed rule change is intended solely to extend temporary relief necessitated by the continued impacts of the COVID–19 outbreak and the related health and safety risks of conducting in-person activities. The Exchange believes that the proposed rule change will prevent unnecessary impediments to its operations, including its critical adjudicatory processes, and its ability to fulfill its statutory obligations to protect investors and maintain fair and orderly markets that would otherwise result if the temporary amendments were to expire on March 31, 2022.

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

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 from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[14] and subparagraph (f)(6) of Rule 19b–4 thereunder.[15]

A proposed rule change filed under Rule 19b–4(f)(6)[16] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[17] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange has indicated that the proposed rule change to extend the expiration date will continue to prevent unnecessary impediments to its operations, including its critical adjudicatory processes, and its ability to fulfill its statutory obligations to protect investors and maintain fair and orderly markets that would otherwise result if the temporary amendments were to expire on March 31, 2022.[18] Importantly, extending the temporary relief provided in SR–NASDAQ–2020–076 immediately upon filing and without a 30-day operative delay will allow the Exchange to continue critical adjudicatory and review processes in a reasonable and fair manner and meet its critical investor protection goals, while also following best practices with respect to the health and safety of its employees.[19] The Commission also notes that this proposal extends without change the temporary relief previously provided by SR–NASDAQ–2020–076.[20] As proposed, the temporary changes would be in place through July 31, 2022 and the amended rules will revert back to their original state at the conclusion of the temporary relief period and, if

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *See* Securities Exchange Act Release No. 94430 (March 16, 2022), 87 FR 16262 (March 22, 2022) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2022–004).

[14] 15 U.S.C. 78s(b)(3)(A)(iii).

[15] 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.

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] *See supra* Item II.

[19] *See* Securities Exchange Act Release No. 94430 (March 16, 2022); 86 FR 16262, 16264 (March 16, 2022) (noting the same in granting FINRA's request to waive the 30-day operative delay so that SR–FINRA–2022–004 would become operative immediately upon filing).

[20] *See supra* note 9.

applicable, any extension thereof.[21] For these reasons, the Commission believes that waiver of the 30-day operative delay for this proposal is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[22]

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 (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2022–028 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–NASDAQ–2022–028. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2022–028 and should be submitted on or before May 2, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–07625 Filed 4–8–22; 8:45 am]

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[21] *See supra* note 4. As noted above, the Exchange states that if it requires temporary relief from the rule requirements identified in this proposal beyond July 31, 2022, it may submit a separate rule filing to extend the effectiveness of the temporary relief under these rules.

[22] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94607; File No. SR–ICEEU–2022–004]

Self-Regulatory Organizations; ICE Clear Europe Limited; Order Approving Proposed Rule Change Relating to Amendments to the ICE Clear Europe CDS Clearing Stress-Testing Policy and CDS Clearing Back-Testing Policy

April 5, 2022.

I. Introduction

On February 10, 2022, ICE Clear Europe Limited (''ICE Clear Europe'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend its CDS Clearing Back-Testing Policy (''CDS Back-Testing Policy'') and CDS Clearing Stress-Testing Policy (''CDS Stress-Testing Policy''). The proposed rule change was published for comment in the **Federal Register** on February 25, 2022.[3] The Commission did not receive comments regarding the proposed rule change. For the reasons discussed below, the Commission is approving the proposed rule change.

II. Description of the Proposed Rule Change

The proposed rule change would amend the CDS Clearing Back-Testing Policy and CDS Clearing Stress-Testing Policy to remediate the findings of an independent validation. The discussion below describes the proposed amendments in the order they appear in each policy.

i. CDS Back-Testing Policy

The proposed rule change first would correct the capitalization of the title of Section 2.1. In that section, the proposed rule change also would correct a typographical error by replacing the word ''follow'' with ''follows.'' In addition to those typographical corrections, the proposed rule change would add new language at the end of the section. This new language would explain that ICE Clear Europe conducts several types of backtests and that ICE Clear Europe adopts all the available reliable and validated data for each backtest in order to assess the model performance over a long period, where stress market conditions and idiosyncratic events are likely to have manifested.

Next, the proposed rule change would add a new Section 2.2 and re-number the remaining sections accordingly. New Section 2.2 would explain that ICE Clear Europe backtests the CDS risk model with overlapping data and non-overlapping data. This section also would explain that ICE Clear Europe prefers to backtest with non-overlapping data for static portfolios. Because the CDS risk model covers a multi-days risk horizon, the lack of sufficiently long data sets limits ICE Clear Europe's ability to use non-overlapping data, however. ICE Clear Europe would address this limitation by using overlapping data to make a statistically significant sample.

This new Section 2.2, as well as the new language at the end of Section 2.1, would document ICE Clear Europe's existing practice of backtesting using overlapping data and non-overlapping data, and, in doing so, using all the available reliable and validated data for each backtest in order to assess the model performance over a long period.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Proposed Rule Change Relating to Amendments to the ICE Clear Europe CDS Clearing Stress Testing Policy and CDS Clearing Back-Testing Policy, Exchange Act Release No. 94280 (Feb. 18, 2022); 87 FR 10878 (Feb. 25, 2022) (SR–ICEEU–2022–004) (''Notice'').

Backtesting using overlapping data potentially double-counts exceedances if the exceedances occur when data overlap. Because of this possible double-counting, backtesting with non-overlapping data is the preferred approach, but ICE Clear Europe still conducts backtesting with overlapping data, using all available reliable and validated data, to ensure it has an appropriate sample size.

The proposed rule change next would amend re-numbered Section 2.4 (currently Section 2.2), which describes the Basel Traffic Light System (''BTLS'').[4] The proposed rule change would explain how ICE Clear Europe addresses one of the main assumptions of the BTLS, which is that excessive losses are time independent. As described above, ICE Clear Europe relies on overlapping data as necessary to ensure sufficiently long backtesting data sets. Conducting backtests with overlapping data could double-count exceedances if the exceedances occur when the data overlap. Because the BTLS assumes that exceedances are time independent, however, ICE Clear Europe corrects the number of consecutive exceedances within the risk time horizon.

The proposed rule change would re-number current Section 2.3 to Section 3.1, and add a title for a new Section 3 immediately before re-numbered Section 3.1. The proposed rule change would change the title of re-numbered Section 3.1 to Multi-days horizon backtesting. Within re-numbered Section 3.1, the proposed rule change would make four clarifications. First, the proposed rule change would specify that the observed loss is the minimum net asset value change over 5 days for house accounts, as distinct from 7 days for client accounts. Second, the proposed rule change would specify that the difference between the maximum observed unrealized loss and the backtested component of initial margin is also known as the ''back-test exceedances.'' Third, the proposed rule change would clarify that the maximum observed unrealized loss is also known as the ''worst N-days P&L.'' [5] Finally, the proposed rule change would explain that ICE Clear Europe's use of the worst N-days P&L may lead to multiple consecutive backtest exceedances following one large market move in the overlapping backtesting approach.

Next, the proposed rule change would correct the capitalization of the title of Section 3.2 (re-numbered from Section 2.4). In that section the proposed rule change also would explain that the last two examples in Table 2 could be the 4-days P/L or 3-days P/L.[6]

In Section 3.3 (re-numbered from Section 2.5), the proposed rule change would clarify that a minimum of one year of observations is required to define the statistical significance of backtesting results.

The proposed rule change would correct the capitalization of the title of Section 3.4 (re-numbered from Section 2.6). In that section the proposed rule change also would describe how ICE Clear Europe backtests special strategy portfolios. ICE Clear Europe backtests special strategy portfolios that cover certain trading strategies, such as Index arbitrage. The proposed rule change also would specify that the Clearing Risk Department reviews backtest results at the 99.5% quantile monthly, while backtest results at the 99.75% quantile would be reviewed on an ad-hoc basis, when there is a large market move. Finally, the proposed rule change would delete a table showing portfolio construction for special strategy backtesting because it is unnecessary in light of the new detail added to Section 3.4.

The proposed rule change would correct the capitalization of the title of Section 3.5 (re-numbered from Section 2.7).

The proposed rule would add a new section numbered 3.6 to explain how ICE Clear Europe backtests stylized portfolios. Stylized portfolios are portfolios that replicate certain trading strategies. This new section would explain that the Clearing Risk Department backtests a series of stylized portfolios when ICE Clear Europe clears a new risk factor.[7] ICE Clear Europe backtests these portfolios, which replicate trading strategies, to assess the CDS risk model's treatment of the new risk factors. ICE Clear Europe also backtests risk factors that have the largest open interest. ICE Clear Europe represents that these changes reflect current backtesting practice and are intended to more clearly document such practices in the CDS Back-Testing Policy.[8]

The proposed rule change would correct the capitalization of the title of Section 3.7 (re-numbered from Section 2.8).

Finally, the proposed rule change would amend Section 4 (re-numbered from Section 3). Section 4 would describe ICE Clear Europe's univariate backtesting. The proposed rule change would clarify that the Clearing Risk Department reviews backtest results at the 99.5% quantile monthly and reports these results to the Model Oversight Committee monthly. Backtest results at the 99.75% quantile would be reviewed ad-hoc, when stress market conditions might cause breaches at the 99.5% quantile.

ii. CDS Stress-Testing Policy

The proposed rule change would make one change to the CDS Stress-Testing Policy. In Section 4.1.2 the proposed rule change would add the words ''and hypothetical'' to a paragraph describing forward-looking credit events scenarios. The change would clarify that the described forward-looking credit events scenarios are based on both historically observed and hypothetical extreme but plausible market scenarios. ICE Clear Europe represents that this change reflects current stress-testing practice.[9]

III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to such organization.[10] For the reasons discussed below, the Commission finds that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act,[11] and Rules

[4] For a general description of the BTLS, *see* BIS, revisions to market risk disclosure requirements, *available at https://www.bis.org/bcbs/publ/d484.htm.*

[5] The proposed rule change would make similar updates to these terms throughout the CDS Back-Testing Policy.

[6] ICE Clear Europe calculates daily back-testing results for each Clearing Member's account for each of the 5 business days beginning 10 business days prior to the reporting date for house accounts (or 7 business days beginning 14 business days prior to the reporting period for client accounts). For each backtested day, ICE Clear Europe calculates the maximum observed unrealized loss with positions from the relevant Clearing Member's accounts as of that day. Table 2 shows an example of this reporting.

[7] As explained in ICE Clear Europe's CDS Risk Model Description, the term risk factor refers to a CDS index, sub-index, or single-name. *See* Self-Regulatory Organizations; ICE Clear Europe Limited; Order Approving Proposed Rule Change Relating to the ICE Clear Europe CDS Clearing Stress Testing Policy, CDS End of Day Price Discovery Policy, CDS Risk Model Description and CDS Risk Policy and CDS Parameters Review Procedures, Exchange Act Release No. 91586 (Apr. 16, 2021); 86 FR 21418 (Apr. 22, 2021) (SR–ICEEU–2021–006).

[8] Notice, 87 FR at 10879.

[9] Notice, 87 FR at 10880.

[10] 15 U.S.C. 78s(b)(2)(C).

[11] 15 U.S.C. 78q–1(b)(3)(F).

17Ad–22(e)(4)(vi)(A) and 17Ad–22(e)(6)(vi)(A) thereunder.[12]

i. 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 ICE Clear Europe be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions.[13] Based on its review of the record, and for the reasons discussed below, the Commission believes the proposed changes to the CDS Back-Testing Policy and CDS Stress-Testing Policy are consistent with the promotion of the prompt and accurate clearance and settlement of securities transactions.

The Commission believes that the proposed rule change would make the CDS Back-Testing Policy and CDS Stress-Testing Policy easier to use and apply. One way it would do so is by explaining ICE Clear Europe's backtesting and stress testing practices. These practices would include: A preference for backtesting using non-overlapping data; corrections to exceedances in overlapping data to conform to the assumption from the BTLS that losses are time-independent; the requirement of a minimum of one year of observations to define the statistical significance of backtesting results; use of all available reliable and validated data for each backtest; and, with respect to the CDS Stress-Testing Policy, that forward-looking credit event scenarios are based on both historically observed and hypothetical extreme but plausible market scenarios. The Commission believes that documenting these practices in ICE Clear Europe's policies should facilitate more consistent and predictable backtesting and stress testing.

Another way the proposed rule change would make the CDS Back-Testing Policy easier to use and apply is by explaining how ICE Clear Europe backtests special strategy portfolios. The proposed rule change would describe the set of portfolios used in backtesting of special strategy portfolios, and also would explain how ICE Clear Europe reviews and reports results at 99.5% quantiles and 99.75% quantiles for special strategy portfolios and univariate backtesting. The proposed rule change also would explain how ICE Clear Europe backtests stylized portfolios when it clears a new risk factor. The Commission believes that documenting such additional explanations would help to clarify how ICE Clear Europe backtests portfolios that use special trading strategies and reports the results of those backtests.

The proposed rule change also would make the CDS Back-Testing Policy easier to use and apply by clarifying certain terminology used in the policy and by correcting typographical errors. For example, the proposed rule change would clarify that the shortfall between the maximum observed unrealized loss and the backtested component of initial margin is also known as ''back-test exceedances'' and that the maximum observed unrealized loss is also known as ''worst N-days P&L.'' The proposed rule also would clarify that the observed loss is calculated as the minimum net asset value change over 5 days for house accounts as distinct from 7 days for client accounts, and that the last two examples in Table 2 could be the 4-days P/L or 3-days P/L. In addition to these clarifications, the proposed rule change would correct typographical errors and re-number sections. The Commission believes these particular changes would help to increase the clarity and accuracy of the CDS Back-Testing Policy.

Because ICE Clear Europe backtests and stress tests the CDS risk model using the CDS Back-Testing Policy and CDS Stress-Testing Policy, the Commission believes that these improvements to the policies would improve ICE Clear Europe's backtesting and stress testing. Improved backtesting and stress testing should help ICE Clear Europe to find deficiencies in, and correct, the CDS risk model. Better risk models should, in turn, increase the likelihood that ICE Clear Europe will have sufficient financial resources in excess of margin to address losses that could arise from the default of a Clearing Member. The Commission believes that by increasing the likelihood that ICE Clear Europe will have sufficient financial resources, the proposed rule change would enhance ICE Clear Europe's ability to continue to promptly and accurately clear and settle securities transactions during periods of market stress, consistent with Section 17A(b)(3)(F) of the Act.[14]

Therefore, the Commission finds that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act.[15]

ii. Consistency With Rule 17Ad–22(e)(4)(vi)(A) Under the Act

Rule 17Ad–22(e)(4)(vi)(A) requires that ICE Clear Europe establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by testing the sufficiency of its total financial resources available to meet the minimum financial resource requirements under Rule 17Ad–22(e)(4)(i) through (iii),[16] as applicable, by conducting stress testing of its total financial resources once each day using standard predetermined parameters and assumptions.[17] As discussed above, the Commission believes the proposed rule change should improve ICE Clear Europe's CDS Stress-Testing Policy by clarifying that the forward-looking credit events scenarios are based on both historically observed and hypothetical extreme but plausible market scenarios. Because ICE Clear Europe uses the CDS Stress-Testing Policy and the forward-looking credit event scenarios to conduct daily stress testing of its total financial resources, the Commission believes this aspect of the proposed rule change should help to ensure that ICE Clear Europe conducts stress testing of its total financial resources once each day using standard predetermined parameters and assumptions, including forward-looking credit event scenarios that are based on both historically observed and hypothetical extreme but plausible market scenarios.[18]

Therefore, the Commission finds that this aspect of the proposed rule change is consistent with Rule 17Ad–22(e)(4)(vi)(A).[19]

iii. Consistency With Rule 17Ad–22(e)(6)(vi)(A) Under the Act

Rule 17Ad–22(e)(6)(vi)(A) requires that ICE Clear Europe establish, implement, maintain and enforce written policies and procedures reasonably designed to cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, is monitored by management on an ongoing basis and is regularly reviewed, tested, and verified

[12] 17 CFR 240.17Ad–22(e)(4)(vi)(A) and 17 CFR 240.17Ad–22(e)(6)(vi)(A).

[13] 15 U.S.C. 78q–1(b)(3)(F).

[14] 15 U.S.C. 78q–1(b)(3)(F).

[15] 15 U.S.C. 78q–1(b)(3)(F).

[16] 17 CFR 240.17Ad–22(e)(4)(i)–(iii).

[17] 17 CFR 240.17Ad–22(e)(4)(vi)(A).

[18] The CDS Stress-Testing Policy requires that ICE Clear Europe conduct stress testing daily. *See* Self-Regulatory Organizations; ICE Clear Europe Limited; Order Approving Proposed Rule Change Relating to Amendments to the ICE Clear Europe CDS Risk Policy (the ''CDS Risk Policy''), CDS Clearing Back-Testing Policy (the ''Back-Testing Policy'') and CDS Stress-Testing Policy (the ''Stress-Testing Policy'') (Collectively, the ''CDS Policies''), Exchange Act Release No. 85236 (Mar. 1, 2019); 84 FR 8348 (Mar. 7, 2019) (SR–ICEEU–2018–010).

[19] 17 CFR 240.17Ad–22(e)(4)(vi)(A).

by conducting backtests of its margin model at least once each day using standard predetermined parameters and assumptions.[20] As discussed above, the Commission believes the changes to the CDS Back-Testing Policy would overall make the policy easier to use and apply. Because ICE Clear Europe uses the CDS Back-Testing Policy to conduct daily backtests of its margin model, the Commission believes these aspects of the proposed rule change should help to ensure that ICE Clear Europe conducts backtests of its margin model at least once each day using standard predetermined parameters and assumptions.[21] Therefore, the Commission finds that this aspect of the proposed rule change is consistent with Rule 17Ad–22(e)(6)(vi)(A).[22]

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act, and in particular, with the requirements of Section 17A(b)(3)(F) of the Act,[23] and Rules 17Ad–22(e)(4)(vi)(A) and 17Ad–22(e)(6)(vi)(A) thereunder.[24]

It is therefore ordered pursuant to Section 19(b)(2) of the Act [25] that the proposed rule change (SR–ICEEU–2022–004) be, and hereby is, approved.[26]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

J. Matthew DeLesDernier,

Assistant Secretary.

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[20] 17 CFR 240.17Ad–22(e)(6)(vi)(A).

[21] The CDS Back-Testing Policy requires that ICE Clear Europe conduct back-testing daily. *See* Self-Regulatory Organizations; ICE Clear Europe Limited; Order Approving Proposed Rule Change Relating to Amendments to the ICE Clear Europe CDS Risk Policy (the ''CDS Risk Policy''), CDS Clearing Back-Testing Policy (the ''Back-Testing Policy'') and CDS Stress-Testing Policy (the ''Stress-Testing Policy'') (Collectively, the ''CDS Policies''), Exchange Act Release No. 85236 (Mar. 1, 2019); 84 FR 8348 (Mar. 7, 2019) (SR–ICEEU–2018–010).

[22] 17 CFR 240.17Ad–22(e)(6)(vi)(A).

[23] 15 U.S.C. 78q–1(b)(3)(F).

[24] 17 CFR 240.17Ad–22(e)(4)(vi)(A) and 17 CFR 240.17Ad–22(e)(6)(vi)(A).

[25] 15 U.S.C. 78s(b)(2).

[26] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[27] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94611; File No. SR–Phlx–2022–15]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Expiration Date of the Temporary Amendments Concerning Video Conference Hearings

April 5, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 23, 2022, Nasdaq PHLX LLC (''Phlx'' 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 Exchange has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. 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 extend the expiration date of the temporary amendments in SR–Phlx–2020–53 from March 31, 2022, to July 31, 2022.[4] The proposed rule change would not make any changes to the text of the Exchange rules.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/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 Exchange proposes to continue to harmonize Exchange Rule General 3, Section 16 with recent changes by the Financial Industry Regulatory Authority, Inc. (''FINRA'') to its Rule 1015 in response to the COVID–19 global health crisis and the corresponding need to restrict in-person activities.[5] The Exchange originally filed proposed rule change SR–Phlx–2020–53, which allows the Exchange Review Council (''ERC'') to conduct hearings in connection with appeals of Membership Application Program decisions, on a temporary basis, by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing. In December 2021, the Exchange filed a proposed rule change, SR–Phlx–2021–75, to extend the expiration date of the temporary amendments in SR–Phlx–2020–53 from December 31, 2021, to March 31, 2022.[6] While there are material signs of improvement, uncertainty still remains for the coming months. The continued presence of COVID–19 variants, dissimilar

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

[4] If the Exchange seeks to provide additional temporary relief from the rule requirements identified in this proposed rule change beyond July 31, 2022, the Exchange will submit a separate rule filing to further extend the temporary extension of time. The amended Exchange rules will revert to their original form at the conclusion of the temporary relief period and any extension thereof.

[5] *See* Securities Exchange Act Release No. 94430 (March 16, 2022), 87 FR 16262 (March 22, 2022) (Notice of Filing and Immediate Effectiveness of File No. SR–FINRA–2022–004) (''FINRA Filing''). The Exchange notes that the FINRA Filing also proposed to temporarily amend FINRA Rules 9261, 9524, and 9830, which govern hearings in connection with appeals of disciplinary actions, eligibility proceedings, and temporary and permanent cease and desist orders. The Exchange's Rules 9261, 9524, and 9830 incorporate by reference The Nasdaq Stock Market LLC rules, which are the subject of a separate filing. *See* SR–NASDAQ–2022–028. Therefore, the Exchange is not proposing to adopt that aspect of the FINRA Filing.

[6] *See* Securities Exchange Act Release No. 93853 (December 22, 2021), 86 FR 74164 (December 29, 2021) (Notice of Filing and Immediate Effectiveness of File No. SR–Phlx–2021–75); *see also* Securities Exchange Act Release No. 92906 (September 9, 2021), 86 FR 51404 (September 15, 2021) (Notice of Filing and Immediate Effectiveness of File No. SR–Phlx–2021–49); Securities Exchange Act Release No. 91766 (May 4, 2021), 86 FR 25014 (May 10, 2021) (Notice of Filing and Immediate Effectiveness of File No. SR–Phlx–2021–27); Securities Exchange Act Release No. 90758 (December 21, 2020), 85 FR 85782 (December 29, 2020) (Notice of Filing and Immediate Effectiveness of File No. SR–Phlx–2020–053).

vaccination rates throughout the United States, and the current medium to high COVID–19 community levels in many states indicate that COVID–19 remains an active and real public health concern.[7] Due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions,[8] the Exchange believes that there is a continued need for temporary relief beyond March 31, 2022. Accordingly, the Exchange proposes to extend the expiration date of the temporary rule amendments in SR–Phlx–2020–53 from March 31, 2022, to July 31, 2022.

As set forth in SR–Phlx–2020–53, the Exchange also relies on COVID–19 data and criteria to determine whether the current public health risks presented by an in-person hearing may warrant a hearing by video conference. Based on that data and criteria, the Exchange does not believe the COVID–19-related health concerns necessitating this relief will meaningfully subside by March 31, 2022, and believes that there will be a continued need for this temporary relief beyond that date. Accordingly, the Exchange proposes to extend the expiration date of the temporary rule amendments originally set forth in SR–Phlx–2020–53 from March 31, 2022, to July 31, 2022. The extension of the temporary amendments allowing for specified ERC hearings to proceed by video conference will allow the Exchange's critical adjudicatory functions to continue to operate effectively in these extraordinary circumstances—enabling the Exchange to fulfill its statutory obligations to protect investors and maintain fair and orderly markets—while also protecting the health and safety of hearing participants.

The Exchange has filed the proposed rule change for immediate effectiveness and has requested that the SEC waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so the Exchange can implement the proposed rule change immediately.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Section 6(b)(5) of the Act,[10] in particular, in that it is designed to promote just and equitable principles of trade, 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, by providing greater harmonization between the Exchange rules and FINRA rules of similar purpose,[11] resulting in less burdensome and more efficient regulatory compliance.

The proposed rule change, which extends the expiration date of the temporary amendments to the Exchange rules set forth in SR–Phlx–2020–53, will continue to aid the Exchange's efforts to timely conduct hearings in connection with its core adjudicatory functions. Given the current and frequently changing COVID–19 conditions and the uncertainty around when those conditions will see meaningful, widespread and sustained improvement, without this relief allowing ERC hearings to proceed by video conference, the Exchange might be required to postpone some or almost all hearings indefinitely. The Exchange must be able to perform its critical adjudicatory functions to fulfill its statutory obligations to protect investors and maintain fair and orderly markets. As such, this relief is essential to the Exchange's ability to fulfill its statutory obligations and allows hearing participants to avoid the serious COVID–19-related health and safety risks associated with in-person hearings.

Among other things, this relief will allow the ERC to timely provide members, disqualified individuals and other applicants an approval or denial of their applications. As set forth in detail in SR–Phlx–2020–53, this temporary relief allowing ERC hearings to proceed by video conference accounts for fair process considerations and will continue to provide fair process while avoiding the COVID–19-related public health risks for hearing participants. Accordingly, the proposed rule change extending this temporary relief is in the public interest and consistent with the Act's purpose.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the temporary proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. As set forth in SR–Phlx–2020–53, the proposed rule change is intended solely to extend temporary relief necessitated by the continued impacts of the COVID–19 outbreak and the related health and safety risks of conducting in-person activities. The Exchange believes that the proposed rule change will prevent unnecessary impediments to its operations, including its critical adjudicatory processes, and its ability to fulfill its statutory obligations to protect investors and maintain fair and orderly markets that would otherwise result if the temporary amendments were to expire on March 31, 2022.

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

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 from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[12] and subparagraph (f)(6) of Rule 19b–4 thereunder.[13]

A proposed rule change filed under Rule 19b–4(f)(6)[14] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[15] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon

[7] For example, on February 18, 2022, President Joe Biden continued the national emergency concerning COVID–19 beyond March 1, 2022, because COVID–19 ''continues to cause significant risk to the public health and safety'' of the United States. *See* Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID–19) Pandemic, 87 FR 10289 (February 23, 2022).

[8] For instance, the Centers for Disease Control (''CDC'') recommends that people wear a mask in public indoor settings in areas with a high COVID–19 community level regardless of vaccination status or individual risk. *See https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html*. Furthermore, numerous states currently have COVID–19 restrictions in place. Hawaii requires most people to wear masks in indoor public places regardless of vaccination status and several other states have mask mandates in certain settings, such as healthcare and correctional facilities.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *See supra* note 5.

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 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.

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

filing. The Exchange has indicated that the proposed rule change to extend the expiration date will continue to prevent unnecessary impediments to its operations, including its critical adjudicatory processes, and its ability to fulfill its statutory obligations to protect investors and maintain fair and orderly markets that would otherwise result if the temporary amendments were to expire on March 31, 2022.[16] Importantly, extending the temporary relief provided in SR–Phlx–2020–53 immediately upon filing and without a 30-day operative delay will allow the Exchange to continue critical adjudicatory and review processes in a reasonable and fair manner and meet its critical investor protection goals, while also following best practices with respect to the health and safety of its employees.[17] The Commission also notes that this proposal extends without change the temporary relief previously provided by SR–Phlx–2020–53.[18] As proposed, the temporary changes would be in place through July 31, 2022 and the amended rules will revert back to their original state at the conclusion of the temporary relief period and, if applicable, any extension thereof.[19] For these reasons, the Commission believes that waiver of the 30-day operative delay for this proposal is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[20]

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.

[16] *See supra* Item II.

[17] *See* FINRA Filing, 86 FR 16262, 16264 (noting the same in granting FINRA's request to waive the 30-day operative delay so that SR–FINRA–2022–004 would become operative immediately upon filing).

[18] *See supra* note 6.

[19] *See supra* note 4. As noted above, the Exchange states that if it requires temporary relief from the rule requirements identified in this proposal beyond July 31, 2022, it may submit a separate rule filing to extend the effectiveness of the temporary relief under these rules.

[20] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–Phlx–2022–15 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2022–15. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2022–15 and should be submitted on or before May 2, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

J. Matthew DeLesDernier,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94614; File No. SR–MEMX–2022–03]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Fee Schedule To Adopt Market Data Fees

April 5, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 24, 2022, MEMX LLC (''MEMX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the 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 is filing with the Commission a proposed rule change to amend the Exchange's fee schedule applicable to Members [3] and non-Members (the ''Fee Schedule'') pursuant to Exchange Rules 15.1(a) and (c). The Exchange proposes to implement the changes to the Fee Schedule pursuant to this proposal on April 1, 2022. The text of the proposed rule change is provided in Exhibit 5.

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

[21] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Rule 1.5(p).

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

Background

The purpose of the proposed rule change is to amend the Fee Schedule to adopt fees the Exchange will charge to Members and non-Members for each of its three proprietary market data feeds, namely MEMOIR Depth, MEMOIR Top, and MEMOIR Last Sale (collectively, the ''Exchange Data Feeds''). As set forth below, the Exchange believes that the proposed fees are fair and reasonable and has based its proposal on the fact that competitive forces exist with respect to the Exchange Data Feeds, a comparison to competitor pricing, as well as a cost analysis intended to provide transparency to the Commission and to the industry at large. The Exchange is proposing to implement the proposed fees on April 1, 2022.

Before setting forth the additional details regarding the existence of competitive forces, the comparison to competitor pricing and the Exchange's cost analysis for transparency purposes, immediately below is a description of the proposed fees.

Proposed Market Data Pricing

The Exchange offers three separate data feeds to subscribers—MEMOIR Depth, MEMOIR Top and MEMOIR Last Sale. The proposed pricing for each of these products is set forth below.

MEMOIR Depth

The MEMOIR Depth feed is a MEMX-only market data feed that contains all displayed orders for securities trading on the Exchange (*i.e.,* top and depth-of-book order data), order executions (*i.e.,* last sale data), order cancellations, order modifications, order identification numbers, and administrative messages.[4] The Exchange proposes to charge each of the fees set forth below for MEMOIR Depth.

1. *Internal Distribution Fee.* For the receipt of access to the MEMOIR Depth feed, the Exchange proposes to charge $1,500 per month. This proposed access fee would be charged to any data recipient that receives a data feed of the MEMOIR Depth feed for purposes of internal distribution (*i.e.,* an ''Internal Distributor''). The Exchange proposes to define an Internal Distributor as ''a Distributor that receives an Exchange Data product and then distributes that data to one or more data recipients within the Distributor's own organization.'' [5] The proposed access fee for internal distribution will be charged only once per month per subscribing entity (''Firm''). The Exchange notes that it has proposed to use the phrase ''own organization'' in the definition of Internal Distributor and External Distributor because a Firm will be permitted to share data received from an Exchange Data product to other legal entities affiliated with the Firm that have been disclosed to the Exchange without such distribution being considered external to a third party. For instance, if a company has multiple affiliated broker-dealers under the same holding company, that company could have one of the broker-dealers or a non-broker-dealer affiliate subscribe to an Exchange Data product and then share the data with other affiliates that have a need for the data. This sharing with affiliates would not be considered external distribution to a third party but instead would be considered internal distribution to data recipients within the Distributor's own organization.

2. *External Distribution Fee.* For redistribution of the MEMOIR Depth feed, the Exchange proposes to establish an access fee of $2,500 per month. The proposed redistribution fee would be charged to any External Distributor of the MEMOIR Depth feed, which would be defined to mean ''a Distributor that receives an Exchange Data product and then distributes that data to a third party or one or more data recipients outside the Distributor's own organization.'' [6] The proposed access fee for external distribution will be charged only once per month per Firm. As noted above, while a Firm will be permitted to share data received from an Exchange Data product to other legal entities affiliated with the Firm that have been disclosed to the Exchange without such distribution being considered external to a third party, if a Firm distributes data received from an Exchange Data product to an unaffiliated third party that would be considered distribution to data recipients outside the Distributor's own organization and the access fee for external distribution would apply.

3. *Non-Display Use Fees.* The Exchange proposes to establish separate non-display fees for usage by Trading Platforms and other Users (*i.e.,* not by Trading Platforms).[7] Non-Display Usage would be defined to mean ''any method of accessing an Exchange Data product that involves access or use by a machine or automated device without access or use of a display by a natural person or persons.'' [8] For Non-Display Usage of the MEMOIR Depth feed not by Trading Platforms, the Exchange proposes to establish a fee of $1,500 per month.[9] For Non-Display Usage of the MEMOIR Depth feed by Trading Platforms, the Exchange proposes to establish a fee of $4,000 per month. The proposed fees for Non-Display Usage will be charged only once per category per Firm.[10] In other words, with respect to Non-Display Usage Fees, a Firm that uses MEMOIR Depth for non-display purposes but does not operate a Trading Platform would pay $1,500 per month, a Firm that uses MEMOIR Depth in connection with the operation of one or more Trading Platforms (but not for other purposes) would pay $4,000 per month, and a Firm that uses MEMOIR Depth for non-display purposes other than operating a Trading Platform and for the operation of one or more Trading Platforms would pay $5,500 per month.

4. *User Fees.* The Exchange proposes to charge a Professional User Fee (per User) of $30 per month and a Non-Professional User Fee (per User) of $3 per month. The proposed User fees would apply to each person that has access to the MEMOIR Depth feed for

[4] *See* MEMX Rule 13.8(a).

[5] *See* Market Data Definitions under the proposed MEMX Fee Schedule. The Exchange also proposes to adopt a definition for ''Distributor'', which would mean any entity that receives an Exchange Data product directly from the Exchange or indirectly through another entity and then distributes internally or externally to a third party.

[6] *See* Market Data Definitions under the proposed MEMX Fee Schedule.

[7] The Exchange proposes to define a Trading Platform as ''any execution platform operated as or by a registered National Securities Exchange (as defined in Section 3(a)(1) of the Exchange Act), an Alternative Trading System (as defined in Rule 300(a) of Regulation ATS), or an Electronic Communications Network (as defined in Rule 600(b)(23) of Regulation NMS).'' *See* Market Data Definitions under the proposed MEMX Fee Schedule.

[8] *See* Market Data Definitions under the proposed MEMX Fee Schedule.

[9] Non-Display Usage not by Trading Platforms would include trading uses such as high frequency or algorithmic trading as well as any trading in any asset class, automated order or quote generation and/or order pegging, price referencing for smart order routing, operations control programs, investment analysis, order verification, surveillance programs, risk management, compliance, and portfolio management.

[10] The Exchange proposes to adopt note 1 to the proposed Market Data fees table, which would make clear to subscribers that use of the data for multiple non-display purposes or operate more than one Trading Platform would only be charged once per category per month. Thus, the footnote makes clear that each fee applicable to Non-Display Usage is charged per subscriber (*e.g.,* a Firm) and that each of the fees represents the maximum charge per month per subscriber regardless of the number of non-display uses and/or Trading Platforms operated by the subscriber, as applicable.

displayed usage. Thus, each Distributor's count will include every individual that accesses the data regardless of the purpose for which the individual uses the data. Internal Distributors and External Distributors of the MEMX Depth feed must report all Professional and Non-Professional Users in accordance with the following:

- In connection with a Distributor's distribution of the MEMOIR Depth feed, the Distributor must count as one User each unique User that the Distributor has entitled to have access to the MEMOIR Depth feed.
- Distributors must report each unique individual person who receives access through multiple devices or multiple methods (*e.g.,* a single User has multiple passwords and user identifications) as one User.
- If a Distributor entitles one or more individuals to use the same device, the Distributor must include only the individuals, and not the device, in the count. Thus, Distributors would not be required to report User device counts associated with a User's display use of the data feed.

5. *Enterprise Fee.* Other than the Digital Media Enterprise Fee described below, the Exchange is not proposing to adopt an Enterprise Fee for the MEMOIR Depth feed at this time.

6. *Digital Media Enterprise Fee.* As an alternative to User fees, a recipient Firm may purchase a monthly Digital Media Enterprise license to receive MEMOIR Depth for distribution to an unlimited number of Users for viewing via television, websites, and mobile devices for informational and non-trading purposes only. The Exchange proposes to establish a fee of $5,000 per month for a Digital Media Enterprise license to the MEMOIR Depth feed.

MEMOIR Top

The MEMOIR Top feed is a MEMX-only market data feed that contains top of book quotations based on equity orders entered into the System.[11] The Exchange proposes to charge each of the fees set forth below for MEMOIR Top.

1. *Internal Distribution Fee.* For the receipt of access to the MEMOIR Top feed, the Exchange proposes to charge $750 per month. This proposed access fee would be charged to any data recipient that receives a data feed of the MEMOIR Top feed for purposes of internal distribution (*i.e.,* an Internal Distributor). The proposed access fee for internal distribution will be charged only once per month per Firm.

2. *External Distribution Fee.* For redistribution of the MEMOIR Top feed, the Exchange proposes to establish an access fee of $2,000 per month. The proposed redistribution fee would be charged to any External Distributor of the MEMOIR Top feed. The proposed access fee for external distribution will be charged only once per month per Firm.

3. *Non-Display Use Fees.* The Exchange does not propose to establish non-display fees for usage by Trading Platforms or other Users with respect to MEMOIR Top.

4. *User Fees.* The Exchange proposes to charge a Professional User Fee (per User) of $0.01 per month and a Non-Professional User Fee (per User) of $0.01 per month. The proposed User fees would apply to each person that has access to the MEMOIR Top feed that is provided by an External Distributor for displayed usage. The Exchange does not propose any per User fees for internal distribution of the MEMOIR Top feed. Each External Distributor's count will include every individual that accesses the data regardless of the purpose for which the individual uses the data. External Distributors of the MEMOIR Top feed must report all Professional and Non-Professional Users[12] in accordance with the following:

- In connection with an External Distributor's distribution of the MEMOIR Top feed, the Distributor must count as one User each unique User that the Distributor has entitled to have access to the MEMOIR Top feed.
- External Distributors must report each unique individual person who receives access through multiple devices or multiple methods (*e.g.,* a single User has multiple passwords and user identifications) as one User.
- If an External Distributor entitles one or more individuals to use the same device, the Distributor must include only the individuals, and not the device, in the count. Thus, Distributors would not be required to report User device counts associated with a User's display use of the data feed.

5. *Enterprise Fee.* As an alternative to User fees, a recipient Firm may purchase a monthly Enterprise license to receive MEMOIR Top for distribution to an unlimited number of Professional and Non-Professional Users. The Exchange proposes to establish a fee of $10,000 per month for an Enterprise license to the MEMOIR Top feed.

6. *Digital Media Enterprise Fee.* As an alternative to User fees, a recipient Firm may purchase a monthly Digital Media Enterprise license to receive MEMOIR Top for distribution to an unlimited number of Users for viewing via television, websites, and mobile devices for informational and non-trading purposes only. The Exchange proposes to establish a fee of $2,000 per month for a Digital Media Enterprise license to the MEMOIR Top feed.

MEMOIR Last Sale

The MEMOIR Last Sale feed is a MEMX-only market data feed that contains only execution information based on equity orders entered into the System.[13] The Exchange proposes to charge each of the fees set forth below for MEMOIR Last Sale.

1. *Internal Distribution Fee.* For the receipt of access to the MEMOIR Last Sale feed, the Exchange proposes to charge $500 per month. This proposed access fee would be charged to any data recipient that receives a data feed of the MEMOIR Last Sale feed for purposes of internal distribution (*i.e.,* an Internal Distributor). The proposed access fee for internal distribution will be charged only once per month per Firm.

2. *External Distribution Fee.* For redistribution of the MEMOIR Last Sale feed, the Exchange proposes to establish an access fee of $2,000 per month. The proposed redistribution fee would be charged to any External Distributor of the MEMOIR Last Sale feed. The proposed access fee for external distribution will be charged only once per month per Firm.

3. *Non-Display Use Fees.* The Exchange does not propose to establish separate non-display fees for usage by Trading Platforms or other Users with respect to MEMOIR Last Sale.

4. *User Fees.* The Exchange proposes to charge a Professional User Fee (per User) of $0.01 per month and a Non-Professional User Fee (per User) of $0.01 per month. The proposed User fees would apply to each person that has access to the MEMOIR Last Sale feed that is provided by an External Distributor for displayed usage. The Exchange does not propose any per User fees for internal distribution of the MEMOIR Last Sale feed. Each External Distributor's count will include every individual that accesses the data regardless of the purpose for which the individual uses the data. External Distributors of the MEMOIR Last Sale

[11] *See* MEMX Rule 13.8(b). The Exchange notes that it will file a separate rule proposal to modify paragraph (b) of Rule 13.8 to remove reference to execution information as included in the MEMOIR Top feed, as execution information is not presently included in such feed.

[12] The Exchange notes that while it is not differentiating Professional and Non-Professional Users based on fees (in that it is proposing the same fee for such Users) for this data feed, and thus will not audit Firms based on this distinction, it will request reporting of each distinct category for informational purposes.

[13] *See* MEMX Rule 13.8(c).

feed must report all Professional and Non-Professional Users [14] in accordance with the following:

• In connection with an External Distributor's distribution of the MEMOIR Last Sale feed, the Distributor must count as one User each unique User that the Distributor has entitled to have access to the MEMOIR Last Sale feed.

• External Distributors must report each unique individual person who receives access through multiple devices or multiple methods (*e.g.,* a single User has multiple passwords and user identifications) as one User.

• If an External Distributor entitles one or more individuals to use the same device, the Distributor must include only the individuals, and not the device, in the count. Thus, Distributors would not be required to report User device counts associated with a User's display use of the data feed.

5. *Enterprise Fee.* As an alternative to User fees, a recipient Firm may purchase a monthly Enterprise license to receive MEMOIR Last Sale for distribution to an unlimited number of Professional and Non-Professional Users. The Exchange proposes to establish a fee of $10,000 per month per Firm for an Enterprise license to the MEMOIR Last Sale feed.

6. *Digital Media Enterprise Fee.* As an alternative to User fees, a recipient Firm may purchase a monthly Digital Media Enterprise license to receive MEMOIR Last Sale for distribution to an unlimited number of Users for viewing via television, websites, and mobile devices for informational and non-trading purposes only. The Exchange proposes to establish a fee of $2,000 per month per Firm for a Digital Media Enterprise license to the MEMOIR Last Sale feed.

Additional Discussion—Competitive Forces

The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, 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.'' [15] As the Commission itself recognized, the market for trading services in NMS stocks has become ''more fragmented and competitive.'' [16] Indeed, equity trading is currently dispersed across 16 exchanges,[17] 31 alternative trading systems,[18] and numerous broker-dealer internalizers and wholesalers, all competing for order flow.

The recent growth of MEMX's market share demonstrates the competitive marketplace in which the Exchange operates. The Exchange launched in September 2020 and slowly grew over the next several months as it completed its staged rollout intended to ensure market stability. In January 2021, the Exchange averaged approximately 0.6% of consolidated trading volume.[19] The Exchange experienced significant growth every month from February 2021 to December 2021 and ended 2021 with market share of approximately 4.2% of consolidated volume; MEMX maintained a similar market share percentage in January of 2022, ending the month with 4.2% market share.[20]

As the Exchange's transaction market share has increased, so has the value of its market data. In addition to achieving over 4% of consolidated volume, the Exchange's NBBO Quote Market Share (*i.e.,* the notional value displayed at the inside national best bid or offer, or ''NBBO'', as a percentage of overall notional value at the NBBO) is comparable to that of Cboe BZX Exchange, Inc. (''BZX'') and the New York Stock Exchange (''NYSE''), and higher than that of Cboe EDGX Exchange. Inc.[21] The Exchange determined the level of the fees to charge for the Exchange Data Feeds based on the value of the Exchange's market data as well as the cost analysis described later in this filing. As noted above, over a 16-month period, MEMX has grown from 0% to over 4% market share of consolidated trading volume. During that same period, the Exchange has had a steady increase in the number of subscribers to Exchange Data Feeds.

As a new entrant into the exchange industry, the Exchange is particularly subject to competitive forces. While the Exchange has been able to rapidly grow its market share since its launch in September 2020, MEMX operates only a single U.S. equities exchange with market share that remains significantly lower than the market share of the largest exchange groups. As noted above, MEMX currently does not charge fees for market data provided by the Exchange. The objective of this approach was to eliminate any fee-based barriers for Members when MEMX launched as a national securities exchange in 2020, which the Exchange believes has been helpful in its ability to attract order flow as a new exchange. The Exchange also has not charged for market data because MEMX believes that any exchange should first deliver meaningful value to Members and other market participants before charging fees for its products and services. The Exchange believes that its proposed approach to market data fees is reasonable based on the existence of competition, a comparison to competitors and the cost analysis presented below.

The Exchange is not required to make the Exchange Data Feeds available or to offer any specific pricing alternatives to any customers, nor is any firm required to purchase the Exchange Data Feeds. Firms that choose to subscribe to the Exchange Data Feeds do so for the primary goals of using it to increase their revenues, reduce their expenses, and in some instances to compete directly with the Exchange (including for order flow). Those firms are able to determine for themselves whether or not the Exchange Data Feeds or any other similar products are attractively priced.

Because the Exchange Data Feeds have not been previously subject to fees, the Exchange does not know the full impact of the proposed fees on current data recipients because subscribers may choose to reduce or eliminate their use of MEMX data. The Exchange anticipates that there might be data recipients of the Exchange Data Feeds that subscribe only because they are free and might choose to discontinue using the products once fees are implemented. A data recipient that chooses to discontinue subscribing to the Exchange's Data Feeds may also choose

[14] *See supra* note 12.

[15] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37495, 37499 (June 29, 2005) (S7–10–04) (Final Rule) (''Regulation NMS Adopting Release'').

[16] *See* Securities Exchange Act Release No. 51808, 84 FR 5202, 5253 (February 20, 2019) (File No. S7–05–18) (Transaction Fee Pilot for NMS Stocks Final Rule) (''Transaction Fee Pilot'').

[17] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at: *http://markets.cboe.com/us/equities/market_share/. See generally https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html.*

[18] *See* FINRA ATS Transparency Data, available at *https://otctransparency.finra.org/otctransparency/AtsData.* A list of alternative trading systems registered with the Commission is available at: *https://www.sec.gov/foia/docs/atslist.htm.*

[19] Market share percentage calculated as of February 1, 2022. The Exchange receives and processes data made available through consolidated data feeds (*i.e.,* CTS and UTDF).

[20] *See id.*

[21] *See* Cboe Global Markets NBBO Quote Market Share Statistics, available at: *https://www.cboe.com/us/equities/market_statistics/.* In February 2022, NBBO Quote Market Share of the largest six equities exchanges was as follows: NYSE Arca 18.5%, Nasdaq 17.32%, NYSE 12.6%, BZX 11.02%, MEMX 10.14%, EDGX 8.71%. The remaining ten equities exchanges have NBBO Quote Market Share below 5%.

to shift order flow away from the Exchange, and, given the current competitive environment, if data recipients were to both discontinue the product and shift order flow away from the Exchange, the Exchange would reevaluate the fees and potentially file a separate proposed rule change to amend its fees. In advance of implementing the proposed fees, however, the Exchange cannot estimate with precision the impact of the proposed fees on the Exchange's business or the number of subscribers to the Exchange Data Feeds.

Additional Discussion—Comparison With Other Exchanges

The proposed fee structure is not novel but is instead comparable to the fee structure currently in place for the equities exchanges operated by Cboe Global Markets, Inc., in particular BZX.[22] As noted above, in January 2022, MEMX had 4.2% market share; for that same month, BZX had 5.5% market share.[23] The Exchange is proposing fees for its Exchange Data Feeds that are similar in structure to BZX and rates that are lower in most cases than the rates data recipients pay for comparable data feeds from BZX. The Exchange notes that other competitors maintain fees applicable to market data that are considerably higher than those proposed by the Exchange, including NYSE Arca[24] and Nasdaq.[25] However, the Exchange has focused its comparison on BZX because it is the closest market in terms of market share and offers market data at prices lower than several other incumbent exchanges.[26]

The fees for the BZX Depth feed—which like the MEMOIR Depth feed, includes top of book, depth of book, trades, and security status messages—consist of an internal distributor access fee of $1,500 per month (the same as the Exchange's proposed rate), an external distributor access fee of $5,000 per month (two times the Exchange's proposed rate), a non-display usage fee for non-Trading Platforms of $2,000 per month ($500 more than the Exchange's proposed rate), a non-display usage fee for Trading Platforms of $5,000 per month ($1,000 more than the Exchange's proposed rate), a Professional User fee (per User) of $40 per month ($10 more than the Exchange's proposed rate), and a Non-Professional User fee (per User) of $5 per month ($2 more than the Exchange's proposed rate).[27]

The comparisons of the MEMOIR Last Sale feed and MEMOIR Top feed to the BZX Last Sale feed and BZX Top feed, respectively, are similar in that BZX generally maintains the same fee structure proposed by the Exchange and BZX charges fees that are comparable to, but in most cases higher than, the Exchange's proposed fees. Notably, the User fees proposed by the Exchange for External Distributors of MEMOIR Last Sale and MEMOIR Top ($0.01 for both Professional Users and Non-Professional Users) are considerably lower than those charged by BZX for BZX Top and BZX Last Sale ($4 for Professional Users and $0.10 for Non-Professional Users).

By charging the same low rate for all Users of MEMOIR Top and MEMOIR Last Sale the Exchange believes it is proposing a structure that is not only lower cost but that will also simplify reporting for subscribers who externally distribute these data feeds to Users, as the Exchange believes that categorization of Users as Professional and Non-Professional is not meaningful for these products and requiring such categorization would expose Firms to unnecessary audit risk of paying more for mis-categorization. However, the Exchange does not believe this is equally true for MEMOIR Depth, as most individual Users of MEMOIR Depth are likely to be Professional Users. The Exchange believes that Professional Users are more likely to benefit economically from the use of MEMOIR Depth data than Non-Professional Users, and the Exchange believes that the higher fee charged to Professional Users is reasonable and appropriate given this difference in value.

Additional Discussion—Cost Analysis

In general, the Exchange believes that exchanges, in setting fees of all types, should meet very high standards of transparency to demonstrate why each new fee or fee increase meets the Exchange Act requirements that fees be reasonable, equitably allocated, not unfairly discriminatory, and not create an undue burden on competition among members and markets. In particular, the Exchange believes that each exchange should take extra care to be able to demonstrate that these fees are based on its costs and reasonable business needs. Accordingly, in proposing to charge fees for market data, the Exchange has sought to be especially diligent in assessing those fees in a transparent way against its own aggregate costs of providing the related service, and also carefully and transparently assessing the impact on Members—both generally and in relation to other Members, *i.e.,* to assure the fee will not create a financial burden on any participant and will not have an undue impact in particular on smaller Members and competition among Members in general. The Exchange believes that this level of diligence and transparency is called for by the requirements of Section 19(b)(1)

[22] *See* BZX Fee Schedule, available at: *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/.*

[23] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[24] Fees for the NYSE Arca Integrated Feed, which is the comparable product to MEMOIR Depth, are $3,000 for access (internal use) and $3,750 for redistribution (external distribution), compared to the Exchange's proposed fees of $1,500 and $2,500, respectively. In addition, for its Integrated Feed, NYSE Arca charges for three different categories of non-display usage, each of which is $10,500 and each of which can be charged to the same firm more than one time (*e.g.,* a customer operating a Trading Platform would pay $10,500 compared to the Exchange's proposed fee of $4,000 but would also pay for each Trading Platform, up to three, if they operate more than one, instead of the single fee proposed by the Exchange; if that customer also uses the data for the other categories of non-display usage they would also pay $10,500 for each other category of usage, whereas the Exchange would only charge $1,500 for any non-display usage other than operating a Trading Platform). Finally, the NYSE Arca Integrated Feed user fee for pro devices is $60 compared to the proposed Professional User fee of $30 for MEMOIR Depth and the NYSE Arca Integrated user fee for non-pro devices is $20 compared to the proposed Non-Professional User fee of $3 for MEMOIR Depth. *See* NYSE Proprietary Market Data Pricing list, available at: *https://www.nyse.com/publicdocs/nyse/data/NYSE_Market_Data_Pricing.pdf.*

[25] Fees for the Nasdaq TotalView data feed, which is the comparable product to MEMOIR Depth, are $1,500 for access (internal use) and $3,750 for redistribution (external distribution), compared to the Exchange's proposed fees of $1,500 and $2,500, respectively. In addition, for TotalView, Nasdaq charges Trading Platforms $5,000 compared to the Exchange's proposal of $4,000, and, like NYSE Arca, charges customers per Trading Platform, up to three, if they operate more than one, instead of the single fee proposed by the Exchange. Nasdaq also requires users to report and pay usage fees for non-display access at levels of from $375 per subscriber for smaller firms with 39 or fewer subscribers to $75,000 per firm for a larger firm with over 250 subscribers. The Exchange does not require counting of devices or users for non-display purposes and instead has proposed flat fee of $1,500 for non-display usage not by Trading Platforms. Finally, the Nasdaq TotalView user fee for professional subscribers is $76 compared to the proposed Professional User fee of $30 for MEMOIR Depth and the Nasdaq TotalView user fee for non-professional subscribers is $15 compared to the proposed Non-Professional User fee of $3 for MEMOIR Depth. *See* Nasdaq Global Data Products pricing list, available at: *http://www.nasdaqtrader.com/TraderB.aspx?id=MDDPricingALLN.*

[26] *See supra* notes 24 and 25.

[27] *See* BZX Fee Schedule, Market Data Fees, BZX Depth, available at: *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/.* The Exchange notes that there are differences between the structure of BZX Depth fees and the proposed fees for MEMOIR Depth, including that the Exchange has proposed a Digital Media Enterprise License for MEMOIR Depth but a comparable license is not available from BZX. Additionally, BZX maintains a general enterprise license for User fees, similar to that proposed by the Exchange for MEMOIR Top and MEMOIR Last Sale, but the Exchange has not proposed adding a general Enterprise license at this time.

under the Act,[28] and Rule 19b–4 thereunder,[29] with respect to the types of information self-regulatory organizations (''SROs'') should provide when filing fee changes, and Section 6(b) of the Act,[30] which requires, among other things, that exchange fees be reasonable and equitably allocated,[31] not designed to permit unfair discrimination,[32] and that they not impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[33] This rule change proposal addresses those requirements, and the analysis and data in this section are designed to clearly and comprehensively show how they are met.[34]

In October 2021, MEMX completed a study of its aggregate costs to produce market data and connectivity (the ''Cost Analysis''). The Cost Analysis required a detailed analysis of MEMX's aggregate baseline costs, including a determination and allocation of costs for core services provided by the Exchange—transactions, market data, membership services, physical connectivity, and application sessions (which provide order entry, cancellation and modification functionality, risk functionality, ability to receive drop copies, and other functionality). MEMX separately divided its costs between those costs necessary to deliver each of these core services, including infrastructure, software, human resources (*i.e.,* personnel), and selling, general and administrative expenses (''cost drivers''). Next, MEMX applied an estimated allocation of each cost driver to each core service. By allocating segmented costs to each core service, MEMX was able to estimate by core service the potential margin it might earn based on different fee models. The Exchange notes that as a non-listing venue it has four primary sources of revenue that it can potentially use to fund its operations: Transaction fees, fees for connectivity services, membership and regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these four primary sources of revenue.

The Exchange recently filed to adopt fees for connectivity services, to which the Exchange allocated a monthly aggregate monthly cost of $1,143,715.[35] Based on the pricing adopted by the Exchange, the Exchange estimated it would generate monthly revenue of $1,233,750 from connectivity services (*i.e.,* physical connections and application sessions), providing cost recovery to the Exchange for the aggregate costs of offering connectivity services plus approximately 8% margin. Thus far, fees for connectivity services have generated revenues consistent with the Exchange's estimates.

The Exchange notes that it is difficult, if not impossible, to purely split the costs of generating and producing market data and the costs associated with operation of the system that processes (and displays through market data) orders, cancellations, and transactions and performs related functions (collectively, together with market data, ''Transaction Services''). Instead, because the Exchange believes its costs for providing Transaction Services, including market data, are inextricably linked, the cost analysis below and corollary margin discussion includes all Transaction Services. Through the Cost Analysis, MEMX calculated its aggregate monthly costs for providing Transaction Services, at $2,797,265. The Exchange expects to recoup the majority of this cost from transaction fees and revenues from the public data feeds in which the Exchange participates and receives revenues (*i.e.,* the SIPs). In order to cover operating costs and earn a reasonable profit on its market data, the Exchange is proposing to modify its Fee Schedule, pursuant to MEMX Rules 15.1(a) and (c), as set forth above.

The following chart details the individual line-item (monthly) costs considered by MEMX to be related to offering Transaction Services (transactions and market data) to its Members and other customers.

Costs drivers	Costs
Human Resources	$1,480,822
Infrastructure and Connectivity Technology (servers, switches, etc.)	48,480
Exchange Software and Technology Consulting	305,244
External Market Data Costs	133,266
Data Center Costs	65,538
Hardware and Software Licenses	26,478
Regulatory Costs	155,815
Monthly Depreciation	393,380
Allocated Shared Expenses	187,792
Total	2,797,265

For personnel costs (Human Resources), MEMX calculated an allocation of employee time for employees whose functions include directly providing services necessary to offer Transaction Services, including performance thereof, as well as personnel with ancillary functions related to establishing and providing such services (such as information security and finance personnel). The Human Resources cost was calculated using a blended rate of compensation reflecting salary, equity and bonus compensation, benefits, payroll taxes, and 401(k) matching contributions. The Infrastructure and Connectivity Technology cost includes servers, switches and related hardware required to provide physical access to the Exchange, some of which is owned by the Exchange and some of which is leased by the Exchange in order to allow efficient periodic technology refreshes. Exchange Software and Technology Consulting includes all costs for third party software necessary to offer

[28] 15 U.S.C. 78s(b)(1).

[29] 17 CFR 240.19b–4.

[30] 15 U.S.C. 78f(b).

[31] 15 U.S.C. 78f(b)(4).

[32] 15 U.S.C. 78f(b)(5).

[33] 15 U.S.C. 78f(b)(8).

[34] In 2019, Commission staff published guidance suggesting the types of information that SROs may use to demonstrate that their fee filings comply with the standards of the Exchange Act (''Fee Guidance''). While MEMX understands that the Fee Guidance does not create new legal obligations on SROs, the Fee Guidance is consistent with MEMX's view about the type and level of transparency that exchanges should meet to demonstrate compliance with their existing obligations when they seek to charge new fees. *See* Staff Guidance on SRO Rule Filings Relating to Fees (May 21, 2019) available at *https://www.sec.gov/tm/staff-guidancesro-rule-filings-fees.*

[35] *See* Securities Exchange Act Release No. 93937 (January 10, 2022), 87 FR 2466 (January 14, 2022) (SR–MEMX–2021–22) (the ''Connectivity Filing'').

Transaction Services as well as third party consultants used to help test and review systems necessary to offering Transaction Services. External Market Data Costs includes fees paid to other exchanges and the SIPs under the consolidated plans to obtain data necessary to provide Transaction Services. Data Center costs includes an allocation of the costs the Exchange incurs to provide Transaction Services in the third-party data centers where the Exchange maintains its equipment as well as related costs (the Exchange does not own the Primary Data Center or the Secondary Data Center, but instead, leases space in data centers operated by third parties). Hardware and Software Licenses includes hardware and software licenses used to operate and monitor physical assets necessary to offer Transaction Services. All physical assets and software, which also includes assets used for testing and monitoring of Exchange infrastructure, were valued at cost, depreciated or leased over periods ranging from three to five years. Finally, a limited portion of general shared expenses was allocated to overall Transaction Services costs as without these general shared costs the Exchange would not be able to operate in the manner that it does and provide Transaction Services. The costs included in general shared expenses include general expenses of the Exchange, including office space and office expenses, utilities, recruiting and training, marketing and advertising costs, professional fees for legal, tax and accounting services, and telecommunications costs.

In conducting its Cost Analysis, the Exchange did not allocate any of its expenses in full to any core service and did not double-count any expenses. Instead, as described above, the Exchange allocated applicable cost drivers across its core services and used the same Cost Analysis to form the basis of the Connectivity Filing and this filing, proposing fees for Exchange Data Feeds. For instance, as described in the Connectivity Filing, in calculating the Human Resources expenses to be allocated to physical connections, the Exchange allocated network infrastructure personnel with a high percentage of the cost of such personnel (75%) given their focus on functions necessary to provide physical connections. The salaries of those same personnel were allocated only 2.5% to application sessions and the remaining 22.5% was allocated to transactions and market data.

In total, again as explained in the Connectivity Filing, the Exchange allocated 13.8% of its personnel costs to providing physical connections and 7.7% of its personnel costs to providing application sessions, for a total allocation of 21.5% Human Resources expense to provide connectivity services. In turn, the Exchange allocated the remaining 78.5% of its Human Resources expense to Membership (less than 1%) and Transaction Services (77.5%). Thus, again, the Exchange's allocations of cost across core services were based on real costs of operating the Exchange and were not double-counted across the core services or their associated revenue streams.

As another example, the Exchange allocated depreciation expense to all core services, including Transaction Services, but in different amounts. The Exchange believes it is reasonable to allocate the identified portion of such expense because such expense includes the actual cost of the computer equipment, such as dedicated servers, computers, laptops, monitors, information security appliances and storage, and network switching infrastructure equipment, including switches and taps that were purchased to operate and support the Exchange. Without this equipment, the Exchange would not be able to operate the Exchange and provide Transaction Services to its Members and non-Members and their customers. The Exchange did not allocate all of the depreciation and amortization expense toward the cost of providing Transaction Services, but instead allocated approximately 73% of the Exchange's overall depreciation and amortization expense to Transaction Services.

The Exchange notes that the Cost Analysis was based on the Exchange's first year of operations and projections for the next year. As such, the Exchange believes that its costs will remain relatively similar in future years. It is possible however that such costs will either decrease or increase. To the extent the Exchange sees growth in use of market data or any other core service it will receive additional revenue to offset future cost increases. However, if use of core services, including market data subscriptions is static or decreases, the Exchange might not realize the revenue that it anticipates or needs in order to cover applicable costs. Accordingly, the Exchange commits to periodically review the costs applicable to providing Transaction Services, including the Exchange Data Feeds, and to propose changes to its fees as appropriate.

The proposed fees for Exchange Data Feeds are designed to permit the Exchange to cover the costs allocated to providing Transaction Services with a markup that the Exchange believes is modest (approximately 17%), which would also account for costs related to Transaction Services that the Exchange has previously borne completely on its own and help fund future expenditures (increased costs, improvements, etc.). The Exchange also reiterates that the Exchange has not previously charged any fees for Exchange Data Feeds and its allocation of costs to Exchange Data Feeds was part of a holistic allocation that also allocated costs to other core services without double-counting any expenses.

Looking at the Exchange's operations holistically, the total monthly costs to the Exchange for offering core services is $3,954,537. The Exchange anticipates that the proposed fees for Exchange Data Feeds will generate between $250,000 and $500,000, depending on how many current subscribers stop subscribing to the Exchange Data Feeds once the Exchange commences billing. Incorporating this range into the Exchange's overall projected revenue, the Exchange anticipates monthly revenue ranging from $4,296,950 to $4,546,950 from all sources (*i.e.,* connectivity fees and membership fees that were introduced in January 2022, transaction fees, and revenue from market data, both through the fees proposed herein and through the revenue received from the SIPs). As such, applying the Exchange's holistic Cost Analysis to a holistic view of anticipated revenues, the Exchange would earn approximately 8.5% to 15% margin on its operations as a whole. The Exchange believes that this amount is reasonable.

The Exchange notes that its revenue estimates are based on projections across all potential revenue streams and will only be realized to the extent such revenue streams actually produce the revenue estimated. As a new entrant to the hyper-competitive exchange environment, and an exchange focused on driving competition, the Exchange does not yet know whether such expectations will be realized. For instance, in order to generate the revenue expected from the Exchange Data Feeds, the Exchange will have to be successful in retaining existing subscribers and obtaining new subscribers to the Exchange Data Feeds. Similarly, the Exchange will have to be successful in retaining a positive net capture on transaction fees in order to realize the anticipated revenue from transaction pricing.

To the extent the Exchange is successful in gaining market share, improving its net capture on transaction

fees, encouraging new subscribers to subscribe to the Exchange Data Feeds, and other developments that would help to increase Exchange revenues, the Exchange does not believe it should be penalized for such success. The Exchange like other exchanges is, after all, a for-profit business. Accordingly, while the Exchange believes in transparency around costs and potential margins, the Exchange does not believe that these estimates should form the sole basis of whether or not a proposed fee is reasonable or can be adopted. Instead, the Exchange believes that the information should be used solely to confirm that an Exchange is not earning supra-competitive profits, and the Exchange believes its Cost Analysis and related projections demonstrate this fact.

As described above, there is no requirement that any Firm subscribe to a particular Exchange Data Feed or any Exchange Data Feed whatsoever, but instead, a Firm may choose to maintain subscriptions to those Exchange Data Feeds they deem appropriate based on their business model. The proposed fee will not apply differently based upon the size or type of Firm, but rather based upon the subscriptions a Firm has to Exchange Data Feeds and their use thereof, which are in turn based upon factors deemed relevant by each Firm.

As discussed above, the proposed fees for connectivity services do not by design apply differently to different types or sizes of Members. As discussed in more detail in the Statutory Basis section, the Exchange believes that the likelihood of higher fees for certain Firms subscribing to Exchange Data Feeds than others is not unfairly discriminatory because it is based on objective differences in usage of Exchange Data Feeds among different Firms, which are still ultimately in the control of any particular Firm.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6(b) [36] of the Act in general, and furthers the objectives of Section 6(b)(4) [37] of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. Additionally, the Exchange believes that the proposed fees are consistent with the objectives of Section 6(b)(5) [38] of the Act in that they are designed 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 a free and open market and national market system, and, in general, to protect investors and the public interest, and, particularly, are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Proposed Rule Change Is Reasonable

In adopting Regulation NMS, the Commission granted SROs and broker-dealers increased authority and flexibility to offer new and unique market data to the public. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, 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.'' [39]

With respect to market data, the decision of the United States Court of Appeals for the District of Columbia Circuit in *NetCoalition* v. *SEC* upheld the Commission's reliance on the existence of competitive market mechanisms to evaluate the reasonableness and fairness of fees for proprietary market data:

> In fact, the legislative history indicates that the Congress intended that the market system ''evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed'' and that the SEC wield its regulatory power ''in those situations where competition may not be sufficient,'' such as in the creation of a ''consolidated transactional reporting system.'' [40]

The court agreed with the Commission's conclusion that ''Congress intended that 'competitive forces should dictate the services and practices that constitute the U.S. national market system for trading equity securities.' '' [41]

In this competitive marketplace, the Exchange's executed trading volume has grown from 0% market share to over 4% market share in less than one and a half years and the Exchange believes that it is reasonable to begin charging fees for the Exchange Data Feeds. One of the primary objectives of MEMX is to provide competition and to reduce fixed costs imposed upon the industry. Consistent with this objective, the Exchange believes that this proposal reflects a simple, competitive, reasonable, and equitable pricing structure designed to permit the Exchange to cover certain fixed costs that it incurs for providing market data, with fees that are discounted when compared to products and services offered by competitors.[42]

The Exchange is not aware of any evidence that a market share of approximately 4% provides the Exchange with supra-competitive pricing power because, as shown elsewhere, market participants are not required to subscribe to the Exchange Data Feeds, and if they do so, have a choice with respect to the Exchange Data Feed(s) to which they will subscribe. Separately, the Exchange is not aware of any reason why market participants could not simply unsubscribe or choose not to subscribe to Exchange Data Feeds if the Exchange were to establish unreasonable and uncompetitive prices for its Exchange Data Feeds.

With regard to reasonableness, the Exchange understands that the Commission has traditionally taken a market-based approach to examine whether the SRO making the proposal was subject to significant competitive forces in setting the terms of the proposal. In looking at this question, the Commission considers whether the SRO has demonstrated in its filing that: (i) There are reasonable substitutes for the product or service; (ii) ''platform'' competition constrains the ability to set the fee; and/or (iii) revenue and cost analysis shows the fee would not result in the SRO taking supra-competitive profits. If the SRO demonstrates that the fee is subject to significant competitive forces, the Commission will next consider whether there is any substantial countervailing basis to suggest the fee's terms fail to meet one or more standards under the Exchange Act. If the filing fails to demonstrate that the fee is constrained by competitive forces, the SRO must provide a substantial basis, other than competition, to show that it is consistent with the Exchange Act, which may include production of relevant revenue and cost data pertaining to the product or service.

[36] 15 U.S.C. 78f.

[37] 15 U.S.C. 78f(b)(4).

[38] 15 U.S.C. 78f(b)(5).

[39] *See* Regulation NMS Adopting Release, 70 FR 37495, at 37499.

[40] *NetCoalition* v. *SEC,* 615 F.3d 525, 535 (D.C. Cir. 2010) (''NetCoalition I'') (quoting H.R. Rep. No. 94–229 at 92 (1975), *as reprinted in* 1975 U.S.C.C.A.N. 323).

[41] *Id.* at 535.

[42] *See supra* notes 24–25; *see supra* note 27 and accompanying text.

The Exchange has not previously charged fees for market data, so it does not have MEMX-specific data to support whether or not competitive forces would constrain its ability to set fees for the Exchange Data Feeds. However, the Exchange believes that competitive forces are in effect and that if the proposed fees for the Exchange Data Feeds were unreasonable that the Exchange would lose current or prospective Members and market share. The Exchange does not yet have comprehensive data of the impact of the proposed fees and will not have such data until the fees are imposed. Further, the Exchange has conducted a comprehensive Cost Analysis to determine the reasonability of its proposed fees, including that the Exchange will not take supra-competitive profits.

1. The Proposed Fees Are Constrained by Significant Competitive Forces

a. Exchange Market Data Is Sold in a Competitive Market

In 2018, Charles M. Jones, the Robert W. Lear Professor of Finance and Economics at the Columbia University School of Business, conducted an analysis of the market for equity market data in the United States. He canvassed the demand for both consolidated and exchange proprietary market data products and the uses to which those products were put by market participants, and reported his conclusions in a paper annexed hereto.[43] Among other things, Professor Jones concluded that:

• ''The market [for exchange market data] is characterized by robust competition: exchanges compete with each other in selling proprietary market data products. They also compete with consolidated data feeds and with data provided by alternative trading systems ('ATSs'). Barriers to entry are very low, so existing exchanges must also take into account competition from new entrants, who generally try to build market share by offering their proprietary market data products for free for some period of time [as MEMX has done with its Exchange Data Feeds].'' [44]

• ''Although there are regulatory requirements for some market participants to use consolidated data products, there is no requirement for market participants to purchase any proprietary market data product for regulatory purposes.'' [45]

• ''There are a variety of data products, and consumers of equity market data choose among them based on their needs. Like most producers, exchanges offer a variety of market data products at different price levels. Advanced proprietary market data products provide greater value to those who subscribe. As in any other market, each potential subscriber takes the features and prices of available products into account in choosing what market data products to buy based on its business model.'' [46]

• ''For proprietary exchange data feeds, the main question is whether there is a competitive market for proprietary market data. More than 40 active exchanges and alternative trading systems compete vigorously in both the market for order flow and in the market for market data. The two are closely linked: an exchange needs to consider the negative impact on its order flow if it raises the price of its market data. Furthermore, new entrants have been frequent over the past 10 years or so, and these venues often give market data away for free, [again, as MEMX has done with its Exchange Data Feeds] serving as a check on pricing by more established exchanges. These are all the standard hallmarks of a competitive market.'' [47]

Professor Jones' conclusions are consistent with the Exchange's view of, and experience in, the competitive marketplace for exchanges, including with respect to proprietary data feeds, as a recent entrant to the market.

b. Exchange Market Data Fees Are Constrained by Competition

As the D.C. Circuit recognized in *NetCoalition I,* ''[n]o one disputes that competition for order flow is fierce.'' [48] The court further noted that ''no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers,'' and that an exchange ''must compete vigorously for order flow to maintain its share of trading volume.'' [49]

Similarly, the Commission itself has recognized that the market for trading services in NMS stocks has become ''more fragmented and competitive.'' [50] The Commission's Division of Trading and Markets has also recognized that with so many ''operating equities exchanges and dozens of ATSs, there is vigorous price competition among the U.S. equity markets and, as a result, [transaction] fees are tailored and frequently modified to attract particular types of order flow, some of which is highly fluid and price sensitive.'' [51] Indeed, as noted above, equity trading is currently dispersed across 16 exchanges, 31 alternative trading systems, and numerous broker-dealer internalizers and wholesalers, all competing for order flow.

Further, low barriers to entry mean that new exchanges like the Exchange may rapidly enter the market and offer competition with the Exchange. Due to the ready availability of substitutes and the low cost to move order flow to those substitute trading venues, an exchange setting market data fees that are not at competitive levels would expect to quickly lose business to competitors with more attractive pricing.[52] Although the various exchanges may differ in their strategies for pricing their market data products and their transaction fees for trades—with some offering market data for free along with higher trading costs, and others charging more for market data and comparatively less for trading—all exchanges compete for the same pool of customers and must work to demonstrate to such customers that pricing is reasonable. The Exchange believes that the best way to do this is to provide transparency into the costs of producing and maintaining its services.

Commission staff noted in its Fee Guidance that, as an initial step in assessing the reasonableness of a fee, staff considers whether the fee is constrained by significant competitive forces. To determine whether a proposed fee is constrained by significant competitive forces, staff has said that it considers whether the evidence demonstrates that there are reasonable substitutes for the product or service that is the subject of a proposed fee. As noted elsewhere in this proposal, there is no regulatory requirement that any market participant subscribe to any Exchange Data Feeds or a particular Exchange Data Feed.

The Exchange believes the proposed fees are reasonable because in setting them, the Exchange is constrained by the availability of numerous competitors offering market data products and trading services. Such substitutes need not be identical, but only substantially

[43] *See* Exhibit 3A, Charles M. Jones, Understanding the Market for U.S. Equity Market Data, August 31, 2018 (hereinafter ''Jones Paper'').

[44] *Id.* at 2.

[45] *Id.*

[46] *Id.*

[47] *Id.* at 39–40.

[48] *NetCoalition I,* 615 F.3d at 544 (internal quotation omitted).

[49] *Id.*

[50] *See* Securities Exchange Act Release No. 51808, 84 FR 5202, 5253 (February 20, 2019) (File No. S7–05–18).

[51] Commission Division of Trading and Markets, Memorandum to EMSAC, dated October 20, 2015, available here: *https://www.sec.gov/spotlight/emsac/memo-maker-taker-feeson-equities-exchanges.pdf.*

[52] *See* Jones Paper at 11.

similar to the product at hand. More specifically, in setting fees for the Exchange Data Feeds, the Exchange is constrained by the fact that, if its pricing is unattractive to customers, customers have their pick of a large number of alternative execution venues to use instead of the Exchange. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish reasonable fees. The existence of competition ensures that the Exchange cannot set unreasonable market data fees without suffering the negative effects of that decision in the fiercely competitive market in which it operates.

c. Exchange Data Feeds Are Optional Market Data Products

Subscribing to the Exchange Data Feeds is entirely optional. The Exchange is not required to make the Exchange Data Feeds available to any customers, nor is any customer required to purchase any Exchange Data Feed. Unlike some other data products (*e.g.,* the consolidated quotation and last-sale information feeds) that firms are required to purchase in order to fulfill regulatory obligations,[53] a customer's decision whether to purchase any Exchange Data Feed is entirely discretionary. Most Firms that choose to subscribe to an Exchange Data Feed do so for the primary goals of using it to increase their revenues, reduce their expenses, and in some instances to compete directly with the Exchange for order flow. Such firms are able to determine for themselves whether a particular Exchange Data Feed is necessary for their business needs, and if so, whether or not it is attractively priced. If an Exchange Data Feed does not provide sufficient value to a Firm based on the uses such Firm may have for it, such Firm may simply choose to conduct their business operations in ways that do not use the applicable Exchange Data Feed.[54] If they do not choose to use one or more Exchange Data Feeds, they could also choose not to direct order flow to the Exchange.

Specifically related to the Exchange Data Feed with the highest rates, the MEMOIR Depth Feed, even if a Firm determines that the fees for such feed are too high, customers can access much of the same data at lower rates by subscribing to the MEMOIR Top feed (which includes best-bid-and-offer information for the Exchange on a real-time basis) and MEMOIR Last Sale (which includes last-sale information for the Exchange on a real-time basis). MEMX top-of-book quotation information and last-sale information is also available on the consolidated SIP feeds. In this way, MEMOIR Top, MEMOIR Last Sale, and SIP data products are all substitutes for a significant portion of the data available on the MEMOIR Depth Feed, and SIP data products are also a substitute for a significant portion of data available on the MEMOIR Top and MEMOIR Last Sale feeds. Indeed, several exchange competitors of the Exchange have not subscribed to any Exchange Data Feeds for purposes of executing orders on their exchanges, order routing, and regulatory purposes,[55] even though the Exchange subscribes to and pays for their comparable market data products.[56]

The only content available on the MEMOIR Depth Feed that is not available on these other products is the order-by-order look at the MEMX order book, which provides information about depth-of-book on the Exchange. The Exchange has been a vocal advocate in support of the Commission's Market Data Infrastructure Rule, which mandates the creation of a ''SIP Premium'' product that would include depth-of-book information on the consolidated market data feeds.[57] The Exchange has also been a vocal advocate in support of pricing new content for the consolidated market data feeds in a reasonable and competitive manner that would encourage the use of a SIP Premium product and other content to be provided via the SIPs.[58] Future products such as SIP Premium would include not only integrated depth-of-book information from MEMX, but all other exchanges as well, and would further constrain the Exchange's ability to price any Exchange Data Feed, including MEMOIR Depth, at a supra-competitive price. However, even in the absence of such products, the Exchange believes that use of the Exchange Data Feeds is entirely optional, as described above.

Further, in the case of products that are also redistributed through market data vendors such as Bloomberg and Refinitiv, the vendors themselves provide additional price discipline for proprietary data products because they control the primary means of access to certain end users. These vendors impose price discipline based upon their business models. For example, vendors that assess a surcharge on data they sell are able to refuse to offer proprietary products that their end users do not or will not purchase in sufficient numbers. Even in the absence of fees for the Exchange Data Feeds, many major market data vendors have not elected to make available the Exchange Data Feeds and likely will not unless their customers request it, and customers will not elect to pay the proposed fees unless the applicable Exchange Data Feed can provide value by sufficiently increasing revenues or reducing costs to the customer's business in a manner that will offset the fees. All of these factors operate as constraints on pricing proprietary data products.

In setting the proposed fees for the Exchange Data Feeds, the Exchange considered the competitiveness of the market for proprietary data and all of the implications of that competition. As described elsewhere in this proposal, the Exchange also considered the Cost Analysis conducted by the Exchange and believes it has demonstrated that the fees will not result in any supra-competitive profit. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish reasonable fees. The existence of alternatives to the Exchange and the continued availability of choice between different Exchange Data Feeds, other exchanges' proprietary data products, and the SIPs ensure that the Exchange cannot set unreasonable fees when vendors and subscribers can elect these alternatives or choose not to purchase a specific proprietary data product if the attendant fees are not justified by the returns that any particular vendor or data recipient would achieve through the purchase.

[53] The Exchange notes that broker-dealers are not required to purchase proprietary market data to comply with their best execution obligations. *See In the Matter of the Application of Securities Industry and Financial Markets Association for Review of Actions Taken by Self-Regulatory Organizations,* Release Nos. 34–72182; AP–3–15350; AP–3–15351 (May 16, 2014). Similarly, there is no requirement in Regulation NMS or any other rule that proprietary data be utilized for order routing decisions, and some competing exchanges, broker-dealers and ATSs have chosen not to do so.

[54] *See generally* Jones Paper at 8, 10–11.

[55] *See, e.g.,* NYSE Arca Rule 7.37–E.(d), Order Execution and Routing, and BZX Rule 11.21, each of which discloses the data feeds used by each respective exchange and state that SIP products are used with respect to MEMX.

[56] *See* MEMX Rule 13.4, Usage of Data Feeds, which discloses that the Exchange uses proprietary data feeds for all exchanges that offer them.

[57] *See, e.g.,* Letter from Anders Franzon, General Counsel, MEMX LLC, dated May 26, 2020, regarding proposed Market Data Infrastructure rule, available at: *https://www.sec.gov/comments/s7-03-20/s70320-7235183-217090.pdf.*

[58] *See, e.g.,* Letter from Adrian Griffiths, Head of Market Structure, MEMX LLC, dated November 8, 2021, regarding proposed fees for consolidated data provided pursuant to CTA/CQ/UTP Plans, available at: *https://www.sec.gov/comments/sr-ctacq-2021-03/srctacq202103-9403088-262830.pdf.*

d. The Proposed Fees for Exchange Data Feeds Will Not Result in Supra-Competitive Profits

Commission staff previously noted that the generation of supra-competitive profits is one of several potential factors in considering whether an exchange's proposed fees are consistent with the Act.[59] As described in the Fee Guidance, the term ''supra-competitive profits'' refers to profits that exceed the profits that can be obtained in a competitive market. The proposed fee structure would not result in excessive pricing or supra-competitive profits for the Exchange. The proposed fee structure is merely designed to permit the Exchange to cover the costs allocated to providing Transaction Services with a modest markup (approximately 9%-18%), which would also account for costs related to Transaction Services that the Exchange has previously borne completely on its own and help fund future expenditures (increased costs, improvements, etc.). The Exchange believes that this is fair, reasonable, and equitable. Accordingly, the Exchange believes that its proposal is consistent with Section 6(b)(4) [60] of the Act because the proposed fees will permit recovery of the Exchange's costs and will not result in excessive pricing or supra-competitive profit.

The proposed fees for Exchange Data Feeds will allow the Exchange to cover certain costs incurred by the Exchange associated with providing and maintaining necessary hardware and other network infrastructure as well as network monitoring and support services; without such hardware, infrastructure, monitoring and support the Exchange would be unable to provide Transaction Services, including market data. The Exchange routinely works to improve the performance of the network's hardware and software. The costs associated with maintaining and enhancing a state-of-the-art exchange network is a significant expense for the Exchange, and thus the Exchange believes that it is reasonable and appropriate to help offset those costs by adopting fees for the Exchange Data Feeds. As detailed above, the Exchange has four primary sources of revenue that it can potentially use to fund its operations: Transaction fees, fees for connectivity services, membership and regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these four primary sources of revenue.

The Exchange expects to recoup the majority of its estimated aggregate monthly costs for providing Transaction Services from transaction fees and revenues from the public data feeds in which the Exchange participates and receives revenues (*i.e.,* the SIPs). In order to cover operating costs and earn a reasonable profit on its market data, the Exchange is proposing to charge the fees described herein for the Exchange Data Feeds. In addition, this revenue will allow the Exchange to continue to offer, to enhance, and to continually refresh its infrastructure as necessary to offer a state-of-the-art trading platform. The Exchange believes that, consistent with the Act, it is appropriate to charge fees that represent a reasonable markup over cost given the other factors discussed above, including the lack of other costs to participate on the Exchange and the need for the Exchange to maintain a highly performant and stable platform to allow Members to transact with determinism.

The Exchange's Cost Analysis estimates the costs to provide Transaction Services at $2,797,265. Based on current subscriptions to Exchange Data Feeds (but without definitive data regarding User counts) and projections related to transaction activity and volumes, the Exchange estimates it will generate monthly revenues of approximately $250,000 to $500,000 from the Exchange Data Feeds and between $3,050,000 and $3,300,000 from providing Transaction Services overall. This represents a modest profit when compared to the cost of providing Transaction Services (approximately 9% to 18%). Further, as noted above, applying the Exchange's holistic Cost Analysis to a holistic view of anticipated revenues from all sources, the Exchange would earn approximately 8.5% to 15% margin on its operations as a whole. The Exchange believes that this amount is reasonable.

2. The Proposed Fees Are Reasonable

The specific fees that the Exchange proposes for the Exchange Data Feeds are reasonable for the following additional reasons.

Overall. The Exchange believes the proposed fees for the Exchange Data Feeds are reasonable when compared to fees for comparable products, such as the BZX Depth feed, BZX Top feed, and BZX Last Sale feed, compared to which the Exchange's proposed fees are generally lower, as well as other comparable data feeds priced significantly higher than the Exchange's proposed fees for the Exchange Data Feeds.[61] Specifically with respect to the MEMOIR Depth feed, the Exchange believes that the proposed fees for such feed are reasonable because they represent not only the value of the data available from the MEMOIR Top and MEMOIR Last Sale data feeds, which have lower proposed fees, but also the value of receiving the depth-of-book data on an order-by-order basis. Finally, the Exchange believes that its Cost Analysis and holistic approach thereto demonstrates that the proposed fees for the Exchange Data Feeds would not result in supra-competitive profits.

Internal Distribution Fees. The Exchange believes that it is reasonable to charge Fees to access the Exchange Data Feeds for Internal Distribution because of the value of such data to subscribers in their profit-generating activities. The Exchange also believes that the proposed monthly Internal Distribution fees for MEMOIR Depth, MEMOIR Top, and MEMOIR Last Sale are reasonable as they are the same amounts charged by at least one other exchange of comparable size for comparable data products,[62] and are lower than the fees charged by several other exchanges for comparable data products.[63]

External Distribution Fees. The Exchange believes that it is reasonable to charge External Distribution fees for the Exchange Data Feeds because vendors receive value from redistributing the data in their business products provided to their customers. The Exchange believes that charging External Distribution fees is reasonable because the vendors that would be charged such fees profit by re-transmitting the Exchange's market data to their customers. These fee would be charged only once per month to each vendor account that redistributes any Exchange Data Feed, regardless of the number of customers to which that vendor redistributes the data. The Exchange also believes the proposed monthly External Distribution fee for the MEMOIR Depth Feed is reasonable because it is half the amount of the fee charged by at least one other exchange of comparable size for a comparable

[59] *See* Fee Guidance, *supra* note 33.

[60] 15 U.S.C. 78f(b)(4).

[61] *See supra* notes 24–25; *see supra* note 27 and accompanying text.

[62] *See* BZX Fee Schedule available at *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/.*

[63] *See* NYSE Proprietary Market Data Pricing list, available at: *https://www.nyse.com/publicdocs/nyse/data/NYSE_Market_Data_Pricing.pdf;* Nasdaq Global Data Products pricing list, available at: *http://www.nasdaqtrader.com/TraderB.aspx?id=MDDPricingALLN.*

data product,[64] and significantly less than the amount charged by several other exchanges for comparable data products.[65] Similarly, the Exchange believes the proposed monthly External Distribution fees for the MEMOIR TOP and MEMOIR Last Sale feeds are reasonable because they are discounted compared to same amounts charged by at least one other exchange of comparable size for comparable data products, and significantly less than the amount charged by several other exchanges for comparable data products.[66]

User Fees. The Exchange believes that having separate Professional and Non-Professional User fees for the MEMOIR Depth feed is reasonable because it will make the product more affordable and result in greater availability to Professional and Non-Professional Users. Setting a modest Non-Professional User fee is reasonable because it provides an additional method for Non-Professional Users to access the Exchange Data Feeds by providing the same data that is available to Professional Users. The proposed monthly Professional User fee and monthly Non-Professional User fee are reasonable because they are lower than the fees charged by at least one other exchange of comparable size for comparable data products,[67] and significantly less than the amounts charged by several other exchanges for comparable data products.[68] The Exchange also believes it is reasonable to charge the same low per User fee of $0.01 for both Professional Users and Non-Professional Users receiving the MEMOIR Top and MEMOIR Last Sale feeds, as this is not only pricing such data at a much lower cost than other exchanges charge for comparable data feeds [69] but doing so will also simplify reporting for subscribers who externally distribute these data feeds to Users, as the Exchange believes that categorization of Users as Professional and Non-Professional is not meaningful for these products and that requiring such categorization would expose Firms to unnecessary audit risk of paying more for mis-categorization. The Exchange also believes that the proposal to require reporting of individual Users, but not devices, is reasonable as this too will eliminate unnecessary audit risk that can arise when recipients are required to apply complex counting rules such as whether or not to count devices or whether an individual accessing the same data through multiple devices should be counted once or multiple times.

Non-Display Use Fees. The Exchange believes the proposed Non-Display Usage fees for the MEMOIR Depth feed are reasonable, because they reflect the value of the data to the data recipients in their profit-generating activities and do not impose the burden of counting non-display devices.

The Exchange believes that the proposed Non-Display Usage fees reflect the significant value of the non-display data use to data recipients, which purchase such data on an entirely voluntary basis. Non-display data can be used by data recipients for a wide variety of profit-generating purposes, including proprietary and agency trading and smart order routing, as well as by data recipients that operate Trading Platforms that compete directly with the Exchange for order flow. The data also can be used for a variety of non-trading purposes that indirectly support trading, such as risk management and compliance. Although some of these non-trading uses do not directly generate revenues, they can nonetheless substantially reduce a recipient's costs by automating such functions so that they can be carried out in a more efficient and accurate manner and reduce errors and labor costs, thereby benefiting recipients. The Exchange believes that charging for non-trading uses is reasonable because data recipients can derive substantial value from such uses, for example, by automating tasks so that can be performed more quickly and accurately and less expensively than if they were performed manually.

Previously, the non-display use data pricing policies of many exchanges required customers to count, and the exchanges to audit the count of, the number of non-display devices used by a customer. As non-display use grew more prevalent and varied, however, exchanges received an increasing number of complaints about the impracticality and administrative burden associated with that approach. In response, several exchanges developed a non-display use pricing structure that does not require non-display devices to be counted or those counts to be audited, and instead categorizes different types of use. The Exchange proposes to distinguish between non-display use for the operation of a Trading Platform and other non-display use, which is similar to exchanges such as BZX and EDGX,[70] while other exchanges maintain additional categories and in many cases charge multiple times for different types of non-display use or the operation of multiple Trading Platforms.[71]

The Exchange believes that it is reasonable to segment the fee for non-display use into these two categories. As noted above, the uses to which customers can put the MEMOIR Depth feed are numerous and varied, and the Exchange believes that charging separate fees for these separate categories of use is reasonable because it reflects the actual value the customer derives from the data, based upon how the customer makes use of the data.

The Exchange believes that the proposed fees for non-display use other than operation of a Trading Platform is reasonable. These fees are comparable to, and lower than, the fees charged by at least one other exchange of comparable size for a comparable data product,[72] and significantly less than the amounts charged by several other exchanges for comparable data products.[73] The Exchange believes that the proposed fees directly and appropriately reflect the significant value of using data on a non-display basis in a wide range of computer-automated functions relating to both trading and non-trading activities and that the number and range of these functions continue to grow through innovation and technology developments.

The Exchange also believes, regarding non-display use for operation of a Trading Platform, it is reasonable to charge a higher monthly fee than for other non-display use because such use of the Exchange's data is directly in competition with the Exchange and the

[64] *See* BZX Fee Schedule available at *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/.*

[65] *See id.*

[66] *See* NYSE Proprietary Market Data Pricing list, available at: *https://www.nyse.com/publicdocs/nyse/data/NYSE_Market_Data_Pricing.pdf;* Nasdaq Global Data Products pricing list, available at: *http://www.nasdaqtrader.com/TraderB.aspx?id=MDDPricingALLN.*

[67] *See* BZX Fee Schedule, available at: *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/.*

[68] *See* NYSE Proprietary Market Data Pricing list, available at: *https://www.nyse.com/publicdocs/nyse/data/NYSE_Market_Data_Pricing.pdf;* Nasdaq Global Data Products pricing list, available at: *http://www.nasdaqtrader.com/TraderB.aspx?id=MDDPricingALLN.*

[69] *See id.*

[70] *See* BZX Fee Schedule, available at: *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/;* EDGX Fee Schedule, available at: *https://www.cboe.com/us/equities/membership/fee_schedule/edgx/.*

[71] *See supra* notes 24–25.

[72] *See* BZX Fee Schedule, available at: *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/.*

[73] *See* NYSE Proprietary Market Data Pricing list, available at: *https://www.nyse.com/publicdocs/nyse/data/NYSE_Market_Data_Pricing.pdf;* Nasdaq Global Data Products pricing list, available at: *http://www.nasdaqtrader.com/TraderB.aspx?id=MDDPricingALLN.*

Exchange should be permitted to recoup some of its lost trading revenue by charging for the data that makes such competition possible. The Exchange also believes that it is reasonable to charge the proposed fees for non-display use for operation of a Trading Platform because the proposed fees are comparable to, and lower than, the fees charged at least one other exchange of comparable size for a comparable data product,[74] and significantly less than the amounts charged by several other exchanges for comparable data products, which also charge per Trading Platform operated by a data subscriber subject to a cap in most cases, rather than charging per Firm, as proposed by the Exchange.[75]

The proposed Non-Display Usage fees for the Exchange Data Feeds are also reasonable because they take into account the extra value of receiving the data for Non-Display Usage that includes a rich set of information including top of book quotations, depth-of-book quotations, executions and other information. The Exchange believes that the proposed fees directly and appropriately reflect the significant value of using the MEMOIR Depth feed on a non-display basis in a wide range of computer-automated functions relating to both trading and non-trading activities and that the number and range of these functions continue to grow through innovation and technology developments.[76]

For all of the foregoing reasons, the Exchange believes that the proposed fees for the Exchange Data Feeds are reasonable.

The Proposed Fees Are Equitably Allocated

The Exchange believes the proposed fees for the Exchange Data Feeds are allocated fairly and equitably among the various categories of users of the feeds, and any differences among categories of users are justified and appropriate.

Overall. The Exchange believes that the proposed fees are equitably allocated because they will apply uniformly to all data recipients that choose to subscribe to the Exchange Data Feeds. Any subscriber or vendor that chooses to subscribe to one or more Exchange Data Feeds is subject to the same Fee Schedule, regardless of what type of business they operate, and the decision to subscribe to one or more Exchange Data Feeds is based on objective differences in usage of Exchange Data Feeds among different Firms, which are still ultimately in the control of any particular Firm.

Internal Distribution Fee. The Exchange believes the proposed monthly fees for Internal Distribution of the Exchange Data Feeds are equitably allocated because they would be charged on an equal basis to all data recipients that receive the Exchange Data Feeds for internal distribution, regardless of what type of business they operate.

External Distribution Fees. The Exchange believes the proposed monthly fees for External Distribution of the Exchange Data Feeds are equitably allocated because they would be charged on an equal basis to all data recipients that receive the Exchange Data Feeds that choose to redistribute the feeds externally.

User Fees. The Exchange believes that the fee structure differentiating Professional User fees from Non-Professional User fees for display use of the MEMOIR Depth feed is equitable. This structure has long been used by other exchanges and the SIPs to reduce the price of data to Non-Professional Users and make it more broadly available.[77] Offering the MEMOIR Depth feed to Non-Professional Users at a lower cost than Professional Users results in greater equity among data recipients. These User fees would be charged uniformly to all individuals that have access to the MEMOIR Depth feed based on the category of User. The Exchange also believes the proposed User fees for MEMOIR Top and MEMOIR Last Sale are equitable because the Exchange has proposed to charge Professional Users and Non-Professional Users the same low rate of $0.01 per month.

Non-Display Use Fees. The Exchange believes the proposed Non-Display Usage fees are equitably allocated because they would require subscribers to pay fees only for the uses they actually make of the data. As noted above, non-display data can be used by data recipients for a wide variety of profit-generating purposes (including trading and order routing) as well as purposes that do not directly generate revenues (such as risk management and compliance) but nonetheless substantially reduce the recipient's costs by automating certain functions. The Exchange believes that it is equitable to charge non-display data subscribers that use data for purposes other than operation of a Trading Platform as proposed because all such subscribers would have the ability to use such data for as many non-display uses as they wish for one low fee. As noted above, this structure is comparable to that in place for the BZX Depth feed but several other exchanges charge multiple non-display fees to the same client to the extent they use a data feed in several different trading platforms or for several types of non-display use.[78]

The Exchange also believes, regarding non-display use for operation of a Trading Platform, it is equitable to charge a higher rate for each Firm operating a Trading Platform (as compared to other Non-Display Usage not by Trading Platforms) because such use of the data is directly in competition with the Exchange and the Exchange should be permitted to recoup some of its lost trading revenue by charging for the data that makes such competition possible. The Exchange believes that it is equitable to charge a single fee per Firm rather than multiple fees for a Firm that operates more than one Trading Platform because operators of Trading Platforms are many times viewed as a single competing venue or group, even if there a multiple liquidity pools operated by the same competitor.

For all of the foregoing reasons, the Exchange believes that the proposed fees for the Exchange Data Feeds are equitably allocated.

The Proposed Fees Are Not Unfairly Discriminatory

The Exchange believes the proposed fees for the Exchange Data Feeds are not unfairly discriminatory because any differences in the application of the fees are based on meaningful distinctions between customers, and those meaningful distinctions are not unfairly discriminatory between customers.

Overall. The Exchange believes that the proposed fees are not unfairly discriminatory because they would apply to all data recipients that choose to subscribe to the same Exchange Data

[74] *See* BZX Fee Schedule, available at: *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/.*

[75] *See supra* notes 24–25.

[76] *See also* Exchange Act Release No. 69157, March 18, 2013, 78 FR 17946, 17949 (March 25, 2013) (SR–CTA/CQ–2013–01) (''[D]ata feeds have become more valuable, as recipients now use them to perform a far larger array of non-display functions. Some firms even base their business models on the incorporation of data feeds into black boxes and application programming interfaces that apply trading algorithms to the data, but that do not require widespread data access by the firm's employees. As a result, these firms pay little for data usage beyond access fees, yet their data access and usage is critical to their businesses.''

[77] *See, e.g.,* Securities Exchange Act Release No. 59544 (March 9, 2009), 74 FR 11162 (March 16, 2009) (SR–NYSE–2008–131) (establishing the $15 Non-Professional User Fee (Per User) for NYSE OpenBook); Securities Exchange Act Release No. 20002, File No. S7–433 (July 22, 1983), 48 FR 34552 (July 29, 1983) (establishing Non-Professional fees for CTA data); NASDAQ BX Equity 7 Pricing Schedule, Section 123.

[78] *See supra,* notes 24–25.

Feed(s). Any vendor or subscriber that chooses to subscribe to the Exchange Data Feeds is subject to the same Fee Schedule, regardless of what type of business they operate. Because the proposed fees for MEMOIR Depth are higher, vendors and subscribers seeking lower cost options may instead choose to receive data from the SIPs or through the MEMOIR Top and/or MEMOIR Last Sale feed for a lower cost. Alternatively, vendors and subscribers can choose to pay for the MEMOIR Depth feed in order to receive data in a single feed with depth-of-book information or they can choose to subscribe to a combination of data feeds for redundancy purposes or to use such feeds for different purposes, thereby allowing each vendor or subscriber to choose the best business solution for itself.

Internal Distribution Fees. The Exchange believes the proposed monthly fees for Internal Distribution of the Exchange Data Feeds are not unfairly discriminatory because they would be charged on an equal basis to all data recipients that receive the same Exchange Data Feed(s) for internal distribution, regardless of what type of business they operate.

External Distribution Fees. The Exchange believes the proposed monthly fees for redistributing the Exchange Data Feeds are not unfairly discriminatory because they would be charged on an equal basis to all data recipients that receive the same Exchange Data Feed(s) that choose to redistribute the feed(s) externally.

User Fees. The Exchange believes that the fee structure differentiating Professional User fees from Non-Professional User fees for display use of the MEMOIR Depth feed is not unfairly discriminatory. This structure has long been used by other exchanges and the SIPs to reduce the price of data to Non-Professional Users and make it more broadly available.[79] Offering the Exchange Data Feeds to Non-Professional Users with the same data as is available to Professional Users results in greater equity among data recipients. These User fees would be charged uniformly to all individuals that have access to the Exchange Data Feeds based on the category of User. The Exchange also believes the proposed User fees for MEMOIR Top and MEMOIR Last Sale are not unfairly discriminatory because the Exchange has proposed to charge Professional Users and Non-Professional Users the same low rate of $0.01 per month.

Non-Display Use Fees. The Exchange believes the proposed Non-Display Usage fees for the MEMOIR Depth feed are not unfairly discriminatory because they would require subscribers for non-display use to pay fees depending on their use of the data, either for operation of a Trading Platform or not, but would not impose multiple fees to the extent a Firm operates multiple Trading Platforms or has multiple different types of non-display use. As noted above, non-display data can be used by data recipients for a wide variety of profit-generating purposes as well as purposes that do not directly generate revenues but nonetheless substantially reduce the recipient's costs by automating certain functions. This segmented fee structure is not unfairly discriminatory because no subscriber of non-display data would be charged a fee for a category of use in which it did not actually engage.

The Exchange also believes that, regarding non-display use for operation of a Trading Platform, it is not unreasonably discriminatory to charge a higher fee for each Firm operating a Trading Platform (as compared to other Non-Display Usage not by Trading Platforms) because such use of the data is directly in competition with the Exchange and the Exchange should be permitted to recoup some of its lost trading revenue by charging for the data that makes such competition possible. The Exchange believes that it is not unreasonably discriminatory to charge a single fee for an operator of Trading Platforms that operates more than one Trading Platform because operators of Trading Platforms are many times viewed as a single competing venue or group, even if there a multiple liquidity pools operated by the same competitor.

For all of the foregoing reasons, the Exchange believes that the proposed fees for the Exchange Data Feeds are not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[80] the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange does not believe that the proposed rule change would place certain market participants at the Exchange at a relative disadvantage compared to other market participants or affect the ability of such market participants to compete. In particular, while the Exchange has not officially proposed fees for Exchange Data Feeds until now, Exchange personnel have been informally discussing potential fees for Exchange Data Feeds with a diverse group of market participants that receive data from the Exchange (including large and small firms, trading firms and market data only firms, etc.). The Exchange has received no official complaints from Members, non-Members, or third-parties that redistribute the Exchange Data Feeds, that the Exchange's fees or the proposed fees for Exchange Data Feeds would negatively impact their abilities to compete with other market participants or that they are placed at a disadvantage relative to others. The Exchange does not believe that the proposed fees for Exchange Data Feeds place certain market participants at a relative disadvantage to other market participants because, as noted above, the proposed fees are associated with usage of Exchange Data Feeds by each market participant based on the type of business they operate, and the decision to subscribe to one or more Exchange Data Feeds is based on objective differences in usage of Exchange Data Feeds among different Firms, which are still ultimately in the control of any particular Firm, and such fees do not impose a barrier to entry to smaller participants. Accordingly, the proposed fees for Exchange Data Feeds do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation of the proposed fees reflects the types of Exchange Data Feeds consumed by various market participants and their usage thereof.

Inter-Market Competition

The Exchange does not believe the proposed fees place an undue burden on competition on other SROs that is not necessary or appropriate. In particular, market participants are not forced to subscribe to any of the Exchange Data Feeds, as described above. Additionally, other exchanges have similar market data fees in place for their participants, but with higher rates to connect.[81] The Exchange is also unaware of any assertion that the proposed fees for Exchange Data Feeds would somehow unduly impair its competition with other exchanges.

[79] *See supra* note 77.

[80] 15 U.S.C. 78f(b)(8).

[81] *See supra* notes 24–25; *see also,* supra note 27 and accompanying text.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

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 [82] and Rule 19b-4(f)(2) [83] 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 change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MEMX–2022–03 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MEMX–2022–03. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MEMX–2022–03 and should be submitted on or before May 2, 2022.

April 11, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[84]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–07627 Filed 4–8–22; 8:45 am]

BILLING CODE 8011–01–P

[82] 15 U.S.C. 78s(b)(3)(A)(ii).

[83] 17 CFR 240.19b–4(f)(2).

[84] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94609; File No. SR–IEX–2021–14]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Withdrawal of a Proposed Rule Change To Amend Its Fee Schedule for Market Data Fees

April 5, 2022.

On November 1, 2021, Investors Exchange LLC (''IEX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend its Fee Schedule for Market Data Fees. The proposed rule change was immediately effective upon filing with the Commission pursuant to Section 19(b)(3)(A) of the Act.[3] The proposed rule change was published for comment in the **Federal Register** on November 17, 2021.[4] On December 30, 2021, the Commission temporarily suspended the proposed rule change and instituted proceedings under Section 19(b)(2)(B) of the Act [5] to determine whether to approve or disapprove the proposed rule change.[6] On April 1, 2022, IEX withdrew the proposed rule change (SR–IEX–2021–14).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–07624 Filed 4–8–22; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A). A proposed rule change may take effect upon filing with the Commission if it is designated by the exchange as ''establishing or changing a due, fee, or other charge imposed by the self-regulatory organization on any person, whether or not the person is a member of the self-regulatory organization.'' 15 U.S.C. 78s(b)(3)(A)(ii).

[4] *See* Securities Exchange Act Release No. 93557 (November 10, 2021), 86 FR 64268 (November 17, 2021).

[5] 15 U.S.C. 78s(b)(2)(B).

[6] *See* Securities Exchange Act Release No. 93883 (December 30, 2021), 87 FR 523 (January 5, 2022).

[7] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Delegation of Authority No. 530]

Delegation of Authority to the Assistant Secretary for East Asian and Pacific Affairs Relating to Oversight of the American Institute in Taiwan

By virtue of the authority vested in the Secretary of State by the laws of the United States, including the State Department Basic Authorities Act, as amended (22 U.S.C. 2651a), the Taiwan Relations Act (22 U.S.C. 3301 *et seq.*), E.O. 13014, and the Foreign Service Act of 1980, as amended (22 U.S.C. 3983(d)), I hereby delegate to the Assistant Secretary for East Asian and Pacific Affairs, to the extent authorized by law, oversight authority over the American Institute in Taiwan (AIT), including but not limited to approving staffing changes that require national interest determinations for assignments or details of U.S. government employees as the case may be.

Any act, executive order, regulation, or procedure subject to, or affected by, this delegation shall be deemed to be such act, executive order, regulation, or procedure as amended from time to time. Authorities delegated herein may be re-delegated, to the extent authorized by law.

The Secretary, the Deputy Secretary, the Deputy Secretary for Management and Resources, the Under Secretary for Political Affairs, and the Under

Secretary for Management may also exercise the authorities delegated herein. Nothing in this delegation shall be deemed to supersede or otherwise affect any other delegation of authority.

Any actions related to the functions described herein that may have been taken prior to the date of this delegation are hereby confirmed and ratified. Such actions shall remain in force as if taken under this delegation of authority, unless or until such actions are rescinded, amended, or superseded.

This document shall be published in the **Federal Register**.

Dated: March 17, 2022.

Antony J. Blinken,

Secretary of State.

[FR Doc. 2022–07638 Filed 4–8–22; 8:45 am]

BILLING CODE 4710–30–P

DEPARTMENT OF STATE

[Public Notice: 11709]

Office of the Chief of Protocol; Gifts to Federal Employees From Foreign Government Sources Reported to Employing Agencies in Calendar Year 2020

All information reported to the Office of the Chief of Protocol, including gift appraisal and donor information, is the responsibility of the employing agency, in accordance with applicable law and GSA regulations.

The Office of the Chief of Protocol, Department of State, submits the following comprehensive listing of the statements which, as required by law, federal employees filed with their employing agencies during calendar year 2020 concerning gifts received from foreign government sources. The compilation includes reports of both tangible gifts and gifts of travel or travel expenses of more than minimal value, as defined in 5 U.S.C. 7432 and GSA regulations. For calendar years 2020–2022 (January 1, 2020 through December 31, 2022), minimal value is $415.00.

Pursuant to title 22 of the Code of Federal Regulations section 3.4, the report includes all gifts given on a single occasion when the aggregate value of those gifts exceeds minimal value. Also included are gifts received in previous years including one from 2014, two from 2016, one from 2017, 12 from 2018, and 18 from 2019. These latter gifts are being reported in this year's report for calendar year 2020 because the Office of the Chief of Protocol, Department of State, did not receive the relevant information at the time of reporting to include them in earlier reports. Agencies not listed in this report either did not receive relevant gifts during the calendar year, did not transmit a listing to the Secretary of State of all statements filed during the preceding year by the employees of that agency pursuant to 5 U.S.C. 7432(f)(1), or did not respond to the State Department's Office of the Chief of Protocol's request for data. The U.S. Senate maintains an internal minimal value of $100; therefore, all gifts over the $100 limit are furnished in the U.S. Senate report.

Publication of this listing in the **Federal Register** is required by Section 7342(f) of title 5, United States Code, as added by section 515(a)(1) of the Foreign Relations Authorization Act, Fiscal Year 1978 (Pub. L. 95–105, August 17, 1977, 91 stat. 865).

Dated: March 19, 2022.

John Bass,

Under Secretary for Management, U.S. Department of State.

AGENCY: THE WHITE HOUSE—EXECUTIVE OFFICE OF THE PRESIDENT [1]

[Report of Tangible Gifts Furnished by the White House—Executive Office of the President]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
The Honorable H.R. McMaster, Assistant to the President and National Security Advisor.	Afghan Carpet. Rec'd—Unknown. Est. Value—$980.00. Disposition—Transferred to GSA.[2]	His Excellency Tariq Bahrami, Acting Minister of Defense of the Islamic Republic of Afghanistan.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable H.R. McMaster, Assistant to the President and National Security Advisor.	Carpet Rec'd—Unknown. Est. Value—$6,400.00. Disposition—Transferred to GSA.[3]	His Excellency Shavkat Mirziyoyev, President of the Republic of Uzbekistan.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable H.R. McMaster, Assistant to the President and National Security Advisor.	Cologne Collection. Rec'd—Unknown. Est. Value—$2,485.00. Disposition—Transferred to GSA.[4]	Mr. Sayyid Munthi, Director, Omani Royal Liaison Coordination Service, Sultanate of Oman.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Jared Kushner, Assistant to the President and Senior Advisor.	Orange Robe. Rec'd—Unknown. Est. Value—$1,900.00. Disposition—Transferred to GSA.[5]	His Royal Highness Mohammad bin Salman, Deputy Crown Prince and Second Deputy Prime Minister of the Kingdom of Saudi Arabia.	Non-acceptance would cause embarrassment to donor and U.S. Government.

[1] The State Department's Office of the Chief of Protocol did not submit the request for data to all reporting agencies prior to January 20, 2021 (at which time there was a change in administrations). In addition, the Executive Office of the President did not, prior to that date, transmit to the Secretary of State a listing of all statements filed during the preceding year, 2020. As a result, the data required to fully compile a complete listing for 2020 is unavailable. The Office of the Chief of Protocol has since made attempts to collect the required data from the current authoritative sources, the National Archives and Records Administration (as to gifts for the President and the First Family) and the General Services Administration (as to gifts for the Vice President and Family and for White House staff), but it has confirmed that potentially relevant records are not available to the State Department's Office of the Chief of Protocol under applicable access rules for retired records of the Executive Office of the President and the Office of the Vice President.

[2] Gift was reported to the Office of the Chief of Protocol by the General Services Administration in accordance with Federal Management Regulation 102–42.135.

[3] Gift was reported to the Office of the Chief of Protocol by the General Services Administration in accordance with Federal Management Regulation 102–42.135.

[4] Gift was reported to the Office of the Chief of Protocol by the General Services Administration in accordance with Federal Management Regulation 102–42.135.

[5] Gift was reported to the Office of the Chief of Protocol by the General Services Administration in accordance with Federal Management Regulation 102–42.135.

AGENCY: THE EXECUTIVE OFFICE OF THE VICE PRESIDENT [6]

[Report of Tangible Gifts Furnished by the Executive Office of the Vice President]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance

[6] See footnote 1 above.

AGENCY: THE DEPARTMENT OF STATE

[Report of Tangible Gifts Furnished by the Department of State]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
The Honorable Michael R. Pompeo, Secretary of State.	Painting featuring Apples. Rec'd—6/25/2018. Est. Value—$1060.00. Disposition—Transferred to GSA.	His Excellency Filip Pavel, Prime Minister of the Republic of Moldova.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Michael R. Pompeo, Secretary of State.	Solar Boat Replica. Rec'd—1/10/2019. Est. Value—$445.00 Disposition—Transferred to GSA.	His Excellency Abbas Kamel, Director of the General Intelligence Service of the Arab Republic of Egypt.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Michael R. Pompeo, Secretary of State.	Animal Theme Carpet. Rec'd—11/22/2019. Est. Value—$6,000.00. Disposition—Transferred to GSA.	His Highness Sheikh Abdullah bin Zayed Al Nahyan, Minister of Foreign Affairs and International Cooperation of the United Arab Emirates.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Michael R. Pompeo, Secretary of State.	Wool Carpet. Rec'd—7/19/2020. Est. Value—$2,700.00. Disposition—Transferred to GSA.	His Excellency Mohammad Ashraf Ghani, President of the Islamic Republic of Afghanistan.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Michael R. Pompeo, Secretary of State.	Pilsner Scarf, Stein, and Framed Antique Map of Bohemia. Rec'd—8/11/2020. Est. Value—$455.00. Disposition—Purchased.	His Excellency Tomas Petricek, Minister of Foreign Affairs of the Czech Republic.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Michael R. Pompeo, Secretary of State.	Framed Painting Featuring a House. Rec'd 9/17/2020. Est. Value—$490.00. Disposition—Transferred to GSA.	His Excellency Mohamed Irfaan Ali, President of the Co-operative Republic of Guyana.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Michael R. Pompeo, Secretary of State.	Carved Wooden Chair. Rec'd—9/18/2020. Est. Value—$450.00. Disposition—Transferred to GSA.	His Excellency Albert Ramchand Ramdin, Minister of Foreign Affairs of the Republic of Suriname.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Michael R. Pompeo, Secretary of State.	Japanese Crystal Shot Glasses, Waterman Pen, and Challenge Coin. $470.00. Rec'd—9/24/2020. Disposition—Purchased.	His Excellency Shigeru Kitamura, Secretary General of the National Security Secretariat of Japan.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Michael R. Pompeo, Secretary of State.	Odessa Cobalt Gold Dish Set. Rec'd—10/26/2020. Est. Value—$2,200.00. Disposition—Transferred to GSA.	His Excellency Gotabaya Rajapaksa, President of the Democratic Socialist Republic of Sri Lanka.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Michael R. Pompeo, Secretary of State.	Hand-carved Wooden Maldivian Boat Model. Rec'd—10/28/2020. Est. Value—$1,100.00. Disposition—Transferred to GSA.	His Excellency Abdulla Shahid, Minister of Foreign Affairs of the Republic of Maldives.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Michael R. Pompeo, Secretary of State.	Painting Featuring Water's Edge. Rec'd—10/30/2020. Est. Value—$600.00. Disposition—Transferred to GSA.	His Excellency To Lam, Minister of Public Security of the Socialist Republic of Vietnam.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Michael R. Pompeo, Secretary of State.	Brass Tray and Family Photo of the Jordanian Royal Family. Rec'd—December 2020. Est. Value—$955.00. Disposition—Transferred to GSA.	His Majesty Abdullah II ibn Al Hussein, King of the Hashemite Kingdom of Jordan.	Non-acceptance would cause embarrassment to donor and U.S. Government.

AGENCY: THE DEPARTMENT OF STATE—Continued

[Report of Tangible Gifts Furnished by the Department of State]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
The Honorable Michael R. Pompeo, Secretary of State.	Sword in Case. Rec'd—Unknown. Est. Value—$490.00. Disposition—Transferred to GSA.	Unknown [7].	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable John Sullivan, Deputy Secretary of State.	Framed Embroidery of Eagles. Rec'd—10/4/2017. Est. Value—$600.00. Disposition—Transferred to GSA.	His Excellency Guo Shengkun, State Councilor of the People's Republic of China.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Craig Allen, Ambassador of the United States to Brunei Darussalam.	Watch with Roman Numerals. Rec'd—10/12/2018. Est. Value—$2,400.00. Disposition—Transferred to GSA.	His Majesty Sultan Haji Hassanal Bolkiah Mu'izzaddin Waddaulah, Sultan and Yang Di-Pertuan of Brunei Darussalam.	Non-acceptance would cause embarrassment to donor and U.S. Government.
Ms. Micheline Tusenius, Spouse of the Ambassador of the United States to Brunei Darussalam.	White Gold and Diamond Floral Bracelet. Rec'd—10/12/2018. Est. Value—$2,400.00. Disposition—Transferred to GSA.	Her Majesty Duli Raja Isteri Pengiran Anak Hajah Saleha binti Al-Marhum Pengiran Pemancha Pengiran Anak Haji Mohamed.	Non-acceptance would cause embarrassment to donor and U.S. Government.
Ms. Micheline Tusenius, Spouse of the Ambassador of the United States to Brunei Darussalam.	White Gold and Diamond Bracelet with Flowers. Rec'd—10/12/2018. Est. Value—$3,200.00. Disposition—Transferred to GSA.	Her Majesty Duli Raja Isteri Pengiran Anak Hajah Saleha binti Al-Marhum Pengiran Pemancha Pengiran Anak Haji Mohamed.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Barbara Leaf, Ambassador of the United States to the United Arab Emirates.	Leather Portfolio. Rec'd—9/25/2016. Est. Value—$800.00. Disposition—Transferred to GSA.	His Excellency Anwar Gargash, Minister of State for Foreign Affairs of the United Arab Emirates.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Barbara Leaf, Ambassador of the United States to the United Arab Emirates.	Pearl Necklace. Rec'd—03/18/2018. Est. Value—$600.00. Disposition—Transferred to GSA.	His Highness Sheikh Dr. Sultan bin Muhammad Al Qasimi, Ruler of the Emirate of Sharjah, United Arab Emirates.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Barbara Leaf, Ambassador of the United States to the United Arab Emirates.	Falcon Hood. Rec'd—3/18/2018. Est. Value—$1,100.00. Disposition—Transferred to GSA.	National Falcon Club, Ministry of Sports and Leisure of the United Arab Emirates.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Barbara Leaf, Ambassador of the United States to the United Arab Emirates.	White Gold and Turquoise Pendant. Rec'd—3/22/2018. Est. Value—$11,500.00. Disposition—Transferred to GSA.	Government of the United Arab Emirates.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Michael Corbin, Ambassador of the United States to the United Arab Emirates.	Louis Erard Watch and Baume and Mercier Watch. Rec'd—1/1/2014. Est. Value—$11,550.00. Disposition—Transferred to GSA.	Unknown [8]	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Stuart Jones, Ambassador of the United States to the Republic of Iraq.	Omega Watch. Rec'd—2016. Est. Value—$5,560.00. Disposition—Transferred to GSA.	Government of the Republic of Iraq.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Sean Lawler, Chief of Protocol.	Brass Footed Bowl. Rec'd—1/16/2018. Rec'd—$420.00. Disposition—Transferred to GSA.	His Excellency Nursultan Nazarbayev, President of the Republic of Kazakhstan.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Sean Lawler, Chief of Protocol.	Framed Art with Wooden Carved Colorful Frame. Rec'd—5/16/2018. Est. Value—$1,200.00. Disposition—Transferred to GSA.	His Excellency Shavkat Mirziyoyev, President of the Republic of Uzbekistan.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Sean Lawler, Chief of Protocol.	Silk Carpet. Rec'd—5/16/2018 Est. Value—$1,900.00. Disposition—Transferred to GSA.	His Excellency Javlon Vahhabor, Ambassador of the Republic of Uzbekistan to the United States.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Sam Brownback, Ambassador-at-Large for International Religious Freedom.	Brass Tea Set. Rec'd—1/7/2019. Est. Value—$620.00 Disposition—Transferred to GSA.	Embassy of the Republic of Uzbekistan.	Non-acceptance would cause embarrassment to donor and U.S. Government.
Ms. Ericka Woodard, Spouse of the Chargé d'Affaires, U.S. Embassy Brunei Darussalam.	Dolce and Gabbana Handbag. Rec'd—10/8/2018. Est. Value—$1,770.00. Disposition—Transferred to GSA.	Her Majesty the Duli Raja Isteri Pengiran Anak Hajah Saleha, Queen of Brunei Darussalam.	Non-acceptance would cause embarrassment to donor and U.S. Government.
Ms. Gladys Boluda, Assistant Chief of Protocol for Diplomatic Affairs.	White Decorative Box. Rec'd—5/13/2019. Est. Value—$485.00. Disposition—Transferred to GSA.	His Royal Highness Salman bin Hamad Al Khalifa, Crown Prince of the Kingdom of Bahrain.	Non-acceptance would cause embarrassment to donor and U.S. Government.

AGENCY: THE DEPARTMENT OF STATE—Continued

[Report of Tangible Gifts Furnished by the Department of State]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
Unknown	Montblanc Pen and Portfolio Set. Rec'd—Unknown. Est. Value—$500.00. Disposition—Transferred to GSA.	Unknown [9]	Non-acceptance would cause embarrassment to donor and U.S. Government.
Unknown	Large Carpet. Rec'd—Unknown. Est. Value—$8,700.00. Disposition—Transferred to GSA.	Unknown [10]	Non-acceptance would cause embarrassment to donor and U.S. Government.
Unknown	Round Silver Plate. Rec'd—Unknown. Est. Value—$1,120.00. Disposition—Transferred to GSA.	Unknown [11]	Non-acceptance would cause embarrassment to donor and U.S. Government.
Unknown	Golf Putter. Rec'd—Unknown. Est. Value—$1,660.00. Disposition—Transferred to GSA.	Unknown [12]	Non-acceptance would cause embarrassment
Unknown	Painting of Man Playing Flute. Rec'd—2019 Unknown. Est. Value—$1,100.00 Disposition—Transferred to GSA.	Unknown [13]	Non-acceptance would cause embarrassment to donor and U.S. Government.
Unknown	1714 Map entitled "L'Abrvazo Citra et Vltra Gia delineato dal magini envovamente ampliato secondo lo stato presente Dato in Luce da Domenico de Rofsi de Dedicato All'Illmo Signore Il Sigr Abate Girolamo Samminioti," Rec'd—Unknown. Est. Value—$950.00. Disposition—Transferred to GSA.	Unknown [14]	Non-acceptance would cause embarrassment to donor and U.S. Government.
Unknown	Sand Art of a Man. Rec'd—Unknown. Est. Value—$1,200.00 Disposition—Transferred to GSA.	Unknown [15]	Non-acceptance would cause embarrassment to donor and U.S. Government.

[7] The information is not available. The Department of State's Office of the Inspector General identified the lack of accurate recordkeeping pertaining to diplomatic gifts maintained by the Office of the Chief of Protocol's Gift Unit between January 20, 2017, and January 20, 2021 in Management Assistance Report ESP–22–01, 14 FAM. The gift has since been transferred to the General Services Administration as excess government property.

[8] The information is not available. The Department of State's Office of the Inspector General identified the lack of accurate recordkeeping pertaining to diplomatic gifts maintained by the Office of the Chief of Protocol's Gift Unit between January 20, 2017 and January 20, 2021 in Management Assistance Report ESP–22–01, 14 FAM. The gift has since been transferred to the General Services Administration as excess government property.

[9] The information is not available. The Department of State's Office of the Inspector General identified the lack of accurate recordkeeping pertaining to diplomatic gifts maintained by the Office of the Chief of Protocol's Gift Unit between January 20, 2017 and January 20, 2021 in Management Assistance Report ESP–22–01, 14 FAM. The gift has since been transferred to the General Services Administration as excess government property.

[10] The information is not available. The Department of State's Office of the Inspector General identified the lack of accurate recordkeeping pertaining to diplomatic gifts maintained by the Office of the Chief of Protocol's Gift Unit between January 20, 2017 and January 20, 2021 in Management Assistance Report ESP–22–01, 14 FAM. The gift has since been transferred to the General Services Administration as excess government property.

[11] The information is not available. The Department of State's Office of the Inspector General identified the lack of accurate recordkeeping pertaining to diplomatic gifts maintained by the Office of the Chief of Protocol's Gift Unit between January 20, 2017 and January 20, 2021 in Management Assistance Report ESP–22–01, 14 FAM. The gift has since been transferred to the General Services Administration as excess government property.

[12] The information is not available. The Department of State's Office of the Inspector General identified the lack of accurate recordkeeping pertaining to diplomatic gifts maintained by the Office of the Chief of Protocol's Gift Unit between January 20, 2017 and January 20, 2021 in Management Assistance Report ESP–22–01, 14 FAM. The gift has since been transferred to the General Services Administration as excess government property.

[13] The information is not available. The Department of State's Office of the Inspector General identified the lack of accurate recordkeeping pertaining to diplomatic gifts maintained by the Office of the Chief of Protocol's Gift Unit between January 20, 2017 and January 20, 2021 in Management Assistance Report ESP–22–01, 14 FAM. The gift has since been transferred to the General Services Administration as excess government property.

[14] The information is not available. The Department of State's Office of the Inspector General identified the lack of accurate recordkeeping pertaining to diplomatic gifts maintained by the Office of the Chief of Protocol's Gift Unit between January 20, 2017 and January 20, 2021 in Management Assistance Report ESP–22–01, 14 FAM. The gift has since been transferred to the General Services Administration as excess government property.

[15] The information is not available. The Department of State's Office of the Inspector General identified the lack of accurate recordkeeping pertaining to diplomatic gifts maintained by the Office of the Chief of Protocol's Gift Unit between January 20, 2017 and January 20, 2021 in Management Assistance Report ESP–22–01, 14 FAM. The gift has since been transferred to the General Services Administration as excess government property.

AGENCY: DEPARTMENT OF COMMERCE

[Report of Tangible Gifts Furnished by the Department of Commerce]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
The Honorable Wilbur Ross, Secretary of Commerce.	Carpet. Rec'd—unknown. Est. Value—$750.00. Disposition—Transferred to GSA.[16]	His Excellency Shavkat Mirziyoyev, President of the Republic of Uzbekistan.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Wilbur Ross, Secretary of Commerce.	Jewelry Box. Rec'd—Unknown. Est. Value—$900.00. Disposition—Transferred to GSA.[17]	Mrs. Ziroat Mirziyoyev, Spouse of the President of the Republic of Uzbekistan.	Non-acceptance would cause embarrassment to donor and U.S. Government.

[16] Gift was reported to the Office of the Chief of Protocol by the General Services Administration in accordance with Federal Management Regulation 102–42.135.

[17] Gift was reported to the Office of the Chief of Protocol by the General Services Administration in accordance with Federal Management Regulation 102–42.135.

AGENCY: BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

[Report of Tangible Gifts Furnished by the Board of Governors of the Federal Reserve System]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
The Honorable Randal Quarles, Vice Chair for Supervision of the Board of Governors of the Federal Reserve System.	Second Edition Book AlUla, Three Saudi Arabian Royal Stamps, Commemorative Coin, Two Nameplates, Coffee Beans, Package of Dates, and a Bottle of Rose Water. Rec'd—11/22/2020. Est. Value—$1,124.27. Disposition—Pending.	Government of the Kingdom of Saudi Arabia.	Non-acceptance would cause embarrassment to donor and U.S. Government.

AGENCY: CENTRAL INTELLIGENCE AGENCY

[Report of Tangible Gifts Furnished by the Central Intelligence Agency]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
The Honorable Gina Haspel, Director, Central Intelligence Agency.	Old Rare Advent Calendar and Holiday Picture. Rec'd—11/20/2020. Est. Value—$1,400.00. Disposition—On Official Display.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Gina Haspel, Director, Central Intelligence Agency.	Chocolate and Scotch. Rec'd—12/23/2020. Est. Value—$593.00. Disposition—Disposed.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.
An Agency Employee	2′ x 4′ Carpet. Rec'd—6/7/2020. Est. Value—$1,200.00. Disposition—Pending Disposal.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.
An Agency Employee	Pistol in Painted Wooden Firearm Box. Rec'd—6/9/2020. Est. Value—$1,641.00. Disposition—On Official Display.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.
An Agency Employee	18-karat Necklace with Name Engraving. Rec'd—6/17/2020. Est. Value—$1,000.00. Disposition—Pending Disposal.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.
An Agency Employee	Black and Silver Colored Chopard Ballpoint Pen. Rec'd—6/25/2020. Est. Value—$450.00. Disposition—Pending Disposal.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.
An Agency Employee	Ladies' Maurice Lacroix Watch in Stainless Steel and Yellow Gold. Rec'd—7/8/2020. Est. Value—$1,000.00. Disposition—Pending Disposal.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.

AGENCY: CENTRAL INTELLIGENCE AGENCY—Continued

[Report of Tangible Gifts Furnished by the Central Intelligence Agency]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
An Agency Employee	Maurice Lacroix Watch in Stainless Steel. Rec'd—7/7/2020. Est. Value—$815.00. Disposition—Pending Disposal.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.
An Agency Employee	Ladies' Maurice Lacroix Watch in Stainless Steel and Yellow Gold. Rec'd—7/12/2020. Est. Value—$1,000.00. Disposition—Pending Disposal.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.
An Agency Employee	Men's Maurice Lacroix Watch in Stainless Steel. Rec'd—7/8/2020. Est. Value—$1,000.00. Disposition—Pending Disposal.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.
An Agency Employee	Corum Admiral's Cup Legend 42 Watch. Rec'd—7/15/2020. Est. Value—$2,250.00. Disposition—Pending Disposal.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.
An Agency Employee	Delvaux Pin Mini Bucket Taurillin Soft Surpique Red Leather Handbag. Rec'd—7/14/2020. Est. Value—$2,050.00. Disposition—Pending Disposal.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.
An Agency Employee	Tiddot T-Touch Watch. Rec'd—7/20/2020. Est. Value—$1,150.00. Disposition—Pending Disposal.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.
An Agency Employee	Tactical Wristwatch. Rec'd—8/24/2020. Est. Value—$1,075.00. Disposition—Pending Disposal.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.
An Agency Employee	Garmin Watch. Rec'd—8/27/2020. Est. Value—$550.00. Disposition—Pending Disposal.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.
An Agency Employee	Victorniox Watch. Rec'd—9/9/2020. Est. Value—$650.00. Disposition—Pending Disposal.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.
An Agency Employee	Longines Watch and Spa Gift Certificate. Rec'd—9/9/2020. Est. Value—$1,827.00. Disposition—Pending Disposal.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.
An Agency Employee	Carpet, Local Products, Wool Prayer Carpet, Tissot Watch, and Plaque. Rec'd—3/21/2019. Est. Value—$650.00. Disposition—Pending Disposal.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.
An Agency Employee	Longines Watch, Local Products, Coffee Table Book, and Necklace. Rec'd—9/29/2020. Est. Value—$2,100.00. Disposition—Pending Disposal.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.
An Agency Employee	39mm Watch with Rose Gold Case. Rec'd—6/10/2020. Est. Value—$636.00. Disposition—Pending Disposal.	5 U.S.C. 7342(f)(4)	Non-acceptance would cause embarrassment to donor and U.S. Government.

AGENCY: THE DEPARTMENT OF DEFENSE

[Report of Tangible Gifts Furnished by the Department of the Defense]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
The Honorable Mark T. Esper, Secretary of Defense.	Lapis Lazuli Bowl. Rec'd—2/12/2019. Est. Value—$780.00. Disposition—Pending Transfer to GSA.	His Excellency Mohammad Ashraf Ghani, President of the Islamic Republic of Afghanistan.	Non-acceptance would cause embarrassment to donor and U.S. Government.

AGENCY: THE DEPARTMENT OF DEFENSE—Continued

[Report of Tangible Gifts Furnished by the Department of the Defense]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
The Honorable Mark T. Esper, Secretary of Defense.	Brown Leather Photo Album, Dagger in Sheath of Silver, and Leather Jewelry Box. Rec'd—8/5/2020. Est. Value—$1,400.00. Disposition—Pending Transfer to GSA.	His Excellency Abdelmajid Tebbourne, President of the People's Democratic Republic of Algeria.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Mark T. Esper, Secretary of Defense.	Plaque featuring Stone Mosaic, Plaque Depicting Crossed Sabers/Anchor/Bird, Book, *The Splendours of Tunisian Mosaics,* and Book, *Image in Stone: Tunisia in Mosaic*. Rec'd—8/5/2020. Est. Value—$475.00. Disposition—Pentagon Gift Locker.	His Excellency Ibrahim Bartagi, Minister of Defense of the Republic of Tunisia.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Mark T. Esper, Secretary of Defense.	Bamboo Fan on Display Stand, Two Face Masks, and Sword with Black Lacquered Sheath in Display Case. Rec'd—9/25/2020. Est. Value—$482.00. Disposition Transferred to GSA.	His Excellency Suh Wook, Minister of Defense of the Republic of South Korea.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Mark T. Esper, Secretary of Defense.	Painting Depicting Men with Spears Galloping on Horseback and Table Linen Set. Rec'd—8/5/2020. Est. Value—$1,920.00. Disposition—Transferred to GSA.	His Excellency Abdellatif Loudiyi, Minister Delegate for the Moroccan National Defense Administration, Kingdom of Morocco.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Mark T. Esper, Secretary of Defense.	Handwoven Carpet and Six Bottles of Fragrant Oils in Brown Leather Presentation Box. Rec'd—8/5/2020. Est. Value—$760.00. Disposition—Pending Transfer to GSA.	His Excellency Nasser Bourita, Minister of Foreign Affairs and International Cooperation of the Kingdom of Morocco.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Mark T. Esper, Secretary of Defense.	Sword Ornamented with Gemstones with Presentation Box and Plaque. Rec'd—10/16/2020. Est. Value—$9,090.00. Disposition—Pending Transfer to GSA	His Excellency Prabowo Subianto, Minister of Defense Republic of Indonesia.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Mark T. Esper, Secretary of Defense.	Women's Rolex Watch and West End Watch Company Watch. Rec'd—10/29/2020. Est. Value—$9,390.00. Disposition—Transferred to GSA.	His Excellency Khalifa bin Ahmed Al Khalifa, Commander and Chief of Bahrain Defense Forces, Kingdom of Bahrain.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Mark T. Esper, Secretary of Defense.	Plaque, Polychrome Photos, and Sabre in Leather Carrying Case. Rec'd—10/28/2020. Est. Value—$1,410.00 Disposition-Transferred to GSA.	His Excellency Khalifa bin Ahmed Al Khalifa, Commander and Chief of Bahrain Defense Forces (Field Marshal), Kingdom of Bahrain.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Mark T. Esper, Secretary of Defense.	Lapis Lazuli Bowl. Rec'd –2/12/2019. Est. Value—$780.00. Disposition—PeTransfer to GSA.	His Excellency Mohammad Ashraf Ghani, President, Islamic Republic of Afghanistan.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Christopher C. Miller, Acting Secretary of Defense.	Bottle of Royal Elite Supreme Vodka, Bottle of Toshbentrino Uzbekistan Collection Cognac, Chesnut and Onyx Chess set. Rec'd—11/19/2020. Est. Value—$1,051.00. Disposition—Office of the Secretary of Defense Gift Locker, Pending Transfer to GSA.	His Excellency Abdulaziz Kamilov, Ambassador of the Republic of Uzbekistan to the United States.	Non-acceptance would cause embarrassment to donor and U.S. Government.

AGENCY: THE DEPARTMENT OF DEFENSE—Continued

[Report of Tangible Gifts Furnished by the Department of the Defense]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
The Honorable Christopher C. Miller, Acting Secretary of Defense.	Black Walnut Plaque, Two Photographs in Glass Frames, Sword Ornamented with Semiprecious Stones. Rec'd—12/7/2020. Est. Value—$2,855.00. Disposition—Office of the Secretary of Defense Gift Locker.	His Excellency Prabowo Subianto, Minister of Defense of the Republic of Indonesia.	Non-acceptance would cause embarrassment to donor and U.S. Government.
General Mark A. Milley, Chairman of the Joint Chiefs of Staff.	Red Clay Jar Accompanied by Certificate stating ''1550 B.C.E.—1200 B.C.E. Late Bronze Age'' on Base. Rec'd—1/27/2020. Est. Value—$420.00. Disposition—On Official Display.	His Excellency Aviv Kochavi, Chief of Staff of the Israeli Defense Forces.	Non-acceptance would cause embarrassment to donor and U.S. Government.
Major Gen. Daniel J. Caine, Deputy Commander of the Special Operations Joint Task Force.	Men's Longines Watch. Rec'd—5/18/2019. Est. Value—$1,000.00. Disposition—Pending Transfer to GSA.	General Talib Shaghati Mshari al Kenani, Commander, Iraqi Counter-Terrorism Service, Republic of Iraq.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Ellen Lord, Under Secretary of Defense for Acquisition and Sustainment.	Sandalwood Carving depicting Two Walking Elephants and a Lion, 8–¾″h, in Red Velveteen Flock Presentation Box. Rec'd—10/24/2019. Est. Value—$820.00. Disposition—Pending Transfer to GSA.	Mr. S. Raghuram, Political Counsellor, Head of Chancery, Embassy of the Republic of India.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Ellen Lord, Under Secretary of Defense for Acquisition and Sustainment.	Sandalwood Carving Depicting Walking Elephant with Two Lions Chasing Horned Animal, in Red Velveteen Flock Presentation Box. Rec'd—10/24/2019. Est. Value—$800.00. Disposition—Pending Transfer to GSA.	Mr. S. Raghuram, Political Counsellor, Head of Chancery, Embassy of the Republic of India.	Non-acceptance would cause embarrassment to donor and U.S. Government.

AGENCY: THE DEPARTMENT OF THE AIR FORCE

[Report of Tangible Gifts Furnished by the Department of Air Force]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
The Honorable Barbara Barrett, Secretary of the Air Force.	Large Box of Dates. Rec'd—7/15/2021, Est. Value—$640.34. Disposition—Purchased from GSA.	Her Royal Highness Princess Reema bint Bandar bin Sultan bin Abdulaziz Al Saud, Ambassador of the Kingdom of Saudi Arabia to the United States.	Non-acceptance would cause embarrassment to donor and U.S. Government.

AGENCY: THE DEPARTMENT OF ARMY

[Report of Tangible Gifts Furnished by the Department of Army]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
Captain Quade Sherwood, Company Commander, Headquarters and Headquarters Company, 2–22 Infantry, 1BCT, 10th MTN Division (LI).	82MM Mortar System with Bipod and Base Plate. Rec'd—8/8/2020. Est. Value—$1,229.00. Disposition—On official display.	Brigadier General Mohammad Karim Neyazi, Commander, 4th Division, 201st Corps, Afghan National Army, Islamic Republic of Afghanistan.	Non-acceptance would cause embarrassment to donor and U.S. Government.
Colonel (P), IN Trevor J. Brendenkamp, Commanding, Train, Advice, Assist Command, South Headquarters, Combined Joint Task Force.	Traditional Afghan Carpet. Rec'd—12/14/2019. Est. Value—$495.00. Disposition—On official display.	Mr. Shah Wali Karzai, Popolzai Tribal Leader, Islamic Republic of Afghanistan.	Non-acceptance would cause embarrassment to donor and U.S. Government.

AGENCY: THE DEPARTMENT OF ARMY—Continued

[Report of Tangible Gifts Furnished by the Department of Army]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
Lieutenant General Paul E. Funk II, Commander, Combined Joint Task Force-Operation Inherent Resolve and III Corps.	Collapsible AK–47 Machine Gun. Rec'd—9/12/2018. Est. Value—$1,164.00. Disposition—On official display.	Lieutenant General Najah al-Shimmari, Inspector General for the Iraqi Army, Republic of Iraq.	Non-acceptance would cause embarrassment to donor and U.S. Government.
Lieutenant Darryl A. Williams, Superintendent, United States Military Academy.	18 Piece Jezzine Cutlery Set in Wooden Box. Rec'd—9/25/2019. Disposition—On official display.	His Excellency Gebran Bassil, Minister of Foreign Affairs and Emigrants for the Republic of Lebanon.	Non-acceptance would cause embarrassment to donor and U.S. Government.

AGENCY: THE DEPARTMENT OF NAVY

[Report of Tangible Gifts Furnished by the Department of Navy]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
Vice Admiral James Malloy, United States Navy, Commander, U.S. Naval Forces Central Command, U.S. Fifth Fleet, Combined Maritime Forces.	Jewelry of Gold-tone Necklace, Ring, and Earrings. Rec'd—8/21/2020. Est. Value—$424.40. Disposition—Transferred to GSA.	Commodore Mohammed Al Asam, Commander, Bahraini Royal Navy, Kingdom of Bahrain.	Non-acceptance would cause embarrassment to donor and U.S. Government.
Vice Admiral James Malloy, United States Navy, Commander, U.S. Naval Forces Central Command, U.S. Fifth Fleet, Combined Maritime Forces.	West End Men's Wristwatch. Rec'd—8/17/2020. Est. Value—$795.00. Disposition—Transferred to GSA.	Shaikh Khalifa bin Ahmed Al Khalifa, Commander-in-Chief, Bahrain Defense Force, Kingdom of Bahrain.	Non-acceptance would cause embarrassment to donor and U.S. Government.
Vice Admiral James Malloy, United States Navy, Commander, U.S. Naval Forces Central Command, U.S. Fifth Fleet, Combined Maritime Forces.	West End Men's Wristwatch. Rec'd—8/17/2020. Est. Value—$795.00. Disposition—Transferred to GSA.	Shaikh Khalifa bin Ahmed Al Khalifa, Commander-in-Chief, Bahrain Defense Force, Kingdom of Bahrain.	Non-acceptance would cause embarrassment to donor and U.S. Government.
Vice Admiral James Malloy, United States Navy, Commander, U.S. Naval Forces Central Command, U.S. Fifth Fleet, Combined Maritime Forces.	Rifle. Rec'd—8/17/2020. Est. Value—$1,999.00. Disposition—On Official Display.	Shaikh Khalifa bin Ahmed Al Khalifa, Commander-in-Chief, Bahrain Defense Force, Kingdom of Bahrain.	Non-acceptance would cause embarrassment to donor and U.S. Government.
Vice Admiral James Malloy, United States Navy, Commander, U.S. Naval Forces Central Command, U.S. Fifth Fleet, Combined Maritime Forces.	Aimpoint Micro T–1. Rec'd—8/17/2020. Est. Value—$695.00. Disposition—On Official Display.	Shaikh Khalifa bin Ahmed Al Khalifa, Commander-in-Chief, Bahrain Defense Force, Kingdom of Bahrain.	Non-acceptance would cause embarrassment to donor and U.S. Government.
Vice Admiral James Malloy, United States Navy, Commander, U.S. Naval Forces Central Command, U.S. Fifth Fleet, Combined Maritime Forces.	Rifle Suppressor. Rec'd—8/17/2020. Est. Value—$770.18. Disposition—On Official Display.	Shaikh Khalifa bin Ahmed Al Khalifa, Commander-in-Chief, Bahrain Defense Force, Kingdom of Bahrain.	Non-acceptance would cause embarrassment to donor and U.S. Government.
Vice Admiral James Malloy, United States Navy, Commander, U.S. Naval Forces Central Command, U.S. Fifth Fleet, Combined Maritime Forces.	One Men's Police Wristwatch, One Women's Wristwatch. Rec'd—11/12/2019. Est. Value—$241.33. Disposition—Transferred to GSA.	Rear Admiral Abdullah Al-Shammari, Deputy Commander of Royal Saudi Arabia Naval Forces, Kingdom of Saudi Arabia.	Non-acceptance would cause embarrassment to donor and U.S. Government.
Vice Admiral James Malloy, United States Navy, Commander, U.S. Naval Forces Central Command, U.S. Fifth Fleet, Combined Maritime Forces.	Designer Shaik Arabian Gold Edition Perfume for Women. Rec'd—11/12/2019. Est. Value—$236.03. Disposition—Transferred to GSA.	Rear Admiral Adbullah Al-Shammari, Deputy Commander of Royal Saudi Arabia Naval Forces, Kingdom of Saudi Arabia.	Non-acceptance would cause embarrassment to donor and U.S. Government.
Vice Admiral James Malloy, United States Navy, Commander, U.S. Naval Forces Central Command, U.S. Fifth Fleet, Combined Maritime Forces.	Designer Shaik Arabian Gold Edition Perfume for Men. Rec'd—11/12/2019. Est. Value—$198.00. Disposition—Transferred to GSA.	Rear Admiral Abdullah Al-Shammari, Deputy Commander of Royal Saudi Arabia Naval Forces, Kingdom of Saudi Arabia.	Non-acceptance would cause embarrassment to donor and U.S. Government.

AGENCY: THE ENVIRONMENTAL PROTECTION AGENCY

[Report of Tangible Gifts Furnished by the Environmental Protection Agency]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
Mr. Matthew Crowley, Biologist, Chemistry and Exposure Branch, Health Effects Division, Office of Chemical Safety and Pollution Prevention, Office of Pesticide Programs.	GIFT OF TRAVEL Including hotel cost, ground transportation, meals and incidentals while in Ottawa, Canada. Rec'd—3/2/2020–3/5/2020. Est. Value—$748.00.	Ms. Connie Moase, Director of Health Evaluation Directorate, Pesticide Management Regulatory Agency of Canada.	Non-acceptance would cause embarrassment to donor and U.S. Government.
Mr. Jeffrey L. Dawson, Senior Scientist, Office of the Director, Office of Chemical Safety and Pollution Prevention, Office of Pesticide Programs.	GIFT OF TRAVEL Including hotel cost, meals, and currency conversion while in Ottawa, Canada. Rec'd—3/2/2020–3/5/2020. Est. Value—$588.13.	Ms. Connie Moase, Director of Health Evaluation Directorate, Pesticide Management Regulatory Agency of Canada.	Non-acceptance would cause embarrassment to donor and U.S. Government.
Mr. Michael Doherty, Chemist	GIFT OF TRAVEL Including lodging and meals, transportation, and incidental expenses while in Santiago, Chile. Rec'd—1/22/20. Est. Value—$588.13.	Food and Agriculture Organization of the United Nations.	Non-acceptance would cause embarrassment to donor and U.S. Government.
Dr. Thomas Luben, Senior Epidemiologist, Center for Public Health and Environmental Assessment, Office of Research and Development.	GIFT OF TRAVEL Including meals, local transportation and incidental expenses while in Bonn, Germany. Rec'd—2/2/2020–2/7/2020. Est. Value—$704.00.	European Centre for Environment and Health, World Health Organization.	Non-acceptance would cause embarrassment to donor and U.S. Government.

AGENCY: U.S. INTERNATIONAL DEVELOPMENT FINANCE CORPORATION

[Report of Tangible Gifts Furnished by the U.S. International Development Finance Corporation]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
The Honorable Adam Boehler, Chief Executive Officer.	510 Cloth Face Masks. Rec'd—6/2/2020. Est. Value—$510.00. Disposition—Facilities Office for Official Use.	His Excellency Ha Kim Ngoc, Ambassador of the Socialist Republic of Vietnam to the United States.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Adam Boehler, Chief Executive Officer.	Leather-bound Book *Serbia the Golden Apple.* Rec'd—9/22/2020. Est. Value—$437.00. Disposition—Purchased from GSA.	His Excellency Aleksandar Vučić, President of the Republic of Serbia.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Adam Boehler, Chief Executive Officer.	Carpet, Silver Chest filled with Pastries, and Cosmetic Oils in Box. Rec'd—9/28/2020. Est. Value—$683.00. Disposition—Silver Chest Purchased from GSA, Others at Facilities Office for Official Use.	His Excellency Nasser Bourita, Minister of Foreign Affairs of the Kingdom of Morocco.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Adam Boehler, Chief Executive Officer.	GIFT OF TRAVEL Helicopter tour of Patimban Port. Rec'd—10/25/2020. Est. Value—$590.00.	His Excellency Luhut Binsar Pandjatan, Coordinating Minister for Maritime and Investments Affairs of the Republic of Indonesia.	Non-acceptance would cause embarrassment to donor and U.S. Government.

AGENCY: THE NATIONAL SCIENCE FOUNDATION

[Report of Tangible Gifts Furnished by the National Science Foundation]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
Mr. Christopher L. Hill, Program Director, Division of Graduate Education.	Gift of Travel to Egypt. Rec'd—10/13/2019—11/1/2019. Est. Value—$738.50.	National Science Centre, Republic of Poland.	Non-acceptance would cause embarrassment to donor and U.S. Government.

AGENCY: UNITED STATES SENATE

[Report of Tangible Gifts Furnished by the United States Senate]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
The Honorable Maggie Hassan, United States Senator.	Ruby Necklace and Blue and White Hand-woven Carpet. Rec'd 10/5/2019. Est. Value—$480.00. Disposition—Secretary of the Senate.	General Qamar Javed Bajwa, Chief of Army Staff of the Pakistan Army.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Chuck Grassley, United States Senator.	Overture Napa Valley Red Wine. Rec'd—1/27/2020. Est. Value—$129.00. Disposition—Secretary of the Senate	His Excellency Lee Soo-hyuck, Ambassador of the Republic of Korea to the United States.	Non-acceptance would cause embarrassment to donor and U.S. Government.
The Honorable Jack Reed, United States Senator.	Decorated Box with the Saegimsori Seal, Containing Stamp and Seal Rec'd—1/23/2020. Est. Value—$100.00. Disposition—Secretary of the Senate.	His Excellency Lee Soo-hyuck, Ambassador of the Republic of Korea to the United States.	Non-acceptance would cause embarrassment to donor and U.S. Government.

AGENCY: DEPARTMENT OF VETERANS AFFAIRS

[Report of Travel and Report of Tangible Gifts Furnished by the Department of Veterans Affairs]

Name and title of person accepting the gift on behalf of the U.S. Government	Gift, date of acceptance on behalf of the U.S. Government, estimated value, and current disposition or location	Identity of foreign donor and government	Circumstances justifying acceptance
The Honorable Robert Wilkie, Secretary of Veterans Affairs.	Wooden Hand Carved Storyboard. Rec'd—1/17/20. Est. Value—$500.00. Disposition—VA History Center.	His Excellency Raynold Oilouch, Vice President of Palau.	Non-acceptance would cause embarrassment to donor and U.S. Government.

[FR Doc. 2022–07641 Filed 4–8–22; 8:45 am]
BILLING CODE 4710–20–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36486 (Sub–No. 3)]

Decision; Grainbelt Corporation—Trackage Rights Exemption—BNSF Railway Company

By petition filed on February 11, 2022,[1] Grainbelt Corporation (GNBC) requests that the Board partially revoke the trackage rights exemption granted to it under 49 CFR 1180.2(d)(7) in Docket No. FD 36486 (Sub–No. 2), as necessary to permit that trackage rights arrangement to expire on March 28, 2023. GNBC filed its verified notice of exemption on February 11, 2022, and simultaneously filed its petition for partial revocation. Notice of the exemption was served and published in the **Federal Register** (87 FR 13,039) on March 8, 2022, and the exemption became effective on March 22, 2022.

As explained by GNBC in its verified notice of exemption in Docket No. FD 36486 (Sub–No. 2), GNBC and BNSF Railway Company (BNSF) have entered into an amendment to extend the term of the previously amended, local trackage rights on trackage owned by BNSF between approximately milepost 668.73 in Long, Okla., and approximately milepost 723.30 in Quanah, Tex. (the Line), allowing GNBC to (1) use the Line to access the Plains Cotton Cooperative Association (PCCA) facility near BNSF Chickasha Subdivision milepost 688.6 at Altus, Okla., and (2) operate additional trains on the Line to accommodate the movement of trains transporting BNSF customers' railcars (loaded or empty) located along the Line, to unit train facilities on the Line (collectively, the PCCA Trackage Rights). (GNBC Verified Notice of Exemption 1–3, *Grainbelt Corp.—Trackage Rts. Exemption—BNSF Ry.,* FD 36486 (Sub–No. 2).)

GNBC explains that the trackage rights covered by the verified notice in Docket No. FD 36486 (Sub–No. 2) are local rather than overhead rights and therefore they do not qualify for the Board's class exemption for temporary trackage rights under 49 CFR 1180.2(d)(8). (GNBC Pet. 4.) GNBC therefore filed its verified notice of exemption under the Board's class exemption procedures at 49 CFR 1180.2(d)(7) and a petition for partial revocation of the exemption as necessary to permit the PCCA Trackage Rights to expire on March 28, 2023, pursuant to the parties' agreement. (GNBC Pet 3.) GNBC argues that the requested relief will promote the rail transportation policy and is limited in scope. (*Id.* at 4–5.) GNBC also asserts that the Board has routinely granted similar petitions to allow trackage rights to expire on a negotiated date. (*Id.* at 5.)

Discussion and Conclusions

Although GNBC and BNSF have expressly agreed on the duration of the proposed trackage rights, trackage rights approved under the class exemption at 49 CFR 1180.2(d)(7) typically remain effective indefinitely, regardless of any contract provisions. At times, however, the Board has partially revoked a trackage rights exemption to allow those rights to expire after a limited time rather than lasting in perpetuity. *See, e.g., BNSF Ry.—Trackage Rts.*

[1] The pleadings in this docket were originally filed in Docket No. FD 36580 (Sub–No. 1), but given that the trackage rights at issue are the same as those in Docket No. FD 36486, this proceeding has been changed to a subdocket of that original proceeding.

Exemption—Union Pac. R.R., FD 36377 (Sub–No. 3) (STB served Feb. 23, 2021); *BNSF Ry.—Trackage Rts. Exemption—Union Pac. R.R.,* FD 36377 (Sub–No. 1) (STB served Mar. 11, 2020); *New Orleans Pub. Belt R.R.—Trackage Rts. Exemption—Ill. Cent. R.R.,* FD 36198 (Sub–No. 1) (STB served June 20, 2018).

Under 49 U.S.C. 10502, the Board may exempt a person, class of persons, or a transaction or service, in whole or in part, when the Board finds that: (1) Continued regulation is not necessary to carry out the rail transportation policy of 49 U.S.C. 10101; and (2) either the transaction or service is of limited scope, or regulation is not necessary to protect shippers from the abuse of market power.

Granting partial revocation in these circumstances to permit the trackage rights to expire would eliminate the need for GNBC to file a second pleading seeking discontinuance when the agreement expires, thereby promoting the rail transportation policy at 49 U.S.C. 10101(2), (7), and (15). Moreover, partially revoking the exemption to limit the term of the trackage rights is consistent with the limited scope of the transaction previously exempted.[2] Therefore, the Board will grant the petition and permit the trackage rights exempted in Docket No. FD 36486 (Sub–No. 2) to expire on March 28, 2023.

To provide the statutorily mandated protection to any employee adversely affected by the discontinuance of trackage rights, the Board will impose the employee protective conditions set forth in *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979).

This action is categorically excluded from environmental review under 49 CFR 1105.6(c).

It is ordered:

1. The petition for partial revocation of the trackage rights class exemption is granted.

2. As discussed above, the trackage rights in Docket No. FD 36486 (Sub–No. 2) are permitted to expire on March 28, 2023, subject to the employee protective conditions set forth in *Oregon Short Line Railroad,* 360 I.C.C. 91.

3. Notice of this decision will be published in the **Federal Register**.

4. This decision is effective on May 6, 2022. Petitions to stay must be filed by April 18, 2022. Petitions for reconsideration must be filed by April 26, 2022.

[2] Because the proposed transaction is of limited scope, the Board need not make a market power finding. *See* 49 U.S.C. 10502(a).

Decided: April 5, 2022.

By the Board, Board Members Fuchs, Hedlund, Oberman, Primus, and Schultz.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2022–07699 Filed 4–8–22; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2022–0443]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Procedures for Non-Federal Navigation Facilities

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves aerial navigation aids (NavAids), electrical/electronic facilities, owned and operated by non-Federal sponsors for use by the flying public. ''Non-Federal sponsors'' refers to entities such as state and local governments, businesses, and private citizens. The information to be collected is necessary to ensure that operation and maintenance of these non-Federally owned facilities is in accordance with FAA safety standards. The FAA is not changing its information-collection practices pertaining to non-Federal facilities. It is merely renewing its legal authority to collect that information.

DATES: Written comments should be submitted by June 10, 2022.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By email: Non-Federal-Program@faa.gov (Enter docket number into subject line).

FOR FURTHER INFORMATION CONTACT: Natashia Jones by email at: *Natashia.Jones@faa.gov*; phone: (817) 222–4038.

SUPPLEMENTARY INFORMATION: The collection involves the compilation of:

- Commissioning data, such as the initial standards and tolerances parameters for the aerial navigation aids (NavAids) and electrical/electronic facilities, owned and operated by non-Federal sponsors;
- Maintenance activities and operational history, such as outages and repairs, for facilities owned and operated by non-Federal sponsors; and
- The facilities' periodically verified parameters for the life of the facility.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0014.

Title: Procedures for Non-Federal Navigation Facilities.

Form Numbers: FAA Form 6000–10; FAA Form 6000–8; FAA Form 6030–1.

Type of Review: Renewal of an information collection.

Background: Title 14 CFR part 171 establishes procedures and requirements for non-Federal sponsors, (''non-Federal sponsors'' refers to entities such as state and local governments, businesses, and private citizens) to purchase, install, operate, and maintain electronic NavAids for use by the flying public, in the National Airspace System (NAS). Part 171 describes procedures for receiving permission to install a facility and requirements to keep it in service. Documenting the initial parameters during commissioning is necessary to have a baseline to reference during future inspections. Another requirement is recording maintenance tasks, removal from service, and any other repairs performed on these facilities in on-site logs to have an accurate history on the performance of the facility. In addition, at each periodic inspection, recording the facilities' current parameters provides performance information for the life of the facility. Records must be kept on site and the FAA must receive copies of the logs.

Respondents: Approximately 2,200 non-Federal facilities/respondents.

Frequency: Information is collected (submitted to FAA Inspectors) on occasion.

Estimated Average Burden per Response: 13.72 hours per year.

- Form 6000–10, 1.72 hours per response
- Form 6000–8, 30 minutes per response

- Form 6030–1, 30 minutes per response

Estimated Total Annual Burden: Approximately 26,429 hours per year.

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

Shelly Beauchamp,

Manager, Advanced Systems Design Service Team, AJW–121, NAS Modernization Group, Operations Support Directorate, Technical Operations, Air Traffic Organization, Federal Aviation Administration.

[FR Doc. 2022–07653 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No.: FAA–2021–1199: Notice No. NOA–183–21–01]

Agency Information Collection Activities: Requests for Comments; Renewed Approval of Organization Designation Authorization

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. This collection involves organizations applying to perform certification functions on behalf of the FAA, including approving data and issuing various aircraft and organization certificates. The information will be used to determine an applicant's qualifications to perform certification functions as a representative of the FAA Administrator and to authorize organizations to perform those functions.

DATES: Written comments should be submitted by May 11, 2022.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (enter docket number into search field).

By mail: Scott Geddie, Section Manager, Compliance Systems Section, AIR–634, Systems Policy Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 6500 S MacArthur Blvd., ARB Building Room 304, Oklahoma City, OK 73169.

FOR FURTHER INFORMATION CONTACT: Scott Geddie, Section Manager, Compliance Systems Section telephone 405–954–6897; *scott.geddie@faa.gov.*

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0704.

Title: Organization Designation Authorization.

Form Numbers: FAA Form 8100–13.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on December 27, 2021 (86 FR 73408). 49 U.S.C. Section 44702(d) authorizes the Administrator of the Federal Aviation Administration to delegate to a properly qualified private person functions related to the examination, inspection, and testing necessary to the issuance of certificates. Title 14 of Code of Federal Regulations (CFR) Part 183, Subpart D allows the FAA to appoint organizations as Administrator representatives. As authorized, these organizations perform certification functions on behalf of the FAA. Applications include information about the applicant, the applicant's experience and qualifications, and the authority it seeks. Applications are submitted to the appropriate FAA office responsible for delegating the issuance certificates and approvals and are reviewed by the FAA team assigned to the applicant to determine whether the applicant meets the requirements necessary to be authorized as a representative of the Administrator. Procedures manuals are submitted for applications that are accepted by the FAA and contain the applicant's proposed procedures to be approved by the FAA to ensure that the correct processes are utilized when performing functions on behalf of the FAA as required by part 183 subpart D. These requirements are necessary to manage the various approvals issued by the organization and document approvals issued and must be maintained to address potential future safety issues.

Respondents: This collection involves organizations applying to perform certification functions on behalf of the FAA.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 43.5 hours.

Estimated Total Annual Burden: 5,623 hours.

Issued in Oklahoma City, OK, on April 6, 2022.

Scott A. Geddie,

Manager, Compliance Systems, Systems Policy Branch, AIR–630, Policy and Innovation Division.

[FR Doc. 2022–07666 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2022–0345]

Airport Improvement Program (AIP) Grant Assurances; Errata Notice Extending Comment Date

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

On April 4, 2022, the FAA issued a notice in the above-captioned matter. The notice indicated that the FAA would accept comments concerning the proposed modified grant assurances until ''April 12, 2022.'' This notice extends the comment due date to April 20, 2022.

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

Robert A. Hawks,

Deputy Director, Office of Airport Planning and Programming.

[FR Doc. 2022–07620 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2020–0100; Notice 2]

Nissan North 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: Nissan North America, Inc. (Nissan) has determined that certain model year (MY) 2020 Nissan Sentra motor vehicles do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 108, *Lamps, Reflective*

Devices, and Associated Equipment. Nissan filed a noncompliance report dated August 26, 2020. Nissan subsequently petitioned NHTSA on September 18, 2020, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This notice announces the denial of Nissan's petition.

FOR FURTHER INFORMATION CONTACT: Leroy Angeles, Office of Vehicle Safety Compliance, NHTSA, telephone (202) 366–5304.

SUPPLEMENTARY INFORMATION:

I. Overview

Nissan has determined that certain MY 2020 Nissan Sentra motor vehicles do not fully comply with the requirements of paragraph S10.18.9.1.2 of FMVSS No. 108, *Lamps, Reflective Devices, and Associated Equipment* (49 CFR 571.108). Nissan filed a noncompliance report dated August 26, 2020, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* Nissan subsequently petitioned NHTSA on September 18, 2020, 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 Nissan's petition was published with a 30-day public comment period, on March 24, 2021, in the **Federal Register** (86 FR 15769). One comment was 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–2020–0100.''

II. Motor Vehicles Involved

Approximately 5,520 MY 2020 Nissan Sentra motor vehicles, manufactured between November 26, 2019, and March 24, 2020, are potentially involved.

III. Noncompliance

Nissan explains that the noncompliance is that the right-hand LED headlamp aim in the subject vehicle may be misaligned resulting in a vertical gradient value less than 0.13 as required by paragraph S10.18.9.1.2 of FMVSS No. 108.

IV. Rule Requirements

Paragraph S10.18.9.1.2 of FMVSS No. 108 includes the requirements relevant to this petition: *Vertical gradient.* The gradient of the cutoff measured at either 2.5° L or 2.0° R must be not less than 0.13 based on the procedure of S10.18.9.1.5.

V. Summary of Nissan's Petition

The following views and arguments presented in this section are the views and arguments provided by Nissan and do not reflect the views of the Agency. In its petition, Nissan describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

In support of its petition, Nissan provided NHTSA with the following:

1. Nissan states that ''the supplier (Ichikoh) did not apply the correct aiming logic when setting the head lamp aim parameters'' in the subject vehicles and, ''[a]s a result, the right-hand LED headlamp aim may be misaligned resulting in a vertical gradient value below 0.13.'' Nissan states that ''[a] lower G-Value will lead to a headlamp cut line that is slightly less sharp.'' According to Nissan, ''Ichikoh inspected 3,506 lamps and found 572 lamps with a G-Value below 0.13. However, when the cut-off value is brought down to two decimals instead of three (per the express requirement in FMVSS No. 108), only 286 of the 3,506 lamps (about 8%) fall below the 0.13 minimum threshold. Of the 286 lamps, 248 (about 87%) are at a gradient value of 0.12.''

2. According to Nissan, Ichikoh confirmed that, ''even when the G-Value is below 0.13, all points of the Light Distribution achieve the required specifications of FMVSS 108 for both the low and high beam performance.'' Nissan attached to its petition test data from Ichikoh regarding such photometric performance.

3. Nissan states that it ''has not received any reports from the field of customer complaints, warranty claims, crashes, injuries, or fatalities related to this issue.''

4. Nissan contends that ''[t]he purpose of the gradient requirement is to assist in headlamp re-aiming.'' Nissan states that ''[t]he vehicles potentially affected by this issue were aimed properly at the factory using a different aiming method. Therefore, the only potential concern would relate to re-aiming performed after the vehicle has been in use.'' Nissan stated that ''[a]iming of the headlamps by a service technician in the field is an event that is expected to occur infrequently. To confirm this, Nissan searched its repair order database for repair orders on the previous generation Sentra that involved re-aiming of the headlamps. Out of 1,389,330 vehicles, 161 repair orders were found that involved headlamp aiming. This rate of repair would be 0.011% of vehicles. If the same rate of repair is applied to the expected 420 vehicles in the subject population [Nissan] would expect only 0.05 vehicles of the subject population to require a re-aiming in the field.''

5. Nissan asserts that ''[t]he difference in gradient values between 0.12 and 0.13 does not materially affect the ability of a service technician to properly aim the lamp in the rare case that this would need to be done in the field.''

6. ''Even if the lamps had to be re-aimed at some point,'' according to Nissan, ''it is unlikely the driver or other motorists would notice any glare or observable difference in operation between a fully compliant lamp and the subject lamps based on the conditions described above.''

Nissan concludes that the subject noncompliance is inconsequential as it relates to motor vehicle safety, and that its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

VI. Public Comment

NHTSA received one comment from the general public. The commenter explains that they have owned vehicles manufactured by Nissan and states that the noncompliance is not inconsequential. The comment does not, however, substantively address issues relevant to Nissan's petition with any specificity.

VII. NHTSA's Analysis

A. General Principles

The burden of establishing the inconsequentiality of a failure to comply with a *performance requirement* in a standard—as opposed to a *labeling requirement with no performance implications*—is more substantial and difficult to meet. Accordingly, the Agency has not found many such noncompliances inconsequential.[1]

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.[2] In general, NHTSA does not consider the absence of complaints or injuries to show that the issue is inconsequential to safety. The absence of complaints does not mean vehicle occupants have not experienced a safety

[1] *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).

[2] *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).

issue, nor does it mean that there will not be safety issues in the future.[3]

Arguments that only a small number of vehicles or items of motor vehicle equipment are affected also do not justify granting an inconsequentiality petition.[4] Similarly, mere assertions that only a small percentage of vehicles or items of equipment are likely to actually exhibit a noncompliance are unpersuasive. The percentage of potential occupants that could be adversely affected by a noncompliance is not relevant to whether the noncompliance poses an inconsequential risk to safety. Rather, NHTSA focuses on the consequence to an occupant who is exposed to the consequence of that noncompliance.[5] Indeed, the very purpose of a recall is to protect individuals from risk. *Id.*

B. NHTSA's Response to Nissan's Petition

NHTSA has evaluated the merits of Nissan's petition and has decided to deny the petition.

The purpose of the gradient requirement is to allow for proper aim of a visually/optically aimed headlamp. Failure to properly aim the headlamp can result in glare to surrounding vehicles or less down road visibility which can potentially lead to a crash.

Nissan states that the supplier did not apply the correct aiming logic when setting the headlamp aim parameters and, as a result, the headlamp aim may be misaligned resulting in a vertical gradient value less than 0.13. Nissan does not further describe the technical details surrounding the process that led to the noncompliance, and it is somewhat unclear as to what issue caused these lamps to have a gradient below that permitted by the standard. Generally, the Agency understands that vertical headlamp aim does not impact the value of the gradient calculation (the mathematical description of the change in intensity from one angular location to the next). The headlamp aim that is ''misaligned'' in the subject vehicles might be the horizontal aim, which is permanently set during the manufacturing process. A permanent horizontal misaim could result in the vertical scan line that is used in the gradient calculation to be measured in a location other than that intended by the beam pattern designer. In any case, the precise process failure that led to the noncompliance is not necessary in the Agency's analysis of the noncompliance impact on safety described below.

NHTSA reviewed the test data from Nissan's supplier, Ichikoh, regarding photometric performance of the lower beam and upper beam with G-values less than 0.13, and did not find it compelling. Nissan only provided one set of measurements for one lamp. In addition, their argument does not take into account the potential mis-aim which could be caused by the non-compliant gradient. Furthermore, while Nissan claimed that it is unlikely the driver or other motorists would notice any glare or observable difference in operation between a fully compliant lamp and the subject lamp, Nissan did not submit any data to support this claim.

NHTSA believes that any gradient less than the minimum requirement of 0.13 can affect the ability of the lamp to be properly aimed. As NHTSA has previously stated in the preamble to a final rule amending FMVSS 108,[6] and as provided as background in its associated notice of proposed rulemaking,[7] the gradient is based on a +/−0.1 degree laboratory aim accuracy and a 0.25 degree field aim accuracy with confidence limits of +/−2 sigma. A University of Michigan Transportation Research Institute (UMTRI) study[8] provided the information needed to establish the necessary gradient within the defined confidence bounds. The Society of Automotive Engineers (SAE) Beam Pattern Task Force also conducted a study[9] regarding visually aimable headlamps in which they found the standard deviation of vertical aim to be smaller than the standard deviation in the UMTRI study. Based on the SAE Beam Pattern Task Force study, a NHTSA-established advisory committee for regulatory negotiation to develop recommended specifications for altering the lower beam patterns of FMVSS 108 concluded that a gradient of 0.13 would satisfy the committee's goal for field aim accuracy.[10] Nissan did not provide data to support that the subject headlamps meet the photometric requirements even when misaimed, which is the potential consequence of not meeting the gradient requirement.

NHTSA is also not persuaded by Nissan's contention that the noncompliance involved here does not have a safety impact because it is relatively rare for headlamps to be re-aimed. Nissan's data supporting this claim, which relied on dealer repair records for the previous generation Sentra, is not, in NHTSA's view, representative. As vehicles age and their warranties expire, consumers are less likely to have service performed at a dealership. Instances of headlight service at independent garages and body shops also would not be included in Nissan's survey. And in any event, as stated above, arguments that only a small number of vehicles or items of motor vehicle equipment are affected have also not justified granting an inconsequentiality petition. For similar reasons, also unpersuasive is the number of lamps that exhibit a G-Value less than the 0.13 minimum threshold, or that Nissan has not received any reports from the field of customer complaints, warranty claims, crashes, injuries, or fatalities related to this issue.

VIII. NHTSA's Decision

In consideration of the foregoing, NHTSA has decided that Nissan has not met its burden of persuasion that the subject FMVSS No. 108 noncompliance is inconsequential to motor vehicle safety. Accordingly, Nissan's petition is hereby denied, and Nissan is obligated to provide notification of, and free remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

[3] *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'').

[4] *See Mercedes-Benz, U.S.A., L.L.C.; Denial of Application for Decision of Inconsequential Noncompliance,* 66 FR 38342 (July 23, 2001) (rejecting argument that noncompliance was inconsequential because of the small number of vehicles affected); *Aston Martin Lagonda Ltd.; Denial of Petition for Decision of Inconsequential Noncompliance,* 81 FR 41370 (June 24, 2016) (noting that situations involving individuals trapped in motor vehicles—while infrequent—are consequential to safety); *Morgan 3 Wheeler Ltd.; Denial of Petition for Decision of Inconsequential Noncompliance,* 81 FR 21663, 21664 (Apr. 12, 2016) (rejecting argument that petition should be granted because the vehicle was produced in very low numbers and likely to be operated on a limited basis).

[5] *See Gen. Motors Corp.; Ruling on Petition for Determination of Inconsequential Noncompliance,* 69 FR 19897, 19900 (Apr. 14, 2004); *Cosco Inc.; Denial of Application for Decision of Inconsequential Noncompliance,* 64 FR 29408, 29409 (June 1, 1999).

[6] *Federal Motor Vehicle Safety Standards; Lamps, Reflective Devices and Associated Equipment; Final Rule;* 62 FR 10710 (Mar. 10, 1997).

[7] *See Federal Motor Vehicle Safety Standards; Lamps, Reflective Devices and Associated Equipment; Notice of Proposed Rulemaking,* 61 FR 36334 (July 10, 1996).

[8] *See Visual Aiming of European and U.S. Low-Beam Headlamps,* Report No. UMTRI–91–34, by Sivak, Flannagan, Chandra, and Gellatly (Nov. 1991), *available at https://deepblue.lib.umich.edu/handle/2027.42/936.*

[9] *See Harmonized Vehicle Headlamp Performance Requirements* (first issued Jan. 1, 1995), *available at https://www.sae.org/standards/content/j1735_201102/.*

[10] The committee's consensus was reflected in NHTSA's final rule.

(Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8)

Anne L. Collins,

Associate Administrator for Enforcement.

[FR Doc. 2022–07646 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Comment Request; Survey of Minority Owned Institutions

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA). An agency may not conduct or sponsor, and respondents are not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning a renewal of an information collection titled ''Survey of Minority Owned Institutions.''

DATES: Comments must be submitted on or before June 10, 2022.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, Office of the Comptroller of the Currency, Attention: 1557–0236, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–0236'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Following the close of this notice's 60-day comment period, the OCC will publish a second notice with a 30-day comment period. You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection by the method set forth in the next bullet. Following the close of this notice's 60-day comment period, the OCC will publish a second notice with a 30-day comment period.

- *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Hover over the ''Information Collection Review'' tab and click on ''Information Collection Review'' dropdown. Underneath the ''Currently under Review'' section heading, from the drop-down menu select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0236'' or ''Survey of Minority Owned Institutions.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, Clearance Officer, (202) 649–5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of title 44 requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the OCC is publishing notice of the renewal of the collection of information set forth in this document.

Title: Survey of Minority Owned Institutions.

OMB Control No.: 1557–0236.

Type of Review: Regular review.

Description: The OCC is committed to assessing its efforts to provide supervisory support, technical assistance, education, and other outreach to the minority-owned institutions under its supervision, in accordance with meeting the goals prescribed under section 308 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989.[1] To perform this assessment, it is necessary to obtain feedback from the individual institutions on the effectiveness of the OCC's current efforts in these areas and suggestions on how the OCC might enhance or augment its supervision and technical assistance going forward. The OCC uses the information gathered to assess the needs of minority-owned institutions and its efforts to meet those needs. The OCC also uses the information to focus and enhance its supervisory, technical assistance, education, and other outreach activities with respect to minority-owned institutions.

Affected Public: Businesses or other for-profit.

Type of Review: Regular.

Estimated Number of Respondents: 55.

Estimated Annual Burden: 110 hours.

Frequency of Response: On occasion.

Comments submitted in response to this notice will be summarized, included in the request for OMB approval, and 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 OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the information collection burden;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation,

[1] 12 U.S.C. 1463 note.

maintenance, and purchase of services to provide information.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2022–07682 Filed 4–8–22; 8:45 am]

BILLING CODE 4810–33–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 entities that have been placed on OFAC's Specially Designated Nationals and Blocked Persons 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 entities 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: Andrea M. Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or the Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Actions

On April 5, 2022, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following entities are blocked under the relevant sanctions authorities listed below.

Entity

1. GARANTEX EUROPE OU (Latin: GARANTEX EUROPE OÜ), Harju maakond, Kesklinna linnaosa, J., Poska tn 51a/1–3, Tallinn 10150, Estonia; Harju maakond, Lasnamae linnaosa, Peterburi tee 47, Tallinn 11415, Estonia; Moscow, Russia; St. Petersburg, Russia; website *garantex.io*; Digital Currency Address—XBT 3Lpoy53K625zVeE47 ZasiG5jGkAxJ27kh1; Digital Currency Address—ETH 0x7FF9cFad3877F21d 41Da833E2F775dB0569eE3D9; Digital Currency Address—USDT 3E6ZCKRrsdPc35chA9Eftp1 h3DLW18NFNV; Business Registration Number 14850239 (Estonia) issued 18 Nov 2019 [RUSSIA–EO14024].

Designated pursuant to Section 1(a)(i) of Executive Order 14024 of April 15, 2021, ''Blocking Property With Respect To Specified Harmful Foreign Activities of the Government of the Russian Federation,'' for operating or having operated in the technology sector, defense and related materiel sector, or financial services sector of the Russian Federation economy.

2. HYDRA MARKET (a.k.a. HYDRA MARKETPLACE; a.k.a. ''HYDRA''), Russia; Commonwealth of Independent States; website *http://hydram6esdjf 6otepmr5c3vjyndsoddz22afphbb jznwb5ln2c6op7ad.onion/*; alt. website *http://hydraclubbioknikokex 7njhwuahc2l67lfiz7z36md2 jvopda7nchid.onion/*; Digital Currency Address—XBT 3K4rjdh8A5yi6 LWvft2rbmyZvqEbPSSSX4; alt. Digital Currency Address—XBT 17mhyeBX617ABZ1ff ThhUTJkHUcMvCkfd5; alt. Digital Currency Address—XBT 35qwVtMEohWDdBWR CSR7azoP5cbY8SG1Q; alt. Digital Currency Address—XBT 35KAdTa2vqnJzit F2xiUzZn1Gmcas2Y465; alt. Digital Currency Address—XBT 35LScRJ8hzDvvWh9 t9UA8bHGnGNVz3YEfa; alt. Digital Currency Address—XBT 1PJp8diNa89cVHpi T1VPu7EQ8LxYM5HX6v; alt. Digital Currency Address—XBT 17V7THwHMiDJm DwZK4unhE5HgKFJKx7VCe; alt. Digital Currency Address—XBT 3PiCnZrBvGfWAKQ 9hr4cCpfaDjy64yNSpE; alt. Digital Currency Address—XBT 14gM1HuLVDELNHaFU22qpabjtiWek 4HhV1; alt. Digital Currency Address—XBT 1GYuu9d5HPikaf bys3k5Q3DRJq6debGsoB; alt. Digital Currency Address—XBT 3GXdtA6kbb4M5 aqzZm5qqxcFDFRMW8LqdJ; alt. Digital Currency Address—XBT 1B11Ezqg3 AXjFhMdRq5UpPDpNyriYNVtkn; alt. Digital Currency Address—XBT 16SPDQFFzgsoNSPiFFTfS8 Dw8LLXqia4oc; alt. Digital Currency Address—XBT 19pPbUDvoSBZafk UCYkD2Z9AkuqqV6sWm7; alt. Digital Currency Address—XBT 3BQACtiMXYB9JpU MpkEWt9m8BzswpGHq4X; alt. Digital Currency Address—XBT 1DGsY4ww3BJnWXTsnmTg Wa6UWdoRXgA1pX; alt. Digital Currency Address—XBT 1GcKLUUXodTQcLc PD7VLMgvCc4hs5Q775; alt. Digital Currency Address—XBT 1EvhBad5wCZYhBoAs GaciV6AvmZ1osLpeJ; alt. Digital Currency Address—XBT bc1qsmv6lkrw 65l30yazdqpdjjtwzpvk9f8gfh0cy7; alt. Digital Currency Address—XBT bc1qs9u6j78e3utj08mwvqkkmqm9de5xk3g 4yh8qtq; alt. Digital Currency Address—XBT 12VrYZgS1nmf9K HHped24xBb1aLLRpV2cT; alt. Digital Currency Address—XBT bc1q202ajnhxgg9d9jjczmg 0g4usp6haqldyy2eakl; alt. Digital Currency Address—XBT 1NbGwQwt4uEhg2sr AKppLf8QaF6fbp3PZG; alt. Digital Currency Address—XBT 13LQJQ1oJ9K7PsqsGfjNhoVv6UeU6hgzQz; alt. Digital Currency Address—XBT 1CG1aSCxUnbmv 9G34ofxTQoHtuVnMLJtQV; alt. Digital Currency Address—XBT 3Kp8Qc5z7yev DeoQxhS5RSSKnEi5x7AQ43; alt. Digital Currency Address—XBT 331TS6DyASY7iU5CRA 8UryBnkPS78fP2B1; alt. Digital Currency Address—XBT 1NvJm3jfZx ENNyqws5BKQvhkLxg9chLJdo; alt. Digital Currency Address—XBT 1Licqjca74n8pmNaoARXLLqcTUTHFpxbXH; alt. Digital Currency Address—XBT 175BUqf8JCU1uoG1i TRKTacDa4uvJDUCw2; alt. Digital Currency Address—XBT 1ANpca7g93BwptUJg1zV116v49zn9gjDi3; alt. Digital Currency Address—XBT 1BCWMwpR4M1n YUuuYe2bmzrNuwGoF9ZAbA; alt. Digital Currency Address—XBT 18cFGAdYcvNHkuh XLBE7izQKCyUW8TzCJE; alt. Digital Currency Address—XBT 1QHxyuLGRMHfbNPJikV4D whfx45HWfUMWB; alt. Digital Currency Address—XBT 1GnFTy5F9qi5MfaRZ fgdg2jkyT5xtAHvd8; alt. Digital Currency Address—XBT bc1quyc6j8ca84q9gjej 5jjd2n8hra0vfu0j60 fefs57p6e5rerkq07q0l5u3w; alt. Digital Currency Address—XBT16p2UWTZwXR yK5bTHNVjdDyy1D3EQGsZf2; alt. Digital Currency Address—XBT 1CddRqw7oSPr T4tt5oXKyx2LiHJDPszy7y; alt. Digital Currency Address—XBT 1Hhe61Bwxs8Hd2W xzWY9FQyZicBiZGeSNW; alt. Digital Currency Address—XBT 1D3GuaS9eqK w8dWj9JFQtNufdRtysjSLxZ; alt. Digital Currency Address—XBT 1PWRKxkR5AU7Tc9zPqjdhtu1eGW1Q Zzs4y; alt. Digital Currency Address—XBT 1D1ej7zQzywWBDNXKNY pmH7Hso2U9koDG4; alt. Digital Currency Address—XBT 3KGQ3hX6eFYtB jTBFSdvdkzHmwZyYWLRQh; alt. Digital Currency Address—XBT 1LKE3XA9bf5JFqtGtCHzW j5QGxKGwMfXZw; alt. Digital Currency Address—XBT 1MtsQsw6n2jvJCWhpCw 7jifTfD9Q3rBBVg; alt. Digital Currency Address—XBT 1KkaKujnqwJf7Cbm7 JKAZGF3X9d4685m8n; alt. Digital Currency Address—XBT 1Ge8JodC2HiBiEuT7D3MoH6Fak6XrcT9Kf; alt. Digital Currency Address—XBT bc1qsmqpalp3gtgklt ag4x3ygevmhh9y2hzk73t2ug; alt. Digital Currency Address—XBT 1E9uUnLbyfToazo95vmM 3ysYnzgkrL7GeC; alt. Digital Currency

Address—XBT 1HH8eiuaTMucTNyvGCU mAvmCZCtdMi8SqK; alt. Digital Currency Address—XBT 19FQzHibWDhSP8p KmJS3uagFYoisXtehzw; alt. Digital Currency Address—XBT 3DLGfN7hgsWXXSp 9euXcnmWXLpFQuswW2t; alt. Digital Currency Address—XBT 1PXxwPVtYxZiCRp 9LKq7aKMDFrhAQztvUE; alt. Digital Currency Address—XBT 1Q4tJjH2aBr3A Jrzxqa4Z3jPpf5SDgF4jK; alt. Digital Currency Address—XBT 1PYtgFS2t6i57 WdDvbRa7kPcsagGMBxzfg; alt. Digital Currency Address—XBT 16ZSAEfYpPCj3 D94fsNt2okYj9Ue8mxy6T; alt. Digital Currency Address—XBT bc1qvlzfn6kmezv44d8kw0p5jsmxe 6wchv3zc7gsxs; alt. Digital Currency Address—XBT 3QVyoH4u3qT88u ChAeJVhfB3r6maZt431y; alt. Digital Currency Address—XBT 1FFS6pX1TCKTNy 668Mbk2Lyoem1qB48kYX; alt. Digital Currency Address—XBT 1Dpddb1TMjvmNQeYD qgyd1ww6cmwPJRdSk; alt. Digital Currency Address—XBT 3AjiWiUdKB5mc GUSS9mBeoHCeYJw3Zo8r6; alt. Digital Currency Address—XBT 1EtMuBPQnPCa3 cecerdSH1SzydxnhbTmw; alt. Digital Currency Address—XBT 3CCmt5LjQ5yKka FY1DWC2SbERVEtWRnSRD; alt. Digital Currency Address—XBT 1MQBDeRWsiJBf 7K1VGjJ7PWEL6GJXMfmLg; alt. Digital Currency Address—XBT 1MbtT2ZsTtLp 7EKZUV9r74cTyqvsMtTP2M; alt. Digital Currency Address—XBT 36yS87PLuW7sErLg1 TY26WzaVarTim7AcC; alt. Digital Currency Address—XBT 3AYU365Tcjef7j9pdKF9Xe8rWpEpsH196t; alt. Digital Currency Address—XBT 148LKmyZT3FGE4x1GjsFN6RsAwcjzk5iuE; alt. Digital Currency Address—XBT 16EKTes8ahD8xvwisqjc2xSNLiG3fDHatW; alt. Digital Currency Address—XBT 3GuQjr7kkrR5EjpanMgyAuxuLgrjEUwe21; alt. Digital Currency Address—XBT 35ean Ez5iYg2eYaxCtMrR4SCoypFqrBWUH; alt. Digital Currency Address—XBT 3QWUdP5taP4GrRuue VDud1eWetb7hc3wDH; alt. Digital Currency Address—XBT 3Czhm6xqn8odwz6jgTcjRrUjog28v6aVS8; alt. Digital Currency Address—XBT 1F7UL41qYm6TvnExZz PHBCyeENvX3XDEMS; alt. Digital Currency Address—XBT 123WBUDm SJv4GctdVEz6Qq6z8nXSKrJ4KX; alt. Digital Currency Address—XBT 3BCN3WgMRJwULT z1vsEQ7NZrBjwaUBf5Ca; alt. Digital Currency Address—XBT 35SwVFxosV3AsvnrBfzdXarqavRbvDyyxv; alt. Digital Currency Address—XBT 32pCmCWEjwhkLwh5BgLNAeBQF p5Gi1hv81; alt. Digital Currency Address—XBT 1G64TFMFVJTjhJXra 6x74BBhsfSyiWaFtT; alt. Digital Currency Address—XBT 1A3iYY4c3dkgNYGewz Yzr7EsqfBuWXibGo; alt. Digital Currency Address—XBT 3GAUBtrTtWp1D9ye Xgr3wMg8B599QHa5m5; alt. Digital Currency Address—XBT 3HJN4jRa4mdfkey9JR9jUhr86yPwL86A3C; alt. Digital Currency Address—XBT 1EuUMPBCZtSd5p VVFEqmRqUSfU1qy6ASuL; alt. Digital Currency Address—XBT 1Pu1nAW7kCoSMThMs8Q cpM8JxuByQDZgH; alt. Digital Currency Address—XBT 3QnWE5GVfQu3wVav91 RuFkqip4Ti4NWqAY; alt. Digital Currency Address—XBT 1CNbhgxGRZvsWnEHotf Xge7k2E1UPzBDC7; alt. Digital Currency Address—XBT 3HSZc4BLnQBznjSq7JvXgqNCZUUs3M9fZz; alt. Digital Currency Address—XBT 37dDBCexFPraKW4jGS qkE3NyG52YeZQbJx; alt. Digital Currency Address—XBT 1H8sDTTgJPBK w83EBZDLhXvetCbxZUMMZM; alt. Digital Currency Address—XBT 1BvJRBRp9ZZ6zLyu ZaZsV7g3xP6JokdZQW; alt. Digital Currency Address—XBT bc1q237mvl0heyw0r38wd3 xz8h5mar96rrwpams8pp; alt. Digital Currency Address—XBT 34dxZvijpBM 1YkPybczbQ7DuGuKAnULdfS; alt. Digital Currency Address—XBT 1GkLN7DbA9m AtHNzQWNPANcdWbefaz4Gzm; alt. Digital Currency Address—XBT 13hfsQm6oCaDZehfYBSMFiJVAi1jsL6sQd; alt. Digital Currency Address—XBT 1Sf6e4xQv8muMZqYPTdRFf3e5o5eWcg9F; alt. Digital Currency Address—XBT bc1qj6j6p0jdefl6pvdzx3kx8245yy5m z6q4luhzes; alt. Digital Currency Address—XBT 1B3u21itzjgKtm 7QsNQNCBpSkwzzeDHqrW; alt. Digital Currency Address—XBT 3JhPsVV3KnL 9dBYGSZALS9EbrLr97R865a; alt. Digital Currency Address—XBT bc1qqf8kcc9m57xjqcvsvuf989nnl48ve6d2s24 cx3; alt. Digital Currency Address—XBT 1HuYfoEwsfHgZiRhbhJrCd5ST3iksa8KEx; alt. Digital Currency Address—XBT 1J9wJH2bamZVxscXAvoDH4jvtGKb7s YFDm; alt. Digital Currency Address—XBT 34WWXwFKAsXL9z YxbeNPaPV6vDamkjQLUo; alt. Digital Currency Address—XBT 3PDmRwotTkRAFR LGTUrucCERp2JdM1q4ar; alt. Digital Currency Address—XBT 3AFcE2mbSSndcpYF gHoExSmjUc26ef2gQh; alt. Digital Currency Address—XBT 3P6PzdfETr4275Gn3veLkCyDxA1jV8fHKm; alt. Digital Currency Address—XBT 3HRExd8GKFskZC5 inmVcpiyy9UWG7FVa6o; alt. Digital Currency Address—XBT 3MP7yBGSW2gkXVRE 8S84T2j4KVgPh3rEzv; alt. Digital Currency Address—XBT 1K2fmE9hfhbRNSZo BvCBWZAvsS5idTUxBG; alt. Digital Currency Address—XBT 3ES6pqCueDPC nC4hCqhhYuey6gyiRJZw6E; alt. Digital Currency Address—XBT 3KvBX3jo69Qn8jHy44M33RYoeYcf8DdRBD; alt. Digital Currency Address—XBT 3K26aMKmnrv97P j6YiFcqiXk2LxeHfhnG3; alt. Digital Currency Address—XBT 3BWP6ZQAhc4j5wR1b95z JAthJEFvhdees7; alt. Digital Currency Address—XBT 3JuSgFrwnrNfuhvR4Gp WAPmeJVot4xrEae; alt. Digital Currency Address—XBT 1DKGRGJXGNLAtTeFb 9SNPNHtrkZ87q7qKi; alt. Digital Currency Address—XBT 361AkMKNNWYwZR sCE8pPNmoh5aQf4V7g4p; alt. Digital Currency Address—XBT 33fWcMdms B2Ey4CEbVWbjGFkuevBSyP9nG; alt. Digital Currency Address—XBT 35aTjkBh4yeTypJsi9nuTdoMKHTsawKV gX; Organization Established Date 2015 [CYBER2].

Designated pursuant to Section 1(a)(ii)(D) of Executive Order 13694 of April 1, 2015 ''Blocking the Property of Certain Persons Engaging in Significant Malicious Cyber-Enabled Activities,'' 80 FR 18077, 3 CFR 2015 Comp., p. 297, as amended by Executive Order 13757 of December 28, 2016, ''Taking Additional Steps to Address the National Emergency With Respect to Significant Malicious Cyber-Enabled Activities,'' 82 FR 1, 3 CFR 2016 Comp., p. 659 (E.O. 13694, as amended) for being responsible for or complicit in, or to have engaged in, directly or indirectly, cyber-enabled activities originating from, or directed by persons located, in whole or in substantial part, outside the United States that are reasonably likely to result in, or have materially contributed to, a significant threat to the national security, foreign policy, or economic health or financial stability of the United States and that have the purpose or effect of causing a significant misappropriation of funds or economic resources, trade secrets, personal identifiers, or financial information for commercial or competitive advantage or private financial gain.

Dated: April 5, 2022.

Andrea M. Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2022–07616 Filed 4–8–22; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Debt Management Advisory Committee Meeting

Notice is hereby given, pursuant to 5 U.S.C. app. 2, 10(a)(2), that a meeting will be held at the United States Treasury Department, 15th Street and Pennsylvania Avenue NW, Washington, DC on May 3, 2022 at 9:00 a.m. of the following debt management advisory committee: Treasury Borrowing Advisory Committee.

At this meeting, the Treasury is seeking advice from the Committee on topics related to the economy, financial markets, Treasury financing, and debt management. Following the working session, the Committee will present a written report of its recommendations. The meeting will be closed to the public, pursuant to 5 U.S.C. app. 2, 10(d) and Public Law 103–202, 202(c)(1)(B)(31 U.S.C. 3121 note).

This notice shall constitute my determination, pursuant to the authority placed in heads of agencies by 5 U.S.C. app. 2, 10(d) and vested in me by Treasury Department Order No. 101–05, that the meeting will consist of discussions and debates of the issues presented to the Committee by the Secretary of the Treasury and the making of recommendations of the Committee to the Secretary, pursuant to Public Law 103–202, 202(c)(1)(B).

Thus, this information is exempt from disclosure under that provision and 5 U.S.C. 552b(c)(3)(B). In addition, the meeting is concerned with information that is exempt from disclosure under 5 U.S.C. 552b(c)(9)(A). The public interest requires that such meetings be closed to the public because the Treasury Department requires frank and full advice from representatives of the financial community prior to making its final decisions on major financing operations. Historically, this advice has been offered by debt management advisory committees established by the several major segments of the financial community. When so utilized, such a committee is recognized to be an advisory committee under 5 U.S.C. app. 2, 3.

Although the Treasury's final announcement of financing plans may not reflect the recommendations provided in reports of the Committee, premature disclosure of the Committee's deliberations and reports would be likely to lead to significant financial speculation in the securities market. Thus, this meeting falls within the exemption covered by 5 U.S.C. 552b(c)(9)(A).

The Office of Debt Management is responsible for maintaining records of debt management advisory committee meetings and for providing annual reports setting forth a summary of Committee activities and such other matters as may be informative to the public consistent with the policy of 5 U.S.C. 552(b). The Designated Federal Officer or other responsible agency official who may be contacted for additional information is Fred Pietrangeli, Director for Office of Debt Management (202) 622–1876.

Dated: April 6, 2022.

Frederick E. Pietrangeli,

Director, Office of Debt Management.

[FR Doc. 2022–07664 Filed 4–8–22; 8:45 am]

BILLING CODE 4810–25–P

FEDERAL REGISTER

Vol. 87 Monday,
No. 69 April 11, 2022

Part II

Department of Energy

10 CFR Parts 429 and 431
Energy Conservation Program: Test Procedure for Commercial and Industrial Pumps; Proposed Rule

DEPARTMENT OF ENERGY

10 CFR Parts 429 and 431

[EERE–2020–BT–TP–0032]

RIN 1904–AC54

Energy Conservation Program: Test Procedure for Commercial and Industrial Pumps

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

ACTION: Notice of proposed rulemaking and announcement of public webinar.

SUMMARY: The U.S. Department of Energy (''DOE'') proposes to amend the test procedure for commercial and industrial pumps (''pumps'') to harmonize with updated industry standards, to expand the scope of clean water pumps covered by this test procedure, and to revise calculation methods for pumps sold with motors and controls to better represent field energy use. DOE is seeking comment from interested parties on the proposal and announcing a public meeting to collect comments and data on its proposal.

DATES: DOE will accept comments, data, and information regarding this proposal no later than June 10, 2022. See section V, ''Public Participation,'' for details. DOE will hold a webinar on April 26, 2022, from 1:00 p.m. to 4:00 p.m. See section V, ''Public Participation,'' for webinar registration information, participant instructions, and information about the capabilities available to webinar participants. If no participants register for the webinar, it will be cancelled.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov,* under docket number EERE–2020–BT–TP–0032. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments by email to *pumps2020tp0032@ee.doe.gov.* Include docket number EERE–2020–BT–TP–0032 in the subject line of the message. No telefacsimiles (''faxes'') will be accepted. For detailed instructions on submitting comments and additional information on this process, see section V of this document.

Although DOE has routinely accepted public comment submissions through a variety of mechanisms, including postal mail and hand delivery/courier, the Department has found it necessary to make temporary modifications to the comment submission process in light of the ongoing COVID–19 pandemic. DOE is currently suspending receipt of public comments via postal mail and hand delivery/courier. If a commenter finds that this change poses an undue hardship, please contact Appliance Standards Program staff at (202) 586–1445 to discuss the need for alternative arrangements. Once the COVID–19 pandemic health emergency is resolved, DOE anticipates resuming all of its regular options for public comment submission, including postal mail and hand delivery/courier.

Docket: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts (if a public meeting is held), comments, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly-available.

The docket web page can be found at *www.regulations.gov/docket/EERE-2020-BT-TP-0032.* The docket web page contains instructions on how to access all documents, including public comments, in the docket. See section V for information on how to submit comments through *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Mr. Jeremy Dommu, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–2J, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–9870. Email *ApplianceStandardsQuestions@ee.doe.gov.*

Mr. Michael Kido, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–8145. Email: *Michael.Kido@hq.doe.gov.*

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

SUPPLEMENTARY INFORMATION: DOE proposes to update a previously approved standard by incorporating by reference the following industry standard into part 431: HI 40.6–2021, ''Methods for Rotodynamic Pump Efficiency Testing.''

Copies of HI 40.6–2021 can be obtained from the Hydraulic Institute at 6 Campus Drive, First Floor North, Parsippany, NJ, 07054–4406, or by going to *www.pumps.org.*

DOE proposes to maintain previously approved standards incorporated by reference into part 431, except for the following, which DOE proposes to remove from part 431:

ANSI/HI 1.1–1.2–2014, ''American National Standard for Rotodynamic Centrifugal Pumps for Nomenclature and Definitions.''

ANSI/HI 2.1–2.2–2014, ''American National Standard for Rotodynamic Vertical Pumps of Radial, Mixed, and Axial Flow types for Nomenclature and Definitions.''

For a further discussion of these standards, see section IV.M of this document.

Table of Contents

I. Authority and Background

Commercial and industrial pumps (collectively, ''pumps'') are included in the list of ''covered equipment'' for which DOE is authorized to establish and amend energy conservation standards and test procedures. (42 U.S.C. 6311)(1)(A)) DOE's energy test procedures for pumps are currently prescribed at title 10 of the Code of Federal Regulations (''CFR''), § 431.464, and 10 CFR part 431 subpart Y appendix A (''appendix A''). The following sections discuss DOE's authority to establish test procedures for pumps and relevant background information regarding DOE's consideration of test procedures for this equipment.

A. Authority

The Energy Policy and Conservation Act, as amended (''EPCA''),[1] authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part C of EPCA, added by Public Law 95–619, Title IV, section 441(a), established the Energy Conservation Program for Certain Industrial Equipment, which sets forth a variety of provisions designed to improve energy efficiency. This equipment includes pumps, the subject of this document. (42 U.S.C. 6311(1)(A))

The energy conservation program under EPCA consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. EPCA include definitions (42 U.S.C. 6311), test procedures (42 U.S.C. 6314), labeling provisions (42 U.S.C. 6315), energy conservation standards (42 U.S.C. 6313), and the authority to require information and reports from manufacturers (42 U.S.C. 6316).

The Federal testing requirements consist of test procedures that manufacturers of covered equipment must use as the basis for: (1) Certifying to DOE that their equipment complies with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6316(a); 42 U.S.C. 6295(s)), and (2) making other representations about the efficiency of that equipment (42 U.S.C. 6314(d)). Similarly, DOE must use these test procedures to determine whether the equipment complies with relevant standards promulgated under EPCA. (42 U.S.C. 6316(a); 42 U.S.C. 6295(s))

Federal energy efficiency requirements for covered equipment established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6316(a) and 42 U.S.C. 6316(b); 42 U.S.C. 6297) DOE may, however, grant waivers of Federal preemption for particular State laws or regulations, in accordance with the procedures and other provisions of EPCA. (42 U.S.C. 6316(a))

Under 42 U.S.C. 6314, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered equipment. EPCA requires that any test procedures prescribed or amended under this section must be reasonably designed to produce test results which reflect energy efficiency, energy use or estimated annual operating cost of a given type of covered equipment during a representative average use cycle and requires that test procedures not be unduly burdensome to conduct. (42 U.S.C. 6314(a)(2))

EPCA also requires that, at least once every 7 years, DOE evaluate test procedures for each type of covered equipment, including pumps, to determine whether amended test procedures would more accurately or fully comply with the requirements for the test procedures to not be unduly burdensome to conduct and be reasonably designed to produce test results that reflect energy efficiency, energy use, and estimated operating costs during a representative average use cycle.[2] (42 U.S.C. 6314(a)(1))

In addition, if the Secretary determines that a test procedure amendment is warranted, the Secretary must publish proposed test procedures in the **Federal Register**, and afford interested persons an opportunity (of not less than 45 days' duration) to present oral and written data, views, and arguments on the proposed test procedures. (42 U.S.C. 6314(b)) If DOE determines that test procedure revisions are not appropriate, DOE must publish its determination not to amend the test procedures. (42 U.S.C. 6314(a)(1)(A)(ii)) DOE is publishing this Notice of Proposed Rulemaking (NOPR) in satisfaction of the 7-year review requirement specified in EPCA.

B. Background

DOE's established its test procedure for pumps in a final rule published on January 25, 2016. 81 FR 4086 (''January

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

[2] EPCA also requires after DOE first prescribes a test procedure for regulated industrial equipment, to conduct an evaluation of that test procedure not later than three years after the prescribing of that test procedure—and from time to time thereafter. *See* 42 U.S.C. 6314(c). DOE considers this rulemaking to be in satisfaction of this initial evaluation requirement.

2016 Final Rule'').[3] The January 2016 Final Rule established definitions for the terms ''pump,''[4] ''driver,''[5] and ''controls,''[6] and identified several categories and configurations of pumps. The pumps test procedure currently incorporates by reference the Hydraulic Institute (''HI'') Standard 40.6–2014, ''Methods for Rotodynamic Pump Efficiency Testing'' (''HI 40.6–2014''), along with several modifications to that testing method related to measuring the hydraulic power, shaft power, and electric input power of pumps, inclusive of electric motors and any continuous or non-continuous controls.[7]

On September 28, 2020, DOE published an early assessment review request for information (''RFI'') to determine whether to proceed with a rulemaking to amend the test procedure for commercial and industrial pumps. 85 FR 60734 (''September 2020 Early Assessment RFI''). Following review of the comments received in response to the September 2020 Early Assessment RFI, on April 16, 2021, DOE published an RFI in which it sought data and information pertinent to whether amended test procedures would (1) more accurately or fully comply with the requirement that the test procedure produces results that measure energy use during a representative average use cycle for the equipment without being unduly burdensome to conduct, or (2) reduce testing burden. 86 FR 20075 (''April 2021 RFI''). In response to requests from stakeholders,[8] on May 5, 2021, DOE published an extension of the comment period for an additional 30 days. (86 FR 23875) DOE received comments in response to the April 2021 RFI from the interested parties listed in Table I.1.[9] A parenthetical reference at the end of a comment quotation or paraphrase provides the location of the item in the public record.[10]

Table I.1 List of Commenters with Written Submissions in Response to the April 2021 RFI

Organization(s)	Reference in this NOPR	Organization Type
Appliance Standards Awareness Project, Natural Resources Defense Council	ASAP and NRDC	Efficiency Organization
Pacific Gas and Electric Company, Southern California Gas Company, Southern California Edison, and San Diego Gas and Electric Company (collectively, the California Investor-Owned Utilities)	CA IOUs	Utility Association
Grundfos Americas Corporation	Grundfos	Manufacturer
Hydraulic Institute	HI	Industry Association
Northwest Energy Efficiency Alliance and Northwest Power and Conservation Council	NEEA	Efficiency Organization
Summit Pump, Inc	Summit	Manufacturer

In their comments, Summit asserted that the industry as a whole has become more aware of DOE's energy standards for pumps since January 2020 when the pumps standards went into effect. (Summit, No. 16 at p. 7) Grundfos suggested that DOE consider eliminating multiple open notices that affect a given industry to ensure proper stakeholder engagement. (Grundfos, No. 17 at p. 1)

As noted, EPCA requires DOE to periodically review the test procedures of covered equipment, including pumps, to determine whether amended test procedures would more accurately or fully comply with the requirements for the test procedures to not be unduly burdensome to conduct and be reasonably designed to produce test results that reflect energy efficiency, energy use, and estimated operating costs during a representative average use cycle. (42 U.S.C. 6314(a)(1)) In order to provide stakeholders opportunities to engage as part of DOE's decision making, DOE provided opportunity for stakeholder comment to the September 2020 Early Assessment RFI and the April 2021 RFI. This NOPR provides further opportunity for comment on

[3] On March 23, 2016, DOE published a correction to the January 2016 Final Rule to correct the placement of the product-specific enforcement provisions related to pumps under 10 CFR 429.134(i). 81 FR 15426.

[4] A ''pump'' means equipment designed to move liquids (which may include entrained gases, free solids, and totally dissolved solids) by physical or mechanical action and includes a bare pump and, if included by the manufacturer at the time of sale, mechanical equipment, driver, and controls.

[5] A ''driver'' provides mechanical input to drive a bare pump directly or through the use of mechanical equipment. Electric motors, internal combustion engines, and gas/steam turbines are examples of drivers. (10 CFR 431.462)

[6] A ''control'' is used to operate a driver. (10 CFR 431.462)

[7] A ''continuous control'' is a control that adjusts the speed of the pump driver continuously over the driver operating speed range in response to incremental changes in the required pump flow, head, or power output. A ''non-continuous control'' is a control that adjusts the speed of a driver to one of a discrete number of non-continuous preset operating speeds, and does not respond to incremental reductions in the required pump flow, head, or power output. 10 CFR 431.462.

[8] Price Pump, EERE–2020–BT–TP–0032, No. 10 at p. 1; Hydraulic Institute EERE–2020–BT–TP–0032, No. 11 at p. 1; Grundfos, EERE–2020–BT–TP–0032, No. 12, at p. 1; Xylem, EERE–2020–BT–TP–0032, No. 13 at p. 1.

[9] In addition to the comments listed in Table I.1, DOE also received one comment from an individual, which was unrelated to the test procedures for pumps.

[10] The parenthetical reference provides a reference for information located in the docket of DOE's rulemaking to develop test procedures for pumps (Docket No. EERE–2020–BT–TP–0032, which is maintained at *www.regulations.gov/#!docketDetail;D=EERE-2020-BT-TP-0032*). The references are arranged as follows: (Commenter name, comment docket ID number, page of that document).

proposed amendments to the test procedure for pumps, which are discussed in the following sections. DOE acknowledges that it has multiple open notices that may inordinately impact a given industry at any time. However, DOE notes that the purpose of the rulemaking process is to engage stakeholders. While notices have specific comment dates by which comments are due, stakeholders may submit material to the rulemaking docket at any time during the course of the rulemaking by contacting the DOE program manager.

II. Synopsis of the Notice of Proposed Rulemaking

In this NOPR, DOE is proposing to:

(1) Expand the scope of the test procedure to include additional clean water pumps, specifically:

(a) Between-bearing (''BB'') pumps;

(b) radially-split, multi-stage, horizontal,

(c) in-line diffuser casing (''RSHIL'') pumps;

(d) radially-split, multi-stage, horizontal, end-suction diffuser casing (''RSHES'') pumps;

(e) small vertical in-line (''SVIL'') pumps;

(f) vertical turbine (''VT'') pumps;

(g) pumps sold with 6-pole induction motors or motors with design speeds between 960 rpm and 1,440 rpm;

(h) submersible turbine (''ST'') pumps with bowl diameters larger than 6 inches; and

(i) end-suction pumps not covered by the current test procedure;

(2) Clarify the applicability of the design temperature range scope limitation and modify the range parameters;

(3) Add and modify certain definitions in 10 CFR 431.462 to accommodate the expansion of scope and clarify existing definitions;

(4) Incorporate by reference HI 40.6–2021 into 10 CFR 431.463 and make minor revisions to the test procedure to address provisions in the current DOE test procedure that have been added to HI 40.6–2021;

(5) Remove the incorporations by reference of ANSI/HI 1.1–1.2–2014 and ANSI/HI 2.1–2.2–2014;

(6) Add specifications for stages for testing for expanded scope multi-stage pumps;

(7) Clarify test provisions for pumps with BEP at run-out;

(8) Clarify test provisions for calibration of measurement equipment;

(9) Update part-load loss factor equation coefficients in the calculation method for pumps sold with induction motors and controls;

(10) Provide a calculation method for pumps sold with inverter-only motors;

(11) Update the test procedure for submersible pumps to address proposed DOE coverage of submersible motors;

(12) Update the test procedure to address SVIL pumps;

(13) Add provisions for testing and rating pumps sold with a 6-pole induction motor or with design speeds between 960 rpm and 1,440 rpm; and

(14) Allow use of Alternative Efficiency Determination Methods (''AEDMs'').

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

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Table II.1 Summary of Changes in Proposed Test Procedure Relative to Current Test Procedure

Current DOE Test Procedure	Proposed Test Procedure	Reason for Proposed Change
Does not include in the scope of the test procedure BB, RSHIL, RSHES, SVIL, or VT pumps; pumps distributed in commerce with nominal speeds of 1,200 rpm; ST pumps with bowl diameter greater than 6 inches; or all end-suction pumps	Includes in the scope of the test procedure BB, RSHIL, RSHES, SVIL, and VT pumps; pumps distributed in commerce with nominal speeds of 1,200 rpm; ST pumps with bowl diameter greater than 6 inches; and all end-suction pumps	Improved representativeness
Includes a scope limitation of a design temperature range from 14 to 248 °F.	Specifies a scope limitation of a pump whose design temperature range falls wholly or partially into the range from 15 to 250 °F.	Improved clarity and enforceability
Includes definitions for pump categories within the current scope of the test procedure.	Includes definitions for additional pump categories and clarifications to the definitions for some existing pump categories.	Required for proposed scope expansion; improved enforceability
Incorporates by reference HI 40.6-2014 for determining the constant load pump energy index ("PEI_{CL}") and the variable load pump energy index ("PEI_{VL}") value of pumps	Incorporates by reference HI 40.6-2021 for determining the PEI_{CL} and the PEI_{VL} value of pumps	Updates to applicable industry test standard
Provides example pump categories for certain pump definitions by referencing ANSI/HI 1.1-1.2-2014 and ANSI/HI 2.1-2.2-2014	Removes example pump categories from all relevant definitions.	Simplification of the test procedure
References ANSI/HI 2.1-2.2-2014 to define "intermediate bowl" within the definition for bowl diameter.	Incorporates a definition for "intermediate bowl" in the definition for bowl diameter, removing the reference to ANSI/HI 2.1-2.2-2014	Simplification of the test procedure
Does not include test provisions for multistage pumps other than RSV and ST	Includes specifications for stages for testing for BB, RSHIL, RSHES, and VT pumps	Required for proposed scope expansion
Includes provisions for pumps with BEP at run-out.	Clarifies provisions for pumps with BEP at run-out.	Improved repeatability and reproducibility
References a section of HI 40.6-2014 related to calibration of measurement equipment.	Clarifies the applicable test provisions in HI 40.6-2021 for calibration of measurement equipment.	Improved repeatability and reproducibility
Includes a calculation method for pumps sold with induction motors and controls.	Includes revised part-load loss factor equation coefficients for motors 50 hp and above.	Improved representativeness
Does not provide a calculation method for pumps sold with inverter-only motors	Provides a calculation method for pumps sold with inverter-only motors	Reduced burden

Current DOE Test Procedure	Proposed Test Procedure	Reason for Proposed Change
Includes test provisions specific to submersible pumps based on default motor efficiency.	Includes test provisions specific to submersible pumps based on DOE's proposed coverage of submersible motors.	Responsive to DOE proposals in related rulemaking
Does not include test provisions specific to SVILs.	Includes test provisions specific to SVILs.	Required for proposed scope expansion
Does not include provisions for testing pumps distributed in commerce with 6-pole motors or motors with design speeds between 960 rpm and 1,440 rpm.	Includes provisions for testing pumps sold with 6-pole motors or motors with design speeds between 960 rpm and 1,440 rpm	Improved representativeness
Does not allow use of AEDMs.	Allows use of AEDMs.	Reduced burden

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DOE has tentatively determined that the proposed amendments described in section III of this NOPR would not alter the measured efficiency of commercial and industrial pumps that are currently included in the scope of DOE's energy conservation standards for pumps. Therefore, DOE does not expect that retesting or recertification would be necessary for currently certified pumps as a result of DOE's adoption of the proposed amendments to the test procedures, if made final. Additionally, DOE has tentatively determined that the proposed amendments, if made final, would not increase the cost of testing for these pumps. As such, for pumps currently within the scope of DOE's energy conservation standards, any representations regarding the energy consumption of a pump or the cost of energy consumed by a pump would have to be made in accordance with the amended test procedure beginning 180 days after publication of the final rule. (42 U.S.C. 6314(d))

For pumps that are not currently within the scope of the test procedure and are not currently required to certify pump energy use, DOE is proposing that the test requirements proposed in appendix A, if adopted, would take place on the compliance date of amended energy conservation standards for pumps that DOE may ultimately decide to adopt as part of a separate rulemaking assessing the technological feasibility and economic justification for such standards. In other words, for pumps that DOE is proposing to include in the scope of the proposed test procedure, manufacturers would need to use the results of testing under appendix A to determine compliance with any new energy conservation standards that DOE may establish for these pumps.

Discussion of DOE's proposed actions are addressed in detail in section III of this NOPR.

III. Discussion

In the following sections, DOE proposes certain amendments to its test procedures for pumps. For each proposed amendment, DOE provides relevant background information, explains why the amendment merits consideration, discusses relevant public comments, and proposes a potential approach.

A. Scope of Applicability

The current DOE test procedure for pumps applies to five categories of ''clean water pumps'' with specific defined characteristics, and excludes certain defined categories [11] of pumps. 10 CFR 431.464(a)(1).

DOE defines ''clean water pump'' as a pump that is designed for use in pumping water with a maximum non-absorbent free solid content of 0.016 pounds per cubic foot, and with a maximum dissolved solid content of 3.1 pounds per cubic foot, provided that the total gas content of the water does not exceed the saturation volume, and disregarding any additives necessary to prevent the water from freezing at a minimum of 14 °F. 10 CFR 431.462.

The five categories of clean water pumps to which the current test procedure applies are: End-suction close-coupled (''ESCC''); end-suction frame mounted/own bearings (''ESFM''); in-line (''IL''); radially-split, multi-stage, vertical, in-line diffuser casing (''RSV''); and submersible turbine (''ST''). 10 CFR 431.464(a)(1)(i). The defined characteristics specify limits on flow rate, maximum head, design temperature range, motor type, bowl diameter, and speed.[12] 10 CFR 431.464(a)(1)(ii). In the context of the energy conservation standards, pumps are further delineated into equipment classes based on nominal speed of rotation and operating mode (*i.e.,* constant load or variable load). 10 CFR 431.465.

In the April 2021 RFI, DOE requested comment on the percentage of pump models that fall within the scope of DOE's current test procedure. 86 FR 20075, 20079. Additionally, DOE also sought information regarding how manufacturers communicated performance in catalogs and other related literature for out-of-scope pumps. *Id.* DOE also requested shipment and market performance data for SVIL pumps, pumps operating with motors at speeds different than 1,800 rpm or 3,600 rpm, submersible turbine pumps with a bowl diameter greater than 6 inches, and other pumps that are currently excluded from scope based on the pump characteristics provided at 10 CFR 431.464(a)(1)(ii). *Id.*

In response, Grundfos generally recommended that an expansion to the

[11] The excluded categories of pumps are fire pumps; self-priming pumps; prime-assist pumps; magnet driven pumps; pumps designed to be used in a nuclear facility subject to 10 CFR part 50, ''Domestic Licensing of Production and Utilization Facilities''; and pumps meeting the design and construction requirements set forth in Military Specifications: MIL–P–17639F, ''Pumps, Centrifugal, Miscellaneous Service, Naval Shipboard Use'' (as amended); MIL–P–17881D, ''Pumps, Centrifugal, Boiler Feed, (Multi-Stage)'' (as amended); MIL–P–17840C, ''Pumps, Centrifugal, Close-Coupled, Navy Standard (For Surface Ship Application)'' (as amended); MIL–P–18682D, ''Pump, Centrifugal, Main Condenser Circulating, Naval Shipboard'' (as amended); and MIL–P–18472G, ''Pumps, Centrifugal, Condensate, Feed Booster, Waste Heat Boiler, And Distilling Plant'' (as amended). 10 CFR 431.464(a)(1)(iii).

[12] More specifically, these characteristics include: (A) flow rate of 25 gpm or greater at BEP and full impeller diameter; (B) maximum head of 459 feet at BEP and full impeller diameter and the number of stages required for testing; (C) design temperature range from 14 to 248 °F; (D) designed to operate with either (1) a 2- or 4-pole induction motor, or (2) a non-induction motor with a speed of rotation operating range that includes speeds of rotation between 2,880 and 4,320 revolutions per minute (rpm) and/or 1,440 and 2,160 rpm, and in either case, the driver and impeller must rotate at the same speed; (E) For ST pumps, a 6-inch or smaller bowl diameter; and (F) For ESCC and ESFM pumps, a specific speed less than or equal to 5,000 when calculated using U.S. customary units. 10 CFR 431.464(a)(1)(ii).

pumps test procedure scope should be addressed through a negotiated rulemaking process. (Grundfos, No. 17 at p. 3) Similarly, HI commented that manufacturers and other stakeholders should be involved in creating new pump categories. (HI, No. 20 at p. 3) HI also stated that significant changes to the test procedure and scope may lead to market confusion and result in additional testing burden (HI, No. 20 at p. 1) DOE notes that it published a notice on October 29, 2021 announcing a meeting of the Appliance Standards and Rulemaking Federal Advisory Committee (''ASRAC'') held on December 14, 2021 to discuss and prioritize topic areas for which ASRAC can assist the Appliance and Equipment Standards Program. 86 FR 60020. At this meeting, pumps themselves were not suggested as a category for negotiation, but extended equipment systems (*i.e.,* motor, drive, and driven load) inclusive of the pump were discussed for possible negotiation.

Summit responded that eight percent of their models are within scope of the DOE test procedure and that pump performance information is published in catalogs, pump curves, and brochures. (Summit, No. 16 at p. 3) Additionally, Summit stated that all in-scope pumps are labeled as meeting the DOE standard. *Id.* Grundfos stated that it has 27 basic models that it does not certify based on the scope limitations in the DOE test procedure. (Grundfos, No. 17 at p. 2) HI estimated that approximately 14 percent of manufacturer basic models would not be included in the scope of the current DOE standards because they are SVILs or because of the limitations included in 10 CFR 431.464(a)(1)(ii). (HI, No. 20 at p. 3) HI also stated that for products not within scope, manufacturers generally do not make representations of the pump energy index (''PEI'') value. (HI, No. 20 at p. 3) NEEA stated that it found that 16 percent of pumps reported by distributors (which are typically heating, ventilation, and air conditioning (''HVAC'') and domestic water equipment companies) are not included in DOE's current test procedure scope. (NEEA, No. 21 at p. 3) NEEA asserted that nearly all of the pumps sold by these distributors pump clean water and therefore should be in scope. *Id.*

Although stakeholders did not respond to DOE's request for data on pumps operating with motors at speeds other than 1,800 rotations per minute (''rpm'') or 3,600 rpm in the April 2021 RFI, DOE did receive comments on this issue in response to the August 9, 2021 pumps energy conservation standards early assessment review RFI (''August 2021 ECS RFI'', Docket EERE–2021–BT–STD–0018, No. 1). 86 FR 43430. Specifically, the CA IOUs stated that for one pump distributor, 27 percent of its commercial pump sales were either pumps with motors running at 1,200 rpm or double suction pumps [13] (both of which are not included in the scope of DOE's current test procedure). (CA IOUs, Docket EERE–2021–BT–STD–0018, No. 10 at p. 3)

DOE considered expanding scope to the following pump categories: Chemical process and wastewater pumps, small vertical inline pumps, certain additional clean water pumps (between-bearing, vertical suction, radially-split, multi-stage horizontal, line shaft and cantilever pumps), and pumps sold with motors that operate at 1,200 rpm. The following sections provide additional information and responses to stakeholder comments specific to the pumps that DOE considered for inclusion in the test procedure scope.

DOE notes that it is proposing changes to the current test procedure applicable to currently regulated pumps. Any representations regarding the energy consumption of these pumps or the cost of energy consumed by these pumps would have to be made in accordance with the amended test procedure beginning 180 days after publication of the final rule. (42 U.S.C. 6314(d)) The proposed changes to the test procedure would also apply to those pumps that DOE is proposing to include in its scope; however, for these pumps, the revised test procedure would be required in conjunction with the compliance date of any future amended energy conservation standards that DOE may set.

1. Pumps Not Designed for Clean Water Applications

The scope of the current DOE test procedure, as described previously, excludes both chemical process and wastewater pumps. *See* 10 CFR 431.464(a)(1)(i). Chemical process pumps are designed to pump fluids other than water, and wastewater pumps are designed for water with a higher level of free solids than clean water pumps.

In response to the April 2021 RFI, NEEA stated that there is functional overlap between pumps that are within the scope of the current DOE test procedure and those pumps that are excluded because they are certified under ASME/ANSI B73. (NEEA, No. 21 at p. 6) NEEA also stated that distributors report that a ''significant portion'' of ASME/ANSI B73 pumps are installed in clean water applications and that without this certification designation these pumps would be included in the scope for the DOE test procedure. *Id.* Summit stated that if DOE were to include ASME/ANSI B73 pumps within scope of the DOE test procedure, 80 percent of their pumps would be covered rather than the eight percent currently covered. (Summit, No. 16 at p. 4) ASAP and NRDC recommended that DOE consider how the DOE test procedure could facilitate greater market adoption of wastewater pumps with variable-speed drives, similar to what has been done for clean water pumps. (ASAP and NRDC, No. 18 at p. 2)

DOE also received comments pertaining to non-clean water pumps in the August 2021 ECS RFI. HI stated that the current definition of clean water pumps and the exclusion of non-clean water pumps from the test procedure scope aligns with regulations in both Canada and the EU. (HI, Docket EERE–2021–BT–STD–0018, No. 8 at p. 2) HI asserted that maintaining harmonization between the United States, Canada and the EU is important to minimize burden for manufacturers that distribute their pumps outside of the U.S. *Id.* HI stated that a large number of additional pump categories would need to be added to the DOE test procedure in order to appropriately characterize non-clean water pumps. *Id.* HI explained that there is not a clear distinction between a pump being designed for clean water or for wastewater or chemicals. Instead, HI explained that pump designs constitute a range of operation based on a liquid's chemical compatibility and containment requirements, in addition to the concentration, and hardness of the solids being pumped. *Id.* HI stated that it was not aware of any established definitions that characterize non-clean water pumps into unique groupings, and that any definitions would need to define each pump group and include distinct design features that affect their efficiency. *Id.* HI stated that DOE would need to establish many definitions and classes for non-clean water pumps to accurately develop standards. *Id.* HI also commented that the specificity necessary to group pumps with similar design options and loss characteristics would leave little data in each category to develop C-values, making it difficult to develop energy conservation standards. *Id.* Finally, HI stated that

[13] A double-suction pump is one whose impeller is designed to draw flow from both sides, as opposed to a single-suction pump whose impeller only draws flow from one side.

ASME/American Petroleum Institute, solids handling, slurry, positive displacement, and magnet driven pumps could not be tested with the HI 40.6 standard. (HI, Docket EERE–2021–BT–STD–0018, No. 8 at p. 4)

Also in response to the August 2021 ECS RFI, Grundfos recommended against expanding the DOE scope beyond clean water pumps, asserting that uses for pumping other fluids are too varied. (Grundfos, Docket EERE–2021–BT–STD–0018, No. 9 at p. 2)

DOE acknowledges that certain non-clean water pumps may be used in clean water applications; however, DOE expects the number of non-clean water pumps used in the clean water applications to be relatively small. DOE notes that the scope of HI 40.6–2014, which is currently incorporated by reference into the DOE test procedure, includes clean water pumps only. The scope of the HI 40.6 standard changed in the 2016 version to state that the standard covers pumps that are included in DOE's energy conservation standards and therefore does not provide requirements for testing pumps designed for non-clean water applications. The scope of HI 40.6–2021 is identical to that of HI 40.6–2016. To test non-clean water pumps, DOE would need to reference or develop an alternate test procedure. While this test procedure might enable comparison between non-clean water pumps, it is unlikely that a clean water and non-clean water test procedure would provide comparable results.

Additionally, DOE notes that non-clean water pumps, specifically wastewater pumps, must meet specific performance requirements to ensure the health of the U.S. population. DOE would need to carefully evaluate how the performance of non-clean water pumps could be impacted by energy conservation standards and ensure that public health and safety would not be negatively affected. As such, additional investigation is needed to understand the market, energy savings potential, test procedure implications, and performance requirements of non-clean water pumps (*i.e.,* chemical process and wastewater). DOE notes that because ''C-value'' is specified in the energy conservation standard (*see* 10 CFR 431.465(b)(4)) and C-value is required for determining PEI_{CL} and PEI_{VL}, there would be limited use of the test procedure without corresponding standards. Therefore, DOE has determined that it will continue to limit the applicability of this test procedure to clean water pumps at this time.

2. Small Vertical Inline Pumps

As discussed, the scope of the current DOE test procedure is limited to five categories of pumps designed for clean water applications. 10 CFR 431.464(a)(1)(i). One of these categories is in-line (IL) pumps, which are limited to shaft input power greater than or equal to 1 hp and less than or equal to 200 hp at BEP and full impeller diameter, and in which liquid is discharged in a plane perpendicular to the impeller shaft. 10 CFR 431.462. In 2016, a Circulator Pump Working Group [14] recommended a test procedure and energy conservation standard for circulator pumps, which DOE is addressing in a separate rulemaking, and also made recommendations for SVIL pumps. SVIL pumps have characteristics identical to those for in-line pumps but SVIL pumps have shaft input power of less than 1 hp. The Circulator Pump Working Group recommended that (1) SVIL pumps be evaluated using the PEI_{CL} or PEI_{VL} metric, and (2) SVIL pumps should be tested using the DOE pump test procedure, with any needed modifications determined by DOE. (Docket No. EERE–2016–BT–STD–0004, No. 58 Recommendation #1B at pp. 1–2)

In response to the April 2021 RFI, NEEA, Grundfos, ASAP and NRDC, the CA IOUs, and HI recommended that DOE address SVIL pumps in the commercial and industrial pumps test procedure and energy conservation standards rulemakings, rather than in a rulemaking for circulator pumps (NEEA, No. 21 at p.7; Grundfos, No. 17 at p. 3; ASAP and NRDC, No. 18 at p. 2; CA IOUs No. 19 at p. 11; HI, No. 20 at p. 3) NEEA stated that there is confusion in the market as to whether SVIL pumps are subject to the DOE test procedure and energy conservation standards, and that SVIL pumps may be in the same family as, or have overlapping pump curves with, larger pumps that are currently subject to the test procedure and standards. (NEEA, No. 21 at p. 6) NEEA also stated that there is a trend in the HVAC industry to move away from distributing large central pumps to distributing smaller pumps, and that therefore unregulated SVIL pumps compete with larger regulated pumps. *Id.*

DOE also received comments relative to SVIL pumps in the August 2021 ECS RFI. The CA IOUs stated that in discussions with distributors, one recommended adding fractional SVIL pumps to the scope of regulated equipment. (CA IOUs, Docket EERE–2021–BT–STD–0018, No. 10 at p. 5) According to the CA IOUs, this distributor stated that the lack of coverage currently causes confusion since some pumps within a given product line are covered and some are not. *Id* . For example, 7 percent of Taco's SVIL pump sales are fractional horsepower (''hp'') and are therefore uncovered.[15] *Id.* The CA IOUs also reported that SVIL pump use in hydronic HVAC systems is increasing and asserted that this means that SVIL pumps are competing with larger regulated pumps. *Id.*

Finally, DOE received comments relative to SVIL pumps in the May 7, 2021 Circulator Pumps Test Procedure and Energy Conservation Standard RFI (''May 2021 Circulator Pumps RFI''). 86 FR 24516, 24521. The CA IOUs supported NEEA's comments on SVIL pumps from the April 2021 RFI. (CA IOUs, Docket EERE–2016–BT–STD–0004, No. 116 at p. 6) The CA IOUs supported the incorporation and development of SVIL pump standards based on the PEI metric. *Id.*

In the April 2021 RFI, DOE also requested shipment and market performance data for SVIL pumps. 86 FR 20075, 20079. In response, Grundfos and HI recommended that DOE conduct manufacturer interviews to obtain specific market performance data. (Grundfos, No. 17 at p. 3; HI, No. 20 at p. 4)

Issue 1: Consistent with the Circulator Pump Working Group recommendation and based on the concerns expressed in the comments summarized above regarding SVILs being a part of the same model family as IL pumps and serving as an unregulated alternative to pumps currently subject to DOE test procedures and energy conservation standards, DOE proposes to include SVIL pumps within the test procedure's scope. DOE has tentatively determined that SVIL pumps can be tested using the current DOE pumps test procedure with certain additional modifications. The proposed test procedure and metric for SVIL pumps are discussed in sections III.G

[14] On February 3, 2016, DOE published its intention to establish a working group under the Appliance Standards and Rulemaking Federal Advisory Committee (''ASRAC'') to negotiate a test procedure and energy conservation standards for circulator pumps. 81 FR 5658. Throughout this document this working group shall be referred to as ''the Circulator Pumps working Group''.

[15] The use of the term SVIL here implies such pumps can be over 1 horsepower. The current DOE definition of in-line (''IL'') pumps, and the proposed definition of SVIL in section I.B.6 clarify that IL pumps under one horsepower are SVIL pumps. DOE assumes that the comment may have intended that 7 percent of IL pumps are SVIL pumps.

and III.D of this NOPR. Moreover, DOE expects that including SVIL pumps within the scope of the pumps test procedure would reduce confusion over which inline pumps are and are not regulated. DOE requests comment on its proposal to expand the scope of the test procedure to cover SVIL pumps.

3. Other Clean Water Pump Categories

In the April 2021 RFI, DOE requested comment on whether the five pump categories currently included in DOE's regulations sufficiently represent the market and technology available for clean water pumps; whether these categories are sufficiently defined in order to ensure that the categories are mutually exclusive; or whether any of these categories or descriptions should be amended. 86 FR 20075, 20078.

In response to DOE's request for comment in the April 2021 RFI, Grundfos and HI supported the current pump equipment categories, and Grundfos stated that these pump categories represent the current market. (Grundfos, No. 17 at p. 1; HI, No. 20 at p. 2) NEEA and ASAP and NRDC recommended that DOE expand the scope of the pumps test procedure to cover additional pumps used in clean water applications. (ASAP and NRDC, No. 18 at p. 1; NEEA, No. 21 at p. 2) NEEA identified four categories of pumps that it stated may have overlapping uses and therefore may compete with pumps that are currently within scope of DOE regulations; specifically: Single and two stage axially-split pumps, end-suction multi-stage pumps, vertical turbine pumps, and American Society of Mechanical Engineers (''ASME'')/ANSI B73 certified pumps,[16] (NEEA, No. 21 at p. 2) NEEA stated that having similar pumps that compete in the market but that do not use PEI as a performance metric is confusing for distributors and end users. (NEEA, No. 21 at p. 3) NEEA reiterated its points about pump scope expansion in its comments to the August 2021 ECS RFI. (NEEA, Docket EERE–2021–BT–STD–0018, No. 11 at p. 2)

Similarly, ASAP and NRDC recommended adding double suction pumps, multi-stage end-suction pumps, vertical turbine pumps, and pumps tested at a nominal speed of 1,200 rpm. (ASAP and NRDC, No. 18 at p. 2) ASAP and NRDC stated that this would ensure consistent pump efficiency information is available for purchasers. (ASAP and NRDC, No. 18 at p. 1) ASAP and NRDC additionally commented that some unregulated pumps can be used in the same applications as some regulated pumps. *Id.* ASAP and NRDC contended that including additional pump categories in the test procedure scope would provide a more level playing field for manufacturers. *Id.* In response to the August 2021 ECS RFI, ASAP and NRDC reiterated the points they made in response to the April 2021 RFI. (ASAP and NRDC, Docket EERE–2021–BT–STD–0018, No. 7 at pp. 1–2)

In response to the August 2021 ECS RFI, the CA IOUs supported NEEA's recommendation to expand the scope of the pumps test procedure to the four categories listed above. (CA IOUs, Docket EERE–2021–BT–STD–0018, No. 10 at p. 2) Grundfos stated that DOE should limit its focus of scope expansion to radially-split multi-stage horizontal pumps; and that positive displacement, axial/mixed flow, double suction, multi-stage axially-split, multi-stage radial split vertical immersible, non-submersible vertical turbine, and VS4/VS5 pumps[17] should remain excluded from the DOE scope. (Grundfos, Docket EERE–2021–BT–STD–0018, No. 9 at pp. 1–2) HI commented that DOE should not expand the scope of its regulation to either non-clean water pumps or to clean water pumps that may serve diverse markets and applications and therefore may have multiple design variants within each pump type. (HI, Docket EERE–2021–BT–STD–0018, No. 8 at p. 1). Additionally, HI stated that significant changes to the scope would cause market confusion since current standards and labeling requirements for pumps went into effect only recently in early 2020. *Id.*

The following sections discuss DOE's consideration of additional categories of clean water pumps within the scope of the test procedure, including the specific categories suggested by commenters.

a. Between-Bearing Pumps

Section 1.2.9.2 of ANSI–HI 14.1–14.2–2019 describes between-bearing (''BB'') pumps as pumps that are one- or two-stage, axially-split, mounted to a baseplate, driven by a motor via a flexible coupling, and with bearings on both ends of the rotating assembly.

In the April 2021 RFI, DOE requested comment on whether pumps that meet the description of BB pumps might fall within the current test procedure scope and if BB pumps could be tested with the current DOE test procedure. 86 FR 20075, 20079. In response, ASAP and NRDC and NEEA recommended evaluating double suction pumps for inclusion in the test standards, and stated that most of these pumps are BB1 pumps,[18] many are used in chilled clean water applications, and these pumps are often below 200 hp. (ASAP and NRDC, No. 18 at p. 1; NEEA, No. 21 at p. 2) In addition, DOE understands that NEEA's recommendation that DOE cover single and two-stage axially-split pumps to also refer to BB1 pumps. The CA IOUs also seemed to offer support for NEEA's comments. (CA IOUs, No. 19 at pp. 10–11)

Summit and Grundfos recommended a new category of double suction pumps/between-bearing pumps if DOE decides to expand its scope beyond clean water pumps. (Summit, No. 16 at p. 2; Grundfos, No. 17 at p. 4) Additionally, Grundfos specifically stated that BB1 pumps have different inlet/outlet configurations and losses when compared to IL pumps that are currently within the scope of the DOE test procedure. (Grundfos, No. 17 at p. 4) Summit stated that although they supply BB pumps, none are used in clean water applications, and that testing these pumps would be burdensome. (Summit, No. 16 at p. 3) Grundfos and HI commented that some BB1 pumps are designed for clean water applications and may be rated under 200 hp. (Grundfos, No. 17 at p. 3–4; HI, No. 20 at p. 4) Grundfos agreed that BB1 pumps can be tested according to the current DOE test procedure. (Grundfos, No. 17 at p. 4) While HI also agreed that BB1 pumps can be tested according to the DOE test procedure, they stated that BB1 pumps do not share the same physical and functional characteristics affecting energy consumption of any pump category currently defined by DOE. (HI, No. 20 at p. 4)

[16] Pumps certified under the ASME B73 designation include: B73.1 (''Specification for Horizontal End-suction Centrifugal Pumps for Chemical Process''), B73.2 (''Specification for Vertical In-Line Centrifugal Pumps for Chemical Process''), B73.3 (''Specification for Sealless Horizontal End-suction Centrifugal Pumps for Chemical Process''), and B73.5 (''Thermoplastic/thermoset Polymer Material Horizontal End-suction Centrifugal Pumps Chemical Process''). All B73 pumps are designed for use as chemical process pumps, which have specific design requirements related to reliability and performance such as maximum shaft deflections, bearing frame lubrication, sealing requirements, and vibration limits.

[17] VS4 and VS5 are pump categories defined in HI 14.1–14.2–2019 that both refer to vertically separate discharge pumps. VS4 pumps are line shaft pumps and VS5 pumps are cantilever pumps.

[18] BB1 pumps are a pump class defined by HI 14.1–14.2–2019 that are 1 and 2 stage, axially-split pumps with the impeller(s) mounted between bearings at either end. BB1 pumps are a specific sub-category of BB pumps.

DOE also received comments on the August 2021 ECS RFI relevant to BB pumps. The CA IOUs stated that in discussions with distributors, two distributors suggested that split case and double suction pumps should be included in the scope of the pumps rulemaking. (CA IOUs, Docket EERE–2021–BT–STD–0018, No. 10 at p. 3) It is DOE's understanding that the recommendations to include split case and double suction pumps refer to BB pumps, since these two characteristics synonymous with between-bearing pumps.

Based on a review of the market, BB pumps tend to generally be larger than the pumps currently subject to the DOE test procedure. Many BB pumps exceed the head and horsepower limits in the current DOE test procedure. Additionally, BB pumps are not typically designed for clean water applications. Despite these generalities, DOE has identified certain clean water BB pumps under 200 hp and 459 feet of head that could be viewed as potentially interchangeable with those pumps that fall within the scope of the current DOE test procedure.

In order to address the potential for pumps that provide unregulated alternatives to the pumps currently subject to the DOE test procedure, DOE proposes to include BB pumps within the scope of the DOE test procedure. However, DOE does not propose to expand beyond clean water pumps and does not propose to expand the head or horsepower limitations currently listed in 10 CFR 431.464(1)(ii). Additional investigation is needed to understand the market, energy savings potential, test procedure implications, and performance requirements of non-clean water pumps. DOE has determined that it will continue to limit the applicability of this test procedure to clean water pumps at this time. An expansion of the head and horsepower restrictions has the potential to increase test burden by requiring larger laboratory equipment to test pumps according to the DOE test procedure. Through its literature review DOE has found few BB pumps that exceed the head and horsepower limits and are designed for clean water, leading DOE to tentatively determine that the burden of expanding head and horsepower restrictions outweigh the benefits of expanded scope.

Based on stakeholder comments, literature reviews, and reviews of pump schematics, DOE has tentatively determined that BB pumps can be tested using the methodology in HI 40.6–2021; therefore, DOE is not proposing any modifications specific to testing BB pumps in this test procedure NOPR.

Specific proposals for a definition of BB pumps are detailed in section III.B.5 of this document.

Issue 2: DOE requests comment on its proposal to expand the current test procedure's scope to include BB pumps. Additionally, DOE requests comment on the repeatability and representativeness of testing BB pumps using the current DOE test procedure. DOE also requests comment on any additional burdens associated with testing BB pumps that are different from those burdens associated with pumps currently covered by the DOE test procedure.

b. Vertical Turbine Pumps

Section 1.3.3.1.2 of HI 14.1–14.2–2019 defines VS1 and VS2 pumps as vertically suspended, wet pit pumps with a single casing and discharge through the suspension column. VS1 pumps use a diffuser, while VS2 use a volute.[19] VS1 and VS2 pumps are generally known as vertical turbine pumps. These pumps are generally not designed for clean water applications, and often exceed head and horsepower limits laid out in the current test procedure.

In response to the April 2021 RFI, DOE received comments from ASAP and NRDC and NEEA recommending the inclusion of vertical turbine pumps in the scope of the current DOE test procedure. (ASAP and NRDC, No. 18 at pp. 1–2; NEEA, No. 21 at p. 2) NEEA stated that these pumps present a compliance loophole in DOE's pump regulations and create market confusion. (NEEA, No. 21 at pp. 2–3) The CA IOUs encouraged DOE to evaluate vertical turbine pumps for inclusion in the test procedure. (CA IOUs, No. 19 at p. 11)

Based on a review of literature, DOE has tentatively determined that ST pumps and vertical turbine pumps have similar end uses. Additionally, DOE has tentatively determined that ST and vertical turbine pumps have similar bowl and impeller assemblies, and that vertical turbine pumps may even share an identical assembly with an ST pump produced by the same manufacturer. To address the potential of pumps that provide unregulated alternatives to the pumps currently subject to the DOE test procedure, DOE proposes to include vertical turbine pumps within the scope of the DOE test procedure. However, as discussed previously, DOE does not propose to expand beyond clean water pumps and does not propose to expand the head or horsepower limitations currently listed in 10 CFR 431.464(1)(ii). An expansion of the head and horsepower restrictions has the potential to increase test burden by requiring larger laboratory equipment to test pumps according to the DOE test procedure. Through its literature review, DOE has found few vertical turbine pumps that exceed the head and horsepower limits and are designed for clean water. Therefore, DOE has tentatively determined that the burden of expanding head and horsepower restrictions outweigh the benefits of expanded scope.

Based on literature reviews and reviews of pump schematics, DOE has tentatively determined that vertical turbine pumps can be tested using the methodology in HI 40.6–2021; therefore, DOE is not proposing any modifications specific to testing vertical turbine pumps in this test procedure NOPR.

Specific proposals for a definition of VT pumps are detailed in section III.B.6 of this document.

Issue 3: DOE requests comment on its proposal to expand the current test procedure's scope to include VT pumps. Additionally, DOE requests comment on the repeatability and representativeness of testing VT pumps using the current DOE test procedure. DOE also requests comment on any additional burdens associated with testing VT pumps that differ from those burdens associated with pumps currently covered by the DOE test procedure.

c. Radially-Split Multi-Stage Horizontal Pumps

The current scope of the DOE test procedure includes radially-split, multi-stage, vertical, in-line casing diffuser (RSV) pumps, but does not include radially-split horizontal pumps, which are also multistage pumps used primarily in heating, cooling, and pressure boosting applications. In response to the April 2021 RFI, NEEA and ASAP and NRDC recommended that multi-stage end-suction pumps (specifically OH1j, OH7j, and OH13j)[20] should be included in the scope of the pumps test procedure. (NEEA, No. 21 at p. 2; ASAP and NRDC, No. 18 at p. 1) The CA IOUs supported NEEA's comment and recommended that DOE evaluate multi-stage end-suction pumps

[19] Both diffusers and volutes diffuse velocity energy into pressure as the flow exits a pump's impeller. A volute is a one or two scroll shaped diffusing passageway, while a diffuser is characterized by many radially-symmetric diffusing passageways.

[20] OH1J, OH7J, and OH13J are HI 14.1–14.2–2019 pump class definitions that refer to the multi-stage versions of OH1, OH7, and OH13 end-suction pumps. OH pumps are generally classified as overhung meaning the impeller shaft is only supported by bearings on one side of the impeller. OH1 pumps are horizontal, flexibly coupled, and have a centerline mount. OH7 pumps are horizontal and close coupled. OH13 pumps are horizontal and rigidly/short coupled.

for inclusion in the pumps test procedure. (CA IOUs, No. 19 at p. 10–11) NEEA additionally stated that multi-stage end-suction pumps are often in direct competition with RSV pumps in pressure boosting applications. (NEEA, No. 21 at p. 3) NEEA also provided a list of applications for multi-stage end-suction pumps to demonstrate the similarities between these pumps and those that are included in the scope of the current test procedure. (NEEA, No. 21 at p. 4)

DOE also received comments in response to the August 2021 ECS RFI relevant to multi-stage end-suction pumps. The CA IOUs stated that many distributors sell water booster pumps, which are often multi-stage end-suction pumps. (CA IOUs, Docket EERE–2021–BT–STD–0018, No. 10 at p. 3) Grundfos recommended that DOE focus its scope expansions on radially-split multi-stage horizontal pumps. (Grundfos, Docket EERE–2021–BT–STD–0018, No. 9 at p. 2) Grundfos also suggested that, like RSV pumps, RSH pumps should be limited to in-line flow, and that DOE should consider new categories for multi-stage products that do not have in-line connections. *Id.*

DOE has surveyed materials and product literature available online and has tentatively determined that the multi-stage end-suction pumps discussed by NEEA, ASAP and NRDC, and the CA IOUs would be classified as radially-split, multi-stage, horizontal, (''RSH'') end-suction pumps. DOE's literature survey also tentatively concluded that RSV and RSH pumps were marketed for similar applications, and that RSH could therefore serve as an unregulated loophole to RSV pumps. In addition, through reviews of product literature and HI 14.1–14.2–2019 pump schematics, DOE has tentatively determined that RSH pumps can be tested using the current DOE test procedure. Based on DOE's research, DOE proposes to include RSH pumps with both in-line and end-suction flow configurations in its test procedure scope. Specific proposals for definitions or RSH pump categories are detailed in section III.B.7 of this document.

Issue 4: DOE requests comment on its proposal to expand scope to include RSH pumps. Additionally, DOE requests comment on the repeatability and representativeness of testing RSH pumps using the current DOE test procedure. DOE also requests comment on any additional burdens associated with testing RSH pumps which are different from those burdens associated with pumps currently covered by the DOE test procedure.

d. End-suction Pumps Similar to ESFM and ESCC Pumps

DOE defines a ''close-coupled pump'' as a pump having a motor shaft that also acts as the impeller shaft, and defines a ''mechanically-coupled pump'' as a pump that has its own impeller shaft and bearings separate from the motor shaft. 10 CFR 431.462. As discussed in the April 2021 RFI, DOE is aware that certain pumps may have their own shaft, but with no bearings to support that shaft. 86 FR 20075, 20078. Additionally, while the close-coupled pump definition describes a pump in which the motor shaft also serves as the pump shaft, the definition does not provide detail on how the motor and pump shaft may be connected. DOE has observed that some manufacturers describe close-coupled pumps as using an adapter to mount the impeller directly to the motor shaft. The coupling type is the only differentiator between ESCC pumps, which are ''close-coupled pumps,'' and ESFM pumps, which are ''mechanically-coupled pumps.'' In the January 2016 Final Rule, DOE noted that it intended for ESFM and ESCC pumps to be mutually exclusive in order to ensure that pumps that are close-coupled to the motor and have a single impeller and motor shaft would be part of the ESCC equipment category, while all other end-suction pumps that are mechanically-coupled to the motor and for which the bare pump and motor have separate shafts would be part of the ESFM equipment category. 81 FR 4086, 4096. Despite this intention DOE is aware that these definitions may have left some end-suction pumps out of scope.

In the April 2021 RFI, DOE requested comment on whether there are pumps being sold in commerce that may not meet the ''close-coupled'' or ''mechanically-coupled'' definitions but would otherwise meet the definition for an ''end-suction'' pump. 86 FR 20075, 20078.

HI stated that there are currently pumps that have impellers not directly connected to the motor shaft, with all pump loads supported by the motor bearings, which do not meet either the definition of close-coupled or mechanically-coupled pumps. (HI, No. 20 at p. 3)

Based on HI's response and DOE's review of ESCC and ESFM pumps, DOE has tentatively determined that there is a group of end-suction pumps that do not currently fall into either the ESFM or ESCC definition, but which may be competitors to the currently regulated pumps. Therefore, DOE proposes to include all end-suction pumps within the coverage of this test procedure by modifying the definitions of ESFM and ESCC pumps. The details of this proposal are outlined in section III.B.8 of this document. DOE has tentatively determined that no test procedure revisions would be needed to accommodate these additional end-suction pumps.

Issue 5: DOE requests comment on its tentative determination that there are certain ends suction pumps excluded from the current test procedure due to the ESFM and ESCC definitions. DOE also requests comment on the number of pump models that may fall into this category and whether they are currently being tested according to the DOE test procedure.

e. Line Shaft and Cantilever Pumps

ANSI/HI 14.1–14.2–2019 includes design criteria for different pump configurations, and section 14.1.3.3.1.3 describes vertically separate discharge sump pumps, a category of pump that includes line shaft (''VS4'') pumps and cantilever (''VS5'') pumps. Both VS4 and VS5 pumps are vertically-suspended pumps with a single casing and with a discharge column that is separate from the shaft column. The pump equipment categories defined by DOE do not explicitly reference VS4 or VS5 pumps, and some pumps may be covered by both the DOE definition of an ESFM pump and the HI definition of a VS4 or VS5 pump. 86 FR 20075, 20079.

In the April 2021 RFI, DOE requested comment on whether the test procedure should be amended to explicitly address line shaft and cantilever pumps as described in the ANSI/HI 14.1–14.2–2019. 86 FR 20075, 20079. In response, Grundfos stated that line shaft pumps and cantilever pumps have designs similar to ESFM and ESCC pumps and that some are sold for clean water applications. (Grundfos, No. 17 at p. 3) Grundfos also commented that if DOE were to include line shaft and cantilever pumps within its scope, DOE should create a new equipment class since these pumps have different losses, and DOE would need to define a standard sump depth for testing since these products have a wide variance in sump depth. *Id.* HI stated that VS4 and VS5 are not clean water pumps and therefore there is no need to address their potential test procedures. (HI, No. 20 at p. 4)

Consistent with the comments from HI, DOE's literature survey indicates all cantilever pumps are primarily designed for non-clean water applications including liquids and slurries containing large solids. Therefore, DOE

has tentatively determined that it will not expand the scope of its test procedure to include line shaft or cantilever pumps at this time. This proposed approach is consistent with DOE's tentative decision not to expand the current test procedure's scope to pumps designed for non-clean water applications. DOE agrees that a standard sump depth must be defined for testing of these products but a representative sump depth could be determined for the purpose of this test procedure. DOE has not, however, assessed what a representative depth would be as it is not proposing a test procedure for line shaft and cantilever pumps.

4. Scope Limitations

Within the categories of clean water pumps included in the current DOE test procedure and proposed for inclusion in this notice, DOE also considered potential expansion to scope limitations related to bowl diameter, nominal speed, horsepower, and design temperature range.

a. Submersible Turbine Pumps With Bowl Diameter Greater Than 6 Inches

As discussed previously, the scope of the current DOE test procedure includes submersible turbine pumps with a bowl diameter of 6 inches or smaller. 10 CFR 431.464(a)(1)(i)(E) and (a)(1)(ii)(E). In response to the September 2020 Early Assessment RFI, NEEA listed submersible turbine (ST) pumps with a bowl diameter greater than 6 inches as an example of pumps that DOE should consider including as part of an expanded scope. (NEEA, No. 7 at p. 8) NEEA's reasoning was that pumps within a regulated family may not be rated because they have a bowl diameter greater than 6 inches.[21] (NEEA, No. 7 at p. 8) In the April 2021 RFI, DOE requested shipment data for submersible turbine pumps with a bowl diameter greater than 6 inches. 86 FR 20075, 20079. DOE received no shipment information on submersible turbine pumps with bowl diameters greater than 6 inches.

However, in response to the April 2021 RFI, HI stated that submersible turbine pumps with a flow rate less than 25 gpm at BEP are used in residential well applications and should remain out of scope since they have limited operating time. (HI, No. 20 at p. 3) DOE is not considering expanding scope to pumps with a flow rate less than 25 gpm at this time, due to the limitations leading to the current scope provision. However, DOE understands that flow rate typically increases with bowl diameter, so it is DOE's understanding that HI's comment is unrelated to a potential scope expansion to pumps with a bowl diameter greater than 6 inches.

As discussed in section III.A.3.b, DOE is proposing to include vertical turbine pumps within the scope of the DOE test procedure. These pumps are similar in design to ST pumps and commenters have indicated that the two pump categories can be used in overlapping applications. Stakeholder comments about the addition of vertical turbine pumps did not indicate a suggested bowl diameter limitation. As such DOE is not proposing one. To maintain consistency across pump categories, and in response to NEEA's early assessment RFI comments, DOE is proposing to remove the 6-inch bowl diameter limitations for ST pumps.

Issue 6: DOE requests comment on its proposal to remove the 6-inch maximum bowl diameter restriction from ST pumps, including whether there are any testing limitations for larger bowl diameters.

b. Pumps Designed To Be Operated at 1,200 RPM

As discussed, DOE limits the scope of pumps under the current test procedure to those designed to operate with a 2- or 4-pole induction motor, or a non-induction motor with an operating range that includes speeds of rotation between 2,880 and 4,320 rpm and/or 1,440 and 2,160 rpm. 10 CFR 431.464(a)(1)(ii). In either case, the driver and impeller must rotate at the same speed. 10 CFR 431.464(a)(1)(ii)(D). The current DOE test procedure does not include pumps designed to operate with 6-pole induction motors or with non-induction motors that have a speed of rotation operating range exclusively outside the ranges defined.

In response to the April 2021 RFI, ASAP and NRDC recommended evaluating pumps sold with 6-pole, 1,200 rpm motors and pumps designed to be operated at 1,200 rpm. (ASAP and NRDC, No. 18 at pp. 1–2) Summit stated that if DOE were to expand the nominal motor speeds included in its test procedure, 1,200 rpm would be the best nominal speed to add. (Summit, No. 16 at p. 5)

In addition, DOE received comments in response to the August 2021 ECS RFI pertaining to this topic. The CA IOUs stated that it contacted several distributors, two of whom recommended adding pumps designed to operate at 1,200 rpm. (CA IOUs, Docket EERE–2021–BT–STD–0018, No. 10 at p. 3) The CA IOUs added that one of these distributors stated that 1,200 rpm pumps have a longer life than higher rpm pumps, while the other stated that not including them within the test procedure's scope is confusing to customers. *Id.*

Based on a review of pump performance curves available online, DOE has tentatively determined that unregulated pumps tested with a nominal speed of 1,200 rpm are part of the same pump families as those pumps that currently fall within the scope of the DOE test procedure.[22] To ensure equitable treatment among these pumps, DOE is proposing to extend the scope of this test procedure to cover pumps designed to operate with 6-pole induction motors, and pumps designed to operate with non-induction motors with an operating range that includes speeds of rotation between 960 rpm and 1,440 rpm.[23] DOE proposes test provisions to accommodate these pumps in sections III.E.1 and III.H of this document.

Issue 7: DOE requests comment on its proposal to expand the scope of the test procedure to include pumps designed to operate with a 6-pole induction motor, and pumps designed to operate with non-induction motors with an operating range that includes speeds of rotation between 960 rpm and 1,440.

c. Pump Horsepower and Design Speed

As discussed, the current DOE test procedure's scope is limited to covered pump categories with a 2- or 4-pole induction motor; or a non-induction motor with an operating range that includes speeds of rotation between 2,880 and 4,320 rpm and/or between 1,440 and 2,160 rpm, and for which the driver and impeller rotate at the same speed. 10 CFR 431.464(a)(1)(ii)(D). In addition, DOE's definitions for the five pump categories are limited to pumps with shaft input power greater than or equal to 1 hp and less than or equal to 200 hp at BEP and full impeller diameter. 10 CFR 431.462.

DOE received comments on the August 2021 ECS RFI from the CA IOUs, who stated that in discussions with distributors one stated that some pumps sold with electronically commutated motors (''ECMs'') and intended to run at higher speeds, such as 4,320 rpm, must be normalized to rate at 3,600 rpm and this adjustment causes the power of the

[21] ST pumps with a bowl diameter greater than 6 inches are currently excluded from the scope of the DOE test procedure.

[22] See *https://www.regulations.gov/document/EERE-2020-BT-TP-0032-0024.* (Docket No. EERE–2020–BT–TP–0032–0024.)

[23] 960 and 1440 rpm are ± 20 percent of 1,200 rpm. The acceptable non-induction motor ranges for 1800 and 3600 rpm pumps are also ± 20 percent of the nominal value.

motor to fall below 1 hp. (CA IOUs, Docket EERE–2021–BT–STD–0018, No. 10 at p. 4) The CA IOUs asserted that this limits purchasers from comparing PEI_{VL} values across product lines. *Id.* The CA IOUs argued that this exclusion of ECM pump products from the DOE test procedure is caused by adjusting operation to the BEP operating point and does not consider the real-world use of this product, which is expected to provide similar head and flow as many IL pumps that are within the scope of the current DOE test procedure. (CA IOUs, Docket EERE–2021–BT–STD–0018, No. 10 at p. 7) The CA IOUs commented that ECM pumps would be considered a highly efficient pump, and the aforementioned test issue limits consumer comparison of these pumps with non-ECM pumps, which in turn creates a market distortion that will slow the adoption of more efficient technologies and makes it difficult for PEI pump rebate programs to include this product subset. *Id.* The CA IOUs recommended that DOE revise the inclusion and exclusion criteria for these products to be based on the driver horsepower of the full operating window of the unit. *Id.* The CA IOUs also stated that this issue might be addressed if SVIL pumps are included in the pumps test procedure. (CA IOUs, Docket EERE–2021–BT–STD–0018, No. 10 at p. 6)

As stated previously, the definitions of the pump categories within the scope of the test procedure reference horsepower limitations based on shaft input power at BEP and full impeller diameter. 10 CFR 431.462. DOE defines ''BEP'' as the pump hydraulic power operating point (consisting of both flow and head conditions) that results in maximum efficiency and defines ''full impeller diameter'' as the maximum impeller diameter with which a given pump basic model is distributed in commerce. 10 CFR 431.462. DOE's test procedure for pumps at appendix A to subpart Y of part 431 also includes test provisions for determining both BEP and pump input power (also known as shaft input power), as well as provisions for normalizing all measured data to the specified nominal speed of rotation. As such, while the definitions themselves do not specify that shaft input power is determined at nominal speed, DOE understands the CA IOUs concern that the pump definitions could be read to exclude pumps with shaft input power greater than or equal to 1 HP at BEP at their design speed, but less than 1 HP when tested and corrected to nominal speed. In addition, DOE understands that the value of maximum efficiency varies little with speed, and is often assumed to be constant, and as such the definition of BEP alone would not be sufficient to assume that it must be determined at a certain speed different from that in the test procedure. For these reasons, DOE believes there could be value in clarifying the current scope limitations regarding horsepower that are embedded in the pump category definitions.

However, DOE also notes that, as previously discussed, it is proposing to expand the current test procedure's scope to include SVIL pumps, which the CA IOUs noted might address this issue. Specifically, the proposed inclusion of SVIL pumps would be for fractional horsepower pumps, so even when corrected to nominal speed, the pumps in question would be included in scope. DOE understands that use of high frequency (circa 4,000 rpm) ECMs is likely more prevalent on SVILs than on other pumps in this horsepower range, particularly as a result of their applications and competition with the circulator market. This means that including SVILs in this proposed test procedure would include most, if not all, pumps where motor power decreases below 1 hp when rated at BEP. For these reasons, DOE is not proposing to change the specified horsepower limitations within the pump category definitions at this time.

Issue 8: DOE requests comment on its tentative determination that incorporating SVILs into the test procedure will largely eliminate the issue of higher speed 1 hp pumps falling out of scope when they rate at a nominal speed of 3600 rpm.

d. Horsepower and Number of Stages for Testing

In response to the April 2021 RFI, Grundfos urged DOE to clarify how to handle certification of equipment where some equipment is regulated while others are not and provided the example of an RSV basic model sold with a 1 horsepower (''hp'') motor tested at 3 stages. Grundfos continued that if a similar pump is 2-stage and uses a 0.75 hp motor, it's partially out of scope. Grundfos recommended that equipment that straddles the scope of the test procedure should be considered to be out of scope. (Grundfos, No. 17 at p. 10–11)

DOE understands that the same model of RSV pump may be sold with two stages, three stages, or some other number of stages. DOE's RSV pump definition includes those pumps that have a shaft input power greater than or equal to 1 hp and less than or equal to 200 hp at BEP and full impeller diameter and at the number of stages required for testing. 10 CFR 431.462. DOE's testing provisions for RSV in section C.2 of appendix A to subpart Y of part 431 specify that the number of stages required for testing is three—or, if the basic model is only available with fewer than three stages, to test the basic model with the maximum number of stages with which it is distributed in commerce in the United States. Therefore, the RSV pump model sold with 2 or 3 stages would be included in the scope of the test procedure (and standards) if it has a shaft input power greater than or equal to 1 hp when tested at 3 stages, and the resulting PEI would apply to all stages with which the pump model is sold. For this reason, DOE is not making any changes to the scope of the test procedure.

e. Design Temperature Range

The current scope for the pumps test procedure is limited to pumps with a design temperature range between and including 14 to 248 °F. This range was derived from the original negotiation term sheet for pumps, which recommended limiting the scope to pumps with a design range from –10 °C to 120 °C. (Docket EERE–2013–BT–NOC–0039–0092). For the purposes of its regulations, DOE translated this range to Fahrenheit. DOE has received inquires as to whether a pump marketed for temperatures up to 250 °F is outside of the current test procedure's scope. DOE has reviewed marketing materials for a number of pumps and found that common upper limits of temperature are 212, 225, 248, 250, and 300 °F. Some marketing materials state that standard seals may have one high temperature limit while optional seals provide a higher limit (typically 250 or 300 °F). DOE understands the original intent of the scope limitation was to exclude pumps designed exclusively for low or high temperatures from the test procedure. However, if a manufacturer is offering a pump model across all temperature ranges in order to minimize SKUs, rather than offering separate low temperature and high temperature models, DOE considers that such a pump model should be subject to the regulations. Only pumps designed and marketed for temperatures exclusively outside the range of DOE's scope would be excluded from the test procedure and energy conservation standards. DOE has also recognized that rounding to a temperature limit of 250 °F when translating from °C to °F would be preferable to using the exact value of 248 °F since manufacturers commonly use rounded temperature values in their marketing materials. Similarly, DOE

proposes rounding the lower temperature limit from 14 °F to 15 °F.

To clarify the scope of the pumps test procedure and to improve the enforceability of the regulation, DOE is proposing to change the wording and the values, such that the scope would include pumps with a design temperature inclusive of any part of the range from 15 to 250 °F.

Issue 9: DOE seeks comment on its proposal to clarify the scope of the pumps test procedure with respect to design temperature. Specifically, DOE requests comment on whether 15 °F and 250 °F are more appropriate than 14 °F and 248 °F, or whether other minor adjustments could be made to the range to assist with clarity and enforceability.

B. Definitions

1. Removing Certain References to Volute

Pumps generally have one of two common discharge types, either a volute or a diffuser. A volute is made up of one or two scroll-shaped channels, whereas a diffuser has 3 or more passages that diffuse the liquid that is being pumped. The current definitions for end-suction and in-line pumps use the term ''volute,'' when in practice either volutes or diffusers may be used for these categories of pumps. For example, DOE's current definition for end-suction pump includes the following: ''The liquid is discharged through a volute in a plane perpendicular to the shaft,'' while the definition for ESCC pump, which is an end suction pump, specifically references OH7 pumps. 10 CFR 431.462. However, Table 14.1.3.7 of HI 14.1–14.2–2019 specifies a diffuser as the standard casing for OH7 pumps. Similarly, DOE's current definition for IL pump includes the following: ''in which liquid is discharged through a volute in a plane perpendicular to the shaft,'' and specifically references OH4 and OH5 pumps as examples of end-suction pumps. *Id.* In contrast, Table 14.1.3.7 of HI 14.1–14.2–2019 specifies a diffuser as the standard casing for OH4 and OH5 pumps. DOE notes that HI 1.1–1.2–2014 did not make these casing distinctions.

DOE interprets the term ''volute'' in its definitions for ''end-suction pump'' and ''in-line pump'' to mean the part of the pump casing through which liquid is discharged generally, rather than to reference a specific type of discharge. To avoid this unintentional inconsistency between DOE's terminology and the terminology used by the updated industry standard, DOE proposes to amend the definitions of in-line pump and end-suction pump to remove the distinction that liquid is discharged ''*through a volute* in a plane perpendicular to the shaft'' [emphasis added] by specifying instead that liquid is discharged ''in a plane perpendicular to the shaft.''

Issue 10: DOE requests comment on the proposed changes to the definitions for ''in-line pump'' and ''end-suction pump'' to remove the distinction that liquid is discharged ''through a volute''.

2. HI Pump Class References

The current DOE definitions for ESCC pump, ESFM pump, IL pump, RSV pump, and ST pump all include references to ANSI/HI 2.1–2.2–2014 pump configurations as examples of pumps that would meet the given definition. DOE has tentatively determined that it will be beneficial if the definitions are self-contained, and that these examples may have been causing confusion as to which pumps the definitions applied to. Therefore, DOE proposes to remove references to specific pump configurations as defined in ANSI/HI 1.1–1.2–2014 and ANSI/HI 2.1–2.2–2014 in the definitions for ESCC, ESFM, IL, RSV, and ST pumps.

Issue 11: DOE requests comment on the proposed changes to the definitions for ESCC, ESFM, IL, RSV, and ST pumps to remove references to ANSI/HI 1.1–1.2–2014 pump classes. Specifically, DOE requests comment on the ability of the modified definitions to clearly communicate the intended pump categories to industry stake holders.

3. Bowl Diameter

The current DOE definition for ''bowl diameter'' references the definition of ''intermediate bowl'' in ANSI/HI 2.1–2.2–2014. This is the sole remaining reference to ANSI/HI 2.1–2.2–2014 in the test procedure if the proposed changes to eliminate the HI pump class references are adopted. DOE has tentatively determined it would be more helpful for readers if the bowl diameter definition was self-contained, particularly since HI 2.1–2.2–2014 would not be referenced elsewhere. To disassociate the definition of ''bowl diameter'' from ANSI/HI 2.1–2.2–2014, DOE is proposing to define ''bowl diameter'' as referring to ''the maximum dimension of an imaginary straight line passing through, and in the plane of, the circular shape of the intermediate bowl of the bare pump that is perpendicular to the pump shaft and that intersects the outermost circular shape of the intermediate bowl of the bare pump at both of its ends.'' With respect to ''intermediate bowl,'' DOE proposes to define this term as ''the enclosure within which the impeller rotates and which serves as a guide for the flow from one impeller to the next.''

The proposed definitions would be added to 10 CFR 431.462.

Issue 12: DOE requests comment on the proposed change to the definition of bowl diameter to include a more specific definition of intermediate bowl instead of referring to the term as defined in ANSI/HI 1.1–1.2–2014.

4. Small Vertical Inline Pumps

As discussed in section III.A.2, DOE is proposing to expand the scope of the test procedure to include SVIL pumps, which are identical to IL pumps except for having a shaft input power less 1 hp. The Circulator Pump Working Group recommended the following definition for SVIL pumps:

''Small vertical in-line pump means a single stage, single-axis flow, dry rotor, rotodynamic pump that: (1) Has a shaft input power less than 1 hp at best efficiency point at full impeller diameter, (2) is distributed in commerce with a motor that does not have to be in a horizontal position to function as designed, and (3) discharges the pumped liquid through a volute in a plane perpendicular to the shaft.'' (Docket No. EERE–2016–BT–STD–0004, No. 58 Recommendations #3C at p. 3)

In the May 2021 Circulator Pumps RFI, DOE requested comment on the suitability of the above definition. 86 FR 24516, 24522. In response, HI and NEEA supported the circulator pumps working group definition of SVILs. (HI, Docket EERE–2016–BT–STD–0004, No. 112 at p. 4; NEEA, Docket EERE–2016–BT–STD–0004, No. 115 at p. 4)

The recommended definition would distinguish SVIL pumps from DOE's current IL pump definition [24] in that SVIL pumps have a reduced shaft power input range (IL pump is constrained to greater than or equal to 1 hp and less than or equal to 200 hp; SVIL must be less than 1 hp) and a different maximum pump power output limitation (IL pump has a limit of 5 hp at BEP; SVIL pumps have no hp limitation). The change to

[24] An ''in-line (IL) pump'' means a pump that is either a twin-head pump or a single-stage, single-axis flow, dry rotor, rotodynamic pump that has a shaft input power greater than or equal to 1 hp and less than or equal to 200 hp at BEP and full impeller diameter, in which liquid is discharged through a volute in a plane perpendicular to the shaft. Such pumps do not include pumps that are mechanically-coupled or close-coupled, have a pump power output that is less than or equal to 5 hp at BEP at full impeller diameter, and are distributed in commerce with a horizontal motor. Examples of in-line pumps include, but are not limited to, pumps within the specified horsepower range that comply with ANSI/HI nomenclature OH3, OH4, or OH5, as described in ANSI/HI 1.1–1.2–2014. 10 CFR 431.462.

shaft input power is the primary distinction between IL and SVIL pumps. DOE has tentatively determined this distinction is necessary to adequately separate the two categories. The pump power output is a consequence of the shaft power limitations. DOE has tentatively determined that SVIL pumps do not require a 5 hp pump power output limitation as their shaft input power is already capped below 1 hp.

Another difference is that the IL definition includes a group of three parameters to exclude circulator pumps—namely that they are either mechanically-coupled or close-coupled, have a pump power output that is less than or equal to 5 hp at BEP at full impeller diameter, and are distributed in commerce with a horizontal motor. In contrast, the recommended SVIL definition is meant to exclude circulator pumps through clause (2)—*i.e.,* ''related to distribution in commerce with a motor that does not have to be in a horizontal position to function as designed.'' On December 20, 2021, DOE published a notice of proposed rulemaking to establish a test procedure for circulator pumps (''Circulator Pumps TP NOPR''). 86 FR 72096. In the NOPR, DOE proposed to define a circulator pump as consisting of a wet rotor circulator pump; dry rotor, two-piece circulator pump; or dry rotor, three-piece circulator pumps. The NOPR also included proposed definitions for these subcategories of circulator pumps. *Id.* at 86 FR 72139. For clarity, DOE proposes that for the SVIL definition, rather than including the recommendation in clause (2), to instead exclude circulator pumps. Should a test procedure not be finalized for circulator pumps, DOE could instead finalize an SVIL definition using clause (2). For consistency, DOE also proposes to revise the IL pump definition to explicitly include circulator pumps instead of including the clauses meant to implicitly exclude them. Should a test procedure not be finalized for circulator pumps, DOE would retain the existing relevant clauses of the IL definition.

DOE notes that clause (3) of the recommended SVIL definition (''discharges the pumped liquid through a volute in a plane perpendicular to the shaft'') refers to a volute. For the reasons discussed in section III.B.1 of this document, DOE proposes excluding this reference from the proposed SVIL definition.

The recommended SVIL pump definition, through clause (2), also requires that these pumps be distributed into commerce with a motor, meaning SVIL pumps cannot be sold as a bare pump. Based on a literature search, DOE has tentatively determined that all SVIL pumps are sold with a motor. However, by proposing to replace clause (2) with an exclusion for circulator pumps, this requirement would be eliminated.

Although not addressed in the recommendation from the Working Group, the defined term ''twin-head pump'' (10 CFR 431.462) would be applicable to SVIL pumps. Specifically, in the January 2016 Final Rule, DOE adopted a test procedure for ''twin-head pumps'', where a twin-head pump is defined as a: ''dry rotor, single-axis flow, rotodynamic pump that contains two impeller assemblies, which both share a common casing, inlet, and discharge, and each of which (1) Contains an impeller, impeller shaft (or motor shaft in the case of close-coupled pumps), shaft seal or packing, driver (if present), and mechanical equipment (if present); (2) Has a shaft input power that is greater than or equal to 1 hp and less than or equal to 200 hp at best efficiency point (BEP) and full impeller diameter; (3) Has the same primary energy source (if sold with a driver) and the same electrical, physical, and functional characteristics that affect energy consumption or energy efficiency; (4) Is mounted in its own volute; and (5) Discharges liquid through its volute and the common discharge in a plane perpendicular to the impeller shaft.'' 81 FR 4086, 4095–4096 and 4115–4116 (Jan. 25, 2016).

Since SVIL pumps are similar to IL pumps but operate at a smaller horsepower, and also are available in twin-head configurations DOE proposes to define a new term—''small vertical twin-head pump''—and to extend the twin-head pump test procedure adopted in the January 2016 Final Rule to small vertical twin-head pumps. Accordingly, the proposed definition would read as: ''small vertical twin-head pump'' as a dry rotor, single-axis flow, rotodynamic pump that contains two equivalent impeller assemblies, each of which:

(1) Contains an impeller, impeller shaft (or motor shaft in the case of close-coupled pumps), shaft seal or packing, driver (if present), and mechanical equipment (if present); and

(2) Has a shaft input power that is less than or equal to 1 hp at BEP and full impeller diameter; and

(3) Has the same primary energy source (if sold with a driver) and the same electrical, physical, and functional characteristics that affect energy consumption or energy efficiency; and

(4) Is mounted in its own volute; and

(5) Discharges liquid through its volute and the common discharge in a plane perpendicular to the impeller shaft.

To summarize, DOE is proposing to define SVIL pumps based on the recommended definition from the Circulator Pump Working Group with modifications to include SVILs that are small vertical twin-head pumps; to exclude pumps that are circulator pumps; and to remove the current reference to a volute. Specifically, DOE is proposing to define a ''small vertical in-line pump'' as a small vertical twin-head pump or a single stage, single-axis flow, dry rotor, rotodynamic pump that: (1) Has a shaft input power less than 1 hp at best efficiency point at full impeller diameter, (2) in which liquid is discharged in a plane perpendicular to the shaft; and (3) is not a circulator pump.

Issue 13: DOE also proposes to revise the IL definition to explicitly exclude circulator pumps. DOE requests comment on its proposed definitions for ''small vertical in-line pumps'' and ''small vertical twin-head pump.''

Issue 14: DOE requests comment on the percentage of SVIL pumps, if any, that are not sold with a motor, and whether the definition of SVIL pump should be limited to those sold with a motor.

Issue 15: DOE requests comment on its proposed revision to the IL pump definition to explicitly exclude circulator pumps.

5. Between-Bearing Pumps

As discussed in section III.A.3.a, DOE is proposing to add between-bearing pumps to the scope of this test procedure and is therefore proposing a definition for this pump category.

ANSI/HI 14.1–14.2–2019 defines between-bearing pump as a rotodynamic pump with the impeller(s) mounted on a shaft between-bearings on either end. In addition, all between-bearing pumps described in ANSI/HI 14.1–14–2–2019 are mechanically-coupled and dry rotor. Through a literature review, DOE has tentatively determined that the between-bearing pumps that are most similar to the pumps currently regulated by DOE have axially-split casings and 1 or 2 stages. Accordingly, using ANSI/HI 14.1–14.2–2019 as the basis for its approach, DOE is proposing to use the defined terms ''dry rotor pump'', rotodynamic pump'', and ''mechanically-coupled pump'' to define a between-bearing pump,—*i.e.,* ''an axially-split, mechanically-coupled, one- or two-stage, dry rotor, rotodynamic pump with bearings on both ends of the rotating assembly that has a shaft input power greater than or equal to 1 hp and less than or equal to 200 hp at BEP and full impeller

diameter and at the number of stages required for testing.''

Issue 16: DOE requests comment on its proposed definition for between-bearing pumps, specifically if it is sufficient to identify the intended scope.

In addition to proposing a definition for between-bearing pump, DOE is also proposing to define the associated term ''axially-split pump.'' The term ''axially-split'' refers to a design of pump casing that can be separated, for maintenance and assembly, in a plane parallel to the impeller shaft. DOE proposes to define an ''axially-split pump'' based on ANSI/HI 14.1–14.2–2019 as ''a pump with a casing that can be separated or split in a plane that is parallel to and which contains the axis of the impeller shaft.''

Issue 17: DOE request comment on the proposed definition for axially-split pump.

6. Vertical Turbine Pump

As discussed in section III.A.3.b, DOE is proposing to add vertical turbine pumps to the scope of its test procedure and is therefore proposing a definition for this pump category. ANSI/HI 14.2–14.2 –2019 defines vertical turbine pumps as ''single-casing, non-submersible, pumps with impellers mounted in a vertically suspended shaft, that discharge liquid through the column.'' Based on this definition and existing DOE defined terms and proposed defined terms, DOE is proposing to define the term ''vertical turbine pump'' as a vertically-suspended, single-stage or multi-stage, dry rotor, rotodynamic pump:

(1) That has a shaft input power greater than or equal to 1 hp and less than or equal to 200 hp at BEP and full impeller diameter and at the number of stages required for testing;

(2) For which no external part of such a pump is designed to be submerged in the pumped liquid;

(3) That has a single pressure containing boundary (*i.e.,* is single casing), which may consist of but is not limited to bowls, columns, and discharge heads; and

(4) That discharges liquid through the same casing in which the impeller shaft is contained.

Issue 18: DOE requests comment on the proposed definition for vertical turbine pump.

7. Radially-Split, Multi-Stage Horizontal Pumps

DOE currently defines a RSV pump as a vertically-suspended, multi-stage, single axis flow, dry rotor, rotodynamic pump:

(1) That has a shaft input power greater than or equal to 1 hp and less than or equal to 200 hp at BEP and full impeller diameter and at the number of stages required for testing; and

(2) In which liquid is discharged in a place perpendicular to the impeller shaft; and

(3) For which each stage (or bowl) consists of an impeller and diffuser;

(4) For which no external part of such a pump is designed to be submerged in the pumped liquid; and

(5) Examples include, but are not limited to, pumps complying with ANSI/HI nomenclature VS8, as described in ANSI/HI 2.1–2.2–2014.

As discussed in section III.A.3.c, DOE is proposing to include within the scope of the DOE test procedure RSH pumps with both end-suction and in-line flow configurations. RSH pumps are nearly identical to RSV pumps except for the mounting orientation and flow configurations. In their comments to the August 2021 ECS RFI, Grundfos recommended that DOE consider new categories for products similar to RSV and RSH with connections that are not in line. (Grundfos, Docket EERE–2021–BT–STD–0018, No. 9 at p. 2) As discussed in section III.A.3.c, RSH pumps may have different flow configurations that are expected to impact pump efficiency; therefore, DOE is proposing three definitions for RSH pumps based on the existing DOE definition for pumps: One for an overarching category of RSH pumps, which does not characterize flow; one for in-line RHS pumps; and one for end-suction RSH pumps. The three definitions would be modified to read as follows:

Radially-split, multi-stage, horizontal, diffuser casing (RSH) pump means a horizontal, multi-stage, dry rotor, rotodynamic pump:

(1) That has a shaft input power greater than or equal to 1 hp and less than or equal to 200 hp at BEP and full impeller diameter and at the number of stages required for testing; and

(2) In which liquid is discharged in a plane perpendicular to the impeller shaft; and

(3) For which each stage (or bowl) consists of an impeller and diffuser; and

(4) For which no external part of such a pump is designed to be submerged in the pumped liquid.

Radially-split, multi-stage, horizontal, in-line diffuser casing (''RSHIL'') pump means a single-axis flow RSH pump in which the liquid enters the pump in a plane perpendicular to the impeller shaft.

Radially-split, multi-stage, horizontal, end-suction diffuser casing (''RSHES'') pump means a RSH pump in which the liquid enters the bare pump in a direction parallel to the impeller shaft and on the side opposite of the bare pump's driver-end.

Issue 19: DOE requests comment on the proposed definitions for RSH, RSHIL, and RSHES pumps—particularly whether they are sufficient to identify the intended scope of such pumps as discussed in section III.A.3.c of this document.

8. Close-Coupled and Mechanically-Coupled Pumps

As discussed in section III.A.3.d, DOE defines a close-coupled pump as a pump having a motor shaft that also acts as the impeller shaft, and defines a mechanically-coupled pump as a pump that has its own impeller shaft and bearings separate from the motor shaft. DOE has tentatively determined that these definitions leave a gap in the end-suction pump category and is proposing to modify the definitions to eliminate that gap.

In the April 2021 RFI, DOE requested comment on the definitions of ''close-coupled pump'' and ''mechanically-coupled pump'' and whether the terms should be revised. 86 FR 20075, 20078.

Summit stated that it has no concerns with the current definitions for ESCC and ESFM and that they are definitive enough. (Summit, No. 16 at p. 3) Summit's comments also addressed energy conservation standards topics, which DOE will address in the pumps standards rulemaking. HI suggested the following change to the definitions: (1) A close-coupled pump, for the purposes of this regulation, is defined as a pump in which the driver's bearings absorb the pump axial load; and (2) A mechanically-coupled pump, for the purposes of this regulation, is defined as a pump in which bearings external to the driver absorb the pump axial load. (HI, No. 20 at p. 3) Grundfos agreed with HI's recommendation to modify the definitions for close-coupled pump and mechanically-coupled pump and emphasized that products that do not have bearings and have an impeller that is not on the motor shaft should be covered by these definitions. (Grundfos, No. 17 at p. 2) Grundfos additionally stated that the definitions for these products should utilize how the axial loads are handled as a differentiating factor for these terms. *Id.* Grundfos added that DOE's definitions are not necessarily aligned with standard industry definitions, and therefore recommended that DOE preface its definitions with the phrase, ''For the purposes of this regulation, [product] pump means . . .''. *Id.*

DOE acknowledges that a definition that addresses how the axial load is

absorbed may better differentiate close-coupled and mechanically-coupled pumps. DOE notes that regardless of whether its definitions align with industry definitions, the text in the CFR takes precedence over definitions in industry standards that may be incorporated by reference. *See* 10 CFR 431.462. Based on responses received from stakeholders and DOE's review of ESCC and ESFM pumps, DOE has tentatively determined that there is a group of end-suction pumps that do not currently fall within the ESFM or ESCC definitions. To address this issue, DOE proposes revising its definitions for ''close-coupled pump'' and ''mechanically-coupled pump'' as follows:

A close-coupled pump means a pump in which the driver's bearings absorb the pump's axial load.

A mechanically-coupled pump means a pump in which bearings external to the driver absorb the pump's axial load.

In DOE's view, these revised definitions should capture all end-suction pumps whose axial loads are supported with bearings. This change should encompass the previously uncovered end-suction pumps and clarify the definitions sufficiently to avoid future confusion.

Issue 20: DOE requests comment on the proposed definitional changes to ESFM and ESCC pumps in defining both categories based on the location of the bearings which bear the axial load of the pump. Specifically, DOE seeks comment on whether these proposed changes will capture the end-suction pumps identified by stakeholders as not currently meeting the ESCC or ESFM definitions.

9. Tangential Discharge

The definition for IL pump applies to pumps for which the liquid is discharged from the pump in a plane (*i.e.,* direction) perpendicular to the impeller shaft, and for which the entering and exiting flows are along the same axis (*i.e.,* single-axis flow). *See* 10 CFR 431.462. The definition for end-suction pump applies to pumps for which the liquid enters the pump in a direction parallel to the impeller shaft and exits the pump in a plane perpendicular to the shaft. *Id.* DOE also currently defines the term ''single axis flow pump'' as ''a pump in which the liquid inlet of the bare pump is on the same axis as the liquid discharge of the bare pump.'' *Id.* As discussed in the April 2021 RFI, the ''single axis flow pump'' definition does not explicitly state whether the axis is defined by the suction opening to the volute or the suction opening at the perimeter of the pump. 86 FR 20075, 20078. Close-coupled pumps can be designed with a perpendicular discharge volute which is also tangential (*i.e.,* a design in which the suction and discharge openings do not share a common axis). *See* 10 CFR 431.462 (defining ''single axis flow pump'').

In the April 2021 RFI, DOE requested comment on how manufacturers are currently categorizing close-coupled pumps with tangential discharge volutes relative to the five pump categories defined at 10 CFR 431.464 and whether DOE should provide additional detail in the definitions for single-axis flow pump and/or end-suction pump regarding tangential discharge volute configurations. 86 FR 20075, 20078. Summit, Grundfos, and HI all commented that the existing definitions of end-suction pump and IL pump are sufficient. (Summit, No. 16 at p. 3; Grundfos, No. 17, at p. 2; HI, No. 20 at p. 3) Summit additionally stated that it assumes end-suction was relative to suction and parallel to the shaft, and that tangential discharge pumps are included in end-suction type pumps (Summit, No. 16 at p. 3) DOE interpreted this to mean Summit interprets end-suction as suction parallel to the impeller shaft. HI and Grundfos stated that tangential discharge is not a concern for IL pumps and RSV pumps because of the requirement for single axis flow included in the definitions for IL pump and RSV pump. (HI, No. 20 at p. 3; Grundfos, No. 17 at p. 2) HI and Grundfos additionally stated that tangential discharge is not a design characteristic for ST pumps, since this would imply a pump discharge perpendicular to the pump shaft, and that tangential discharge is already covered in both the ESCC pump and ESFM pump definitions. *Id.* Grundfos recommended that DOE specify whether tangential discharge is the location of the discharge outlet or the discharge exit from the volute. *Id.*

After further reviewing the definitions for single axis flow pump, ESCC pump, ESFM pump, IL pump, and RSV pump, and taking into account stakeholder comments, DOE has tentatively determined that the current definitions are sufficient and is not proposing to revise the definitions for end-suction pump or in-line pump at this time.

10. Pump

DOE currently defines a ''pump'' as ''equipment designed to move liquids (which may include entrained gases, free solids, and totally dissolved solids) by physical or mechanical action and includes a bare pump and, if included by the manufacturer at the time of sale, mechanical equipment, driver, and controls.'' 10 CFR 431.462. DOE currently defines ''bare pump'' as ''a pump excluding mechanical equipment, driver, and controls.'' *Id.* As discussed in the April 2021 RFI, some manufacturers distribute kits of unassembled components that customers (including end users or distributors) may purchase and assemble into finished equipment that meets the definition of a pump or a bare pump. 86 FR 20075, 20078 DOE requested comment on the definitions of ''pump'' and its components and whether any of the terms should be amended, and if so, how the terms should be amended. *Id.* In particular, DOE requested comment on whether the terms are sufficient to identify which equipment is subject to the test procedure and whether any test procedure amendments are required to ensure that all such equipment can be appropriately tested in accordance with the test procedure. *Id.*

In response to the April 2021 RFI, Grundfos and HI supported the definition of a pump as written. (Grundfos, No. 17 at p. 1; HI, No. 20 at p. 2) Summit commented that the pump definition could better describe what pump parts are subject to regulation. (Summit, No. 16 at p. 2) Specifically, Summit stated that it interpreted the definition such that if the parts in a kit alone will only be used to make a pump, with no other kits or parts needed, such a kit would be considered a pump. *Id.* Summit stated that determining the end use of a pump kit can be extremely burdensome. *Id.* Summit additionally commented that if a pump does not meet the PEI standard, Summit will no longer distribute its impeller/casing kit; however, Summit does not consider these spare parts to be covered by the DOE regulation. *Id.*

DOE acknowledges that determining the end use of a pump kit, or a pump part can be burdensome. DOE currently interprets the term ''bare pump'' to include any kit that contains all the parts necessary for an operating pump, barring mechanical equipment, driver, and controls. Replacement parts are not the subject of this regulation.

C. Updates to Industry Standards

The current DOE test procedure for pumps incorporates the following industry test standards: HI 40.6–2014, ANSI/HI 1.1–1.2–2014, and ANSI/HI 2.1–2.2–2014. 10 CFR 431.463. The following sections describe updates to these industry standards and discuss what industry standards DOE is proposing to incorporate by reference in

the NOPR and the relevant provisions of those industry standards that DOE is proposing to reference.

1. ANSI/HI 40.6

As discussed in the April 2021 RFI, the DOE test procedure for pumps generally incorporates HI 40.6–2014. 86 FR 20075, 20080. Since publication of the January 2016 Final Rule, the Hydraulics Institute updated HI 40.6–2014 with the publication of HI Standard 40.6–2016, ''Methods for Rotodynamic Pump Efficiency Testing'' (''HI 40.6–2016''). The definitions and procedures in HI 40.6–2016 align with the DOE test procedure for pumps published in the January 2016 Final Rule. HI published another updated version of HI 40.6 in 2021, ''Methods for Rotodynamic Pump Efficiency Testing'' (''HI 40.6–2021''). HI 40.6–2021 includes the following modifications as compared to HI 40.6–2014 (relevant sections of HI 40.6–2021 are included in parentheses after a summary of the modification):

(1) Clarified that the industy testing standard covers efficiency testing of rotodynamic pumps that are subject to DOE's energy conservation standards. (Section 40.6.1 ''Scope'')

(2) Updated the calculation of bare pump efficiency to match the current DOE test procedure requirements for plotting test data to determine the best efficiency point (''BEP'') rate of flow. (Section 40.6.6.3 ''Performance curve'')

(3) Updated the description and requirements of the pressure tap configuration for measurement sections at inlet and outlet of the pump. (Section A.3.1.3 ''Pressure taps'')

(4) Added an informative appendix for determining, applying, and calculating measurement instrument uncertainty. (Appendix H ''Determination, application, and calculation of instrument (systematic) uncertainty (informative)'')

(5) References ANSI/HI 14.1–14.2 ''Rotodynamic Pumps for Nomenclature and Definitions'' (''ANSI/HI 14.1–14.2'') which supersedes ANSI/HI 1.1–1.2–2014 and ANSI/HI 2.1–2.2–2014. (Section 40.6.4.1 ''Vertically suspended pumps''; Section 40.6.4.3 ''All other pump types'')

(6) Includes a new appendix (Appendix E) for the testing of circulator pumps. (Appendix E ''Testing Circulator Pumps'')

DOE noted in the April 2021 RFI that comments in response to the September 2020 Early Assessment RFI suggested that DOE adopt HI 40.6–2021 instead of HI 40.6–2016, with commenters stating that the 2021 version includes clarifying edits, is no more burdensome to conduct, and includes a section for testing circulator pumps. 86 FR 20075, 20080. In the April 2021 RFI, DOE again requested comment on whether it should adopt HI 40.6–2016 or HI 40.6–2021. *Id.* Grundfos, the CA IOUs, HI, and NEEA all supported the adoption of HI 40.6–2021, stating that the 2021 version does not change the measured test values as compared to HI 40.6–2014 as referenced by the DOE test procedure, and that testing according to the 2021 version would not be more burdensome to conduct. (Grundfos, No. 17 at p. 4; CA IOUs, No. 19 at p. 11; HI, No. 20 at p. 2; NEEA, No. 21 at p. 2)

DOE has tentatively determined that with respect to the provisions of HI 40.6–2014, the corresponding provisions of HI 40.6–2021 are substantively the same and adopting such provisions would not change the current test procedure. As such, in order to reference the most current industry test procedure, DOE is proposing to incorporate by reference HI 40.6–2021 in place of HI 40.6–2014.

While DOE proposes to incorporate by reference HI 40.6–2021 as the basis for its proposed test procedure, DOE has tentatively determined that certain sections of the industry testing standard are not applicable to the DOE test procedure. Specifically, Section 40.6.1, Scope, provides the scope specific to the test methods outlined in HI 40.6; Section 40.6.5.3 provides provisions regarding the generation of a test report; appendix ''B'' provides informative guidance on test report formatting; appendix ''E'' provides normative test procedures for circulator pumps; and appendix ''G'' compares HI 40.6 and DOE's nomenclature. None of these sections are required for testing and rating pumps in accordance with DOE's proposed procedure. As such, DOE is not proposing to adopt Section 40.6.1, Section 40.6.5.3, appendix B, appendix E, and appendix G.

Additionally, certain provisions of HI 40.6–2021 are consistent with the additional provisions established by DOE in appendix A. As such, DOE is proposing to maintain those provisions through reference to HI 40.6–2021, specifically:

(1) Section I.D.1 of appendix A, which addresses damping devices, would be amended to reference the corresponding provisions in HI 40.6.3.2.2;

(2) Section I.D.2 of appendix A, which addresses stabilization, would be amended to reference the corresponding provisions in HI 40.6.5.5.1;

(3) Section I.D.3 of appendix A, which addresses calculations and rounding, would be amended to reference the corresponding provisions in HI 40.6.6.1.1;

(4) Sections III.D.1, IV.D.1, V.D.1, VI.D.1, and VII.D.1 of appendix A, which outline testing the BEP of different pump configurations, would be amended to reference the corresponding provisions in HI 40.6.5.5.1.

2. ANSI/HI 1.1–1.2–2014 and ANSI/HI 2.1–2.2–2014

Subpart Y to part 431 currently incorporates by reference ANSI/HI 1.1–1.2–2014 and ANSI/HI 2.1–2.2–2014. DOE references ANSI/HI 1.1–1.2–2014 and ANSI/HI 2.1–2.2–2014 in defining certain terms in 10 CFR 431.462. In 2019, ANSI/HI 1.1–1.2–2014 and ANSI/HI 2.1–2.2–2014 were updated and combined into ANSI/HI 14.1–14.2–2019, ''American National Standard for Rotodynamic Pumps for Nomenclature and Definitions'' (''ANSI/HI 14.1–14.2–2019''). The notable additions to ANSI/HI 14.1–14.2 which were absent in ANSI/HI 1.1–1.2–2014 and ANSI/HI 2.1–2.2–2014 are outlined below:

(1) ANSI/HI 14.1–14.2–2019 includes additonal figures and tables to represent information included in ANSI/HI 1.1–1.2–2014 and ANSI/HI 2.1–2.2–2014;

(2) ANSI/HI 14.1–14.2–2019 adds new pump definitions and pump classifications;

(3) ANSI/HI 14.1–14.2–2019 includes configuration definitions for vertical in-line, vertical end-suction, vertical self-priming, seal-less, magnetic drive, canned motor, and multi-stage pumps;

(4) ANSI/HI 14.1–14.2–2019 adds new definitions for discharge casing, volute,concentric casing, modified concentric casing, vaned diffuser/collector, bowl, and stage casing; and [25]

(5) ANSI/HI 14.1–14.2–2019 includes a new ''preferred operating region'' section to define a guideline for reccomended operating flow rates.

In the April 2021 RFI, DOE requested comment on incorporating ANSI/HI 14.1–14.2–2019 by reference into the DOE test procedure. 86 FR 20075, 20080–20081. Grundfos and HI encouraged DOE to incorporate ANSI/HI 14.1–14.2–2019 (Grundfos, No. 17 at p. 4; HI, No. 20 at p. 2). However, stakeholders did not address whether adoption of ANSI/HI 14.1–14.2–2019 would substantively change currently defined terms and equipment classes.

As stated previously, in general the current DOE test procedure incorporates pump designations from ANSI/HI 1.1–1.2–2014 and ANSI/HI 2.1–2.2–2014 as examples for the definitions of end-suction close-coupled (ESCC); end-

[25] A volute may also be referred to as a ''housing'' or ''casing.''

suction frame mounted/own bearings (ESFM); in-line (IL); radially-split, multi-stage, vertical, in-line diffuser casing (RSV); and submersible turbine (ST) pump categories under the DOE test procedure. 10 CFR 431.462. DOE notes that generally, the references to ANSI/HI 1.1–1.2–2014 and ANSI/HI 2.1–2.2–2014 are in the context of providing non-limiting examples. DOE is concerned that continued inclusion of HI pump designations as examples of specific pump categories may cause confusion in the market or be misunderstood to limit the scope of the relevant definitions. To avoid any such misreading, DOE is proposing to remove the references to ANSI/HI 1.1–1.2–2014 and ANSI/HI 2.1–2.2–2014 as examples of certain pump category definitions. Additional detail on the proposed changes to the definitions is discussed in section III.B.2 of this document.

Additionally, DOE's current test procedure definition of ''bowl diameter'' relies on the ''intermediate bowl'' definition in ANSI/HI 2.1–2.2–2014. DOE is proposing to modify its definition for ''bowl diameter'' and add a DOE definition for ''intermediate bowl'' to remove the current reference to ANSI/HI 2.1–2.2–2014. These proposed changes will create a more self-contained definition. These proposed changes are discussed in section III.B.3 of this document.

D. Metric

The current energy efficiency standards for pumps are based on the PEI metric. 10 CFR 431.465. The PEI metric is a ratio of the pump energy rating (''PER'') of the tested pump to the PER of a minimally-compliant pump (''PER_{STD}''). *See* section II of appendix A. The current test procedure defines the metric $PEI_{CL,}$ the pump energy index for a constant load, as applicable to pumps rated as bare pumps or sold with motors; and the metric PEI_{VL}, the pump energy index for a variable load, as applicable to pumps sold with motors and continuous controls or noncontinuous controls. Appendix A, section II.A. A ''continuous control'' is a control that adjusts the speed of the pump driver continuously over the driver's operating speed range in response to incremental changes in the required pump flow, head, or power output. 10 CFR 431.462. A ''non-continuous control'' is a control that adjusts the speed of a driver to one of a discrete number of non-continuous preset operating speeds and does not respond to incremental reductions in the required pump flow, head, or power output. *Id.*

The PEI metric is a ratio of the pump energy rating (''PER'') of the tested pump to the PER of a minimally-compliant pump (''PER_{STD}''). *See* appendix A. The pump energy rating for constant load pumps (''PER_{CL}''[+]) is calculated as the average of driver power input at 75 percent, 100 percent, and 110 percent of flow at the BEP, where the flows are achieved by varying the operating head to follow the pump performance curve. *See* appendix A, section II.A.1 and subsequently referenced sections. The pump energy rating for variable load pumps (''PER_{VL}''[+]) is calculated as the average of driver power input at 25%, 50%, 75%, 100% of flow at BEP, where the flows are achieved by speed reduction to follow a specified system curve. *See* appendix A, section II.A.2 and subsequently referenced sections. BEP is defined as the pump hydraulic power operating point (consisting of both flow and head conditions) that results in the maximum efficiency. 10 CFR 431.462.

In response to the April 2021 RFI, NEEA stated that DOE's current pump test procedure generally provides a good representation of pump energy consumption and that the current pump metrics are good indicators of relative efficiency. (NEEA, No. 21 at p. 2)

This section discusses the proposed regulatory metric for SVIL pumps and additional clean water pumps that DOE is proposing to incorporate into its test procedure scope. In the May 2021 Circulator Pumps RFI, DOE discussed that the Circulator Pump Working Group recommended evaluating SVIL pumps using the PEI_{CL} or PEI_{VL} metrics, similar to commercial and industrial pumps, and using the commercial and industrial pump test procedure to measure performance, with any additional modifications necessary as determined by DOE. 86 FR 24516, 24527.

In their comments to the May 2021 Circulator Pumps RFI, the CA IOUs reiterated their support for SVILs to be rated using the PEI_{CL} or PEI_{VL} metric, consistent with the Circulator Pump Working Group term sheet. (CA IOUs, EERE–2016–BT–STD–0004, at No. 10 p. 6)

DOE reviewed the PEI_{CL} and PEI_{VL} metrics and has tentatively determined that, in general, use of PER_{CL} and PER_{VL} and indexing the results against PER_{STD} would be a reasonable and consistent way to evaluate SVIL performance. This tentative determination is based largely on the similarities between SVILs and in-line pumps, which are evaluated using the PER_{CL} and PER_{VL} metrics. As such, DOE is proposing that the rating metric for SVIL pumps would be PEI_{CL} for constant load pumps and PEI_{VL} for variable load pumps, equivalent to the metric already in use for currently covered commercial and industrial pumps.

For the additional clean water pump categories that DOE is proposing to include within the scope of the test procedure (*i.e.,* vertical turbine pumps, between-bearing pumps, and radially-split, multi-stage horizontal pumps), DOE has tentatively determined that its proposed test procedure would measure energy efficiency during a representative average use cycle and not be unduly burdensome to conduct. This determination is based on the similarities between the pump categories that are addressed in the current test procedure and those that DOE is proposing to add. Therefore, DOE tentatively determines that PEI_{CL} and PEI_{VL} are appropriate metrics for use these pumps. DOE tentatively determines that using PEI_{CL} and PEI_{VL} for the additional pump categories would ensure a consistent rating approach in the market. Thus, DOE proposes that the PEI_{CL} and PEI_{VL} metric would be used for rating the performance of small vertical in-line pumps, vertical turbine pumps, between-bearing pumps, and radially-split multi-stage horizontal pumps.

E. Proposed Amendments to Test Method

As discussed in section III.C.1, DOE is proposing to utilize HI 40.6–2021 in its test procedure for pumps with certain exceptions. HI 40.6–2021 specifies calculating pump power input,[26] driver power input (for testing-based methods),[27] pump power output,[28] pump efficiency,[29] bowl efficiency,[30] overall efficiency,[31] and other relevant values at

[26] The term ''pump power input'' in HI 40.6–2021 is defined as ''the power transmitted to the pump by its driver'' and is synonymous with the term ''pump shaft input power,'' as used in this document.

[27] The term ''driver power input'' in HI 40.6–2014 is defined as ''the power absorbed by the pump driver'' and is synonymous with the term ''pump input power to the driver,'' as used in this document.

[28] The term ''pump power output'' in HI–40.6 is defined as ''the mechanical power transferred to the liquid as it passes through the pump, also known as pump hydraulic power.'' It is used synonymously with ''pump hydraulic power'' in this document.

[29] The term ''pump efficiency'' is defined in HI 40.6–2014 as a ratio of pump power output to pump power input.

[30] The term ''bowl efficiency'' is defined in HI 40.6–2014 as a ratio of pump power output to bowl assembly power input and is applicable only to VTS and RSV pumps.

[31] The term ''overall efficiency'' is defined in HI 40.6–2014 as a ratio of pump power output to driver power input and describes the combined efficiency of a pump and driver.

the specified load points necessary to determine PEI_{CL} and PEI_{VL}. HI 40.6–2021 also contains specifications regarding test methodology, standard rating conditions, equipment specifications, uncertainty calculations, and tolerances.

Sections II through VII of the DOE test procedure specify methods for determining PEI_{CL} and PEI_{VL} for pumps based on whether they are distributed into commerce with a motor and or with controls and are summarized below:

- *Section II:* Calculation of PEICL or PEIVL for all pumps based on the pump energy rating for a minimally-compliant reference pump (PERCL or PERVL, respectively);
- *Section III:* Test procedure for bare pumps;
- *Section IV:* Testing-based approach for pumps sold with motors;
- *Section V:* Calculation-based approach for pumps sold with motors;
- *Section VI:* Testing-based approach for pumps sold with motors and controls; and
- *Section VII:* Calculation-based approach for pumps sold with motors and controls.

See appendix A, sections I.A.2 through I.A.6.

In response to the April 2021 RFI, NEEA recommended against any modifications to the test procedure that would minimally improve its representation of efficiency but that would require manufacturers to retest and rerate. (NEEA, No. 21 at p. 2) Similarly, HI recommended making only clarifications to the test procedure, except for the addition of a calculation method for power drive system losses for inverter-only motors. (HI, No. 20 at p. 1) The following sections discuss proposed amendments to the test procedure.

1. Nominal Speed

The scope of the current test procedure is limited to pumps designed to operate with either a 2- or 4-pole induction motor or a non-induction motor with a speed of rotation operating range between 2,880 and 4,320 rpm and/or 1,440 and 2,160 rpm. 10 CFR 431.464(a)(1)(ii). Section I.C.1 of appendix A specifies the selection of nominal speed of rotation of either 1,800 or 3,600 rpm depending on the number of poles of the motor or the operating range of non-induction motors.

As discussed in section III.A.4.b, DOE is proposing to include in the scope of the test procedure pumps that operate between 960 and 1,440 rpm or are designed to operate with 6-pole motors. DOE proposes that these pumps would be tested with a nominal speed of 1,200 rpm. DOE is also proposing updates to the calculation and rounding sections of the test procedure to address this additional nominal speed.

Issue 21: DOE requests comment on its proposal that pumps designed to operate between 960 and 1,440 rpm or with 6-pole motors be assigned a nominal speed of 1,200 rpm.

In the April 2021 RFI, DOE requested comment on whether the nominal motor speeds of 1,800 rpm and 3,600 rpm used in the current DOE test procedure appropriately represent the operation and energy use of pumps that are capable of higher speeds. 86 FR 20075, 20083. If these motor speeds are not representative, DOE requested comment on whether a testing-based or calculation-based approach would provide more representative energy use values and the expected cost burden of each. *Id.* Additionally, DOE requested test data at speeds other than the nominal speeds specified in the current test procedure in order to determine if a calculation-based method is appropriate. *Id.*

HI commented that the test procedure has a gap in regard to pumps sold with higher speed motors but asserted that the comment period did not allow enough time to fully develop a recommendation to modify the test procedure. (HI, No. 20 at p. 7). HI stated that they would continue to work on a recommendation and requested that DOE involve stakeholders in the solution.[32] *Id.* Grundfos supported the work of HI in creating a recommendation for how to handle this equipment. (Grundfos, No. 17 at p. 7) Given that many of the motors in this category would be included in the inverter-only motor category for which a new calculation method is being proposed, and that DOE has not identified any data indicating what nominal speed would be more representative of higher design speeds, DOE has tentatively decided not to propose a higher nominal speed for testing.

2. Testing of Multi-Stage Pumps

The current DOE test procedure specifies that RSV pumps shall be tested with three stages and that ST pumps shall be tested with nine stages. If the unit under test is only available with fewer than the required number of stages, the pump is tested with the maximum number of stages with which the unit is distributed in commerce in the United States. If the unit under test is only available with greater than the number of required stages, the pump is tested with the lowest number of stages with which the unit is distributed in commerce in the United States. If the unit under test is available with both fewer and greater than the required number of stages, but not the required number of stages, the pump is tested with the number of stages closest to the required number of stages. If both the next lower and next higher number of stages are equivalently close to the required number of stages, the pump is tested with the next higher number of stages. *See* appendix A, section I.C.2.

RSH and VT pumps are sold with a varying number of stages, in which the same pump may have options for multiple different stages for multiple applications. To reduce testing burden and mirror the practice established for RSV pumps, DOE proposes that RSH pumps be tested with three stages. To reduce testing burden and mirror the practice established for ST pumps, DOE proposes testing VT pumps with nine stages. If units of the basic model of pump being tested are not distributed in commerce with the number of stages prescribed for testing, the existing instructions for selection of the correct number of stages to use during testing would be followed.

As defined in section IIIB.5, BB pumps can have either one or two stages. For BB basic models that are distributed into commerce with both one and two stages, DOE proposes that the pump would be tested at two stages. This proposed approach would maintain consistency with DOE's current test procedure requiring that multi-stage pumps be tested with more than one stage.

Issue 22: DOE requests comment on the proposed number of stages for testing RSH, VT, and BB pumps.

3. Best Fit Curve

In the current DOE test procedure, BEP flow rate is determined as the flow rate at which maximum pump efficiency is achieved on the pump efficiency curve, as determined in accordance with Section 40.6.6.3 of HI 40.6–2014. Appendix A, Sections III.D.2, IV.D.2, V.D.2, VI.D.2, and VII.D.2. Section 40.6.6.3 of HI 40.6–2014 provides instruction for determining the best fit curve for pump flow rate versus efficiency. Specifically, the best fit curve may be either (1) up to a 6th order polynomial, or (2) a spline function with a single slow reversal in the region of the BEP rate of flow. HI 40.6.6.3.

In response to the April 2021 RFI, Summit recommended better defining

[32] DOE notes that HI's supplemental comments responding to the April 2021 RFI did not provide input on this issue. (HI, No. 22)

''best fit curve'' to the speed corrected data, possibly specifying a degree of polynomial required. (Summit, No. 16 at p. 2) Summit also recommended defining a minimum number of data points required per setpoint, or clarifying that a confidence interval—such as 95%—for each setpoint. (Summit, No. 16 at p. 2)

DOE tentatively concludes that the provisions in Section 40.6.6.3 of HI 40.6–2021 are sufficient for defining the best fit curve. When testing a pump, data relating to flow rate and efficiency can be fit using the allowed methods under HI 40.6–2021 in order to find the method with the best fit. DOE notes that, in general, ''best fit'' refers to a curve that best expresses the relationship between the data, and that can be determined through a least squares method. However, DOE does not fully understand Summit's request regarding the minimum number of data points required per setpoint. The test procedure requires taking a minimum of seven flow points and using a least squares regression to determine a linear relationship between pump power input or driver power input at measured flow points, which is then used to determine pump power input or driver power input at the specified load points. *See, e.g.,* appendix A, section III E.1.1. Because the specified load points are determined from the measured flow points, it is not essential for multiple data points to be taken per measured flow point. DOE notes that appendix A section VI.E.2.1 and section VI.E.2.2, which are relevant to the testing-based approach for pumps sold with motors and controls, provide tolerances and correction equations for the load points that must be measured at reduced speed. For these reasons, DOE is not proposing any changes in response to Summit's comment.

4. Load Profile

The current test procedure requires that constant load pump energy rating be determined using 75, 100 and 110 percent of BEP flow with each value multiplied by 0.33 and the results summed to determine PER_{CL}. Appendix A, sections III.E, IV.E, V.E. Similarly, for variable load pumps, energy ratings are determined at 25, 50, 75, and 100 percent of BEP flow with each point weighted by 0.25 and summed to obtain a value for PER_{VL}. Appendix A, sections VI.E, VII.E. In the April 2021 RFI, DOE sought additional comment on the load profile distribution for constant and variable load pumps and the effect of the distribution on PEI value. 86 FR 20075, 20083.

HI stated that the actual load profile of a pump in use is application specific and will vary widely for the applications covered by clean water pumps. HI stated that the current load profiles are sufficient for calculation of the PEI. (HI, No. 20 at p. 7) Grundfos supported keeping the existing load profiles and stated that given the large number of applications in which regulated pumps are used, the current profiles are sufficient to evaluate general pump performance. (Grundfos, No. 17 at p. 7) NEEA stated that they had no additional comment beyond their response to the September 2020 Early Assessment RFI, which DOE summarized in the April 2021 RFI. (NEEA, No. 21 at p. 11)

The existing load profiles provide a consistent method for comparing the performance of different pumps, which, as noted by stakeholders, exhibit a range of load profiles across the wide range of installation environments. At this time, DOE does not have any indication that the current load profiles are not appropriately representative. Therefore, DOE is not proposing changes to the current test procedure's load profiles.

5. Pumps With BEP at Run-Out

To determine a pump's BEP, the DOE test procedure references testing provisions included in HI 40.6–2014 (excluding sections 40.6.5.3, section A.7 and appendix B) at the following seven flow points: 40, 60, 75, 90, 100, 110, and 120 percent of the expected BEP flow rate of the pump at the nominal speed of rotation. Appendix A, section III.D.1. All pumps have a maximum flow rate which is termed ''run out.'' For pumps where the BEP is expected to be within 20 percent of the maximum flow rate of the pump (BEP at run out), section I.D.4 of appendix A provides alternative flow points, with the maximum flow point equal to 100 percent of the expected maximum flow rate so that the pump may safely operate. As discussed in section III.C.1, Sections 40.6.5.5.1 and 40.6.6.3 of HI 40.6–2021 now include provisions related to pumps with BEP at run-out. Section 40.6.5.5.1 provides alternate test points based on the expected BEP rate of flow for pumps with a maximum allowable flow rate as specified by the manufacturer that is less than 120 percent of the BEP flow rate. Section 40.6.6.3 also provides alternate tested load points for the driver input power as a percentage of BEP flow rate for pumps that cannot be safely tested to flows greater than 120 percent of BEP. However, these provisions are based on flow points with respect to expected BEP flow rate rather than expected maximum flow rate.

In the January 2016 Final Rule, DOE responded to a comment from HI that in order to determine the location of BEP, testing must occur at rates of flow greater than 100 percent of expected BEP flow. 81 FR 4086, 4117. DOE stated that its proposal to use flow points only up to 100 percent was with respect to the expected maximum allowable flow rate rather than with respect to expected BEP. *Id.* DOE notes that the existing regulatory text contains an omission in which section I.D.4(1) of appendix A only refers to ''the expected'' while section I.D.4(2) refers to ''the expected maximum flow rate of the pump.'' DOE proposes to include ''expected maximum flow rate of the pump'' in both section I.D.4(1) and I.D.4(2) of appendix A and would not reference Sections 40.6.5.5.1 or 40.6.6.3 of HI 40.6–2021.

Issue 23: DOE requests comment on whether the alternate flow points for pumps with BEP at run-out should be determined with respect to expected maximum flow rate or expected BEP flow rate.

In addition, upon review and in response to previous stakeholder questions, DOE has tentatively determined that the current regulatory text would benefit from additional detail as to how the revised loading points should be applied in the determination of PER_{STD}. DOE proposes to specify that the revised loading points would only be used in application of the α_i coefficient values when determining pump power input, and not when determining specific speed (''Ns'') or the minimally-compliant pump efficiency (''$\eta_{pump,STD}$''), which should always be based on 100% of BEP flow for standardization purposes.

DOE has also identified that the current provisions for pumps with BEP at run-out do not address how to perform motor sizing for bare pumps, which is based on the horsepower equivalent to, or the next highest horsepower greater than, the pump power input to the bare pump at 120 percent of the BEP flow rate of the tested pump. DOE proposes that for pumps with BEP at run-out, motor sizing would be based on 100 percent of the BEP flow rate of the tested pump, as there are no flow rates available higher than that level. However, DOE acknowledges that this proposed change could result in inequitable motor sizing as compared to pumps not subject to these provisions.

Issue 24: DOE requests comment on how manufacturers are currently

performing motor sizing for bare pumps with BEP at run-out, and whether using 100 percent of the BEP flow rate is appropriate.

6. Calibration of Measurement Equipment

HI 40.6–2014 Appendix D, which the current DOE test procedure adopts, specifies the frequency of measurement equipment calibration. Table D.1 of HI 40.6–2014 provides that manufacturer's recommendations on calibration intervals should be followed if they differ from those in Table D.1. However, DOE notes that its test procedure does not explicitly reference Table D.1 of HI 40.6–2021.

In the dedicated-purpose pool pump test procedures included in appendix B and appendix C to 10 part 431 subpart Y (''appendix B'', ''appendix C''), DOE has, for clarity, included the calibration requirements contained in Appendix D of ANSI/HI 40.6–2014, with modification allowing for calibration periods up to 3 times longer than those specified in Table D.1 of ANSI/HI 40.6–2014 if justified by historical calibration data. *See* appendix B, section I.B.2 and appendix C, section I.B.2.

Similar to the approach DOE has followed with appendices B and C, DOE proposes to specifically reference the calibration requirements in Appendix D of HI 40.6–2021 in section I.B of appendix A to improve the overall clarity of its test procedure.

7. Calculations and Rounding

The DOE test procedure includes provisions for calculations and rounding in section I.D.3 of appendix A. Generally, all measured data must be normalized such that it represents performance at nominal speed of rotation in accordance with HI 40.6–2014, and all calculations must be carried out using raw measured values without rounding. *See* appendix A, section I.D.3. PER is rounded to three significant digits and PEI is rounded to the hundredths place. *Id.* Explicit rounding directions are not provided for other parameters. In the April 2021 RFI, DOE requested comment as to whether the test procedure should specify rounding requirements on parameters other than PER and PEI, and if so, what those rounding requirements should be. 86 FR 20075, 20079 and 20083.

HI stated that rounding is not a concern for parameters other than PER and PEI and that DOE does not need to specify rounding requirements for these parameters. (HI, No. 20 at p. 7) Grundfos commented that additional rounding requirements might result in unnecessary data manipulation and would increase manufacturer burden for data reporting. (Grundfos, No. 17 at p. 7)

With respect to the current rounding provisions for PER and PEI, Summit recommended rounding PER to 3 decimal places and rounding PEI to two decimal places. (Summit, No. 16 at p. 5). Summit also stated that the number of significant figures is dependent on measurement devices and measurement uncertainty. *Id.*

In response to Summit's suggestion for PER, DOE notes that three decimal places represent three significant figures for values less than 1. DOE has not identified any reason why three decimal places would be necessary for values greater than one and has tentatively determined that three significant figures is sufficient. DOE also notes that Summit's recommendation for two decimal places for PEI is consistent with the current test procedure's instruction to round to the hundredths place. For these reasons, DOE is not proposing any changes to its current rounding requirements, except for updates to reference the appropriate section of HI 40.6–2021, as discussed in section III.C.1 of this document.

8. Test Procedure Credits

In response to the April 2021 RFI, NEEA recommended that DOE add a credit for self-sensing ''smart'' pumps with continuous controls. NEEA stated that ''smart'' pump technologies use self-sensing technologies to measure power draw and speed to calculate load and then adjust speed to maximize performance and reduce energy consumption required to meet the load, and that the drive is programmed with the specific pump curve with which it is installed. NEEA stated that these features potentially reduce energy consumption by optimizing pump performance compared to traditional control strategies. NEEA commented that the potential performance improvements of such technology is not reflected in the test procedure. NEEA recommended that DOE investigate the potential for energy savings from such controls and develop minimally burdensome ways to incorporate them in the test procedure, such as the Controls Verification Procedure for Variable Refrigerant Flow (''VRF'') Systems or credit for occupancy systems given to certain beverage vending machines (''BVM''). (NEEA, No. 21 at p. 12)

According to DOE research, at this time the technology referenced by NEEA is proprietary, and DOE is unable to conduct sufficient testing on available proprietary technologies in applications to determine achievable energy savings. Furthermore, NEEA has not presented data demonstrating the viability of the asserted potential energy savings. For these reasons, DOE is not proposing a test procedure accommodation for pumps that incorporate self-sensing technologies at this time.

F. Calculation-Based and Testing-Based Options According to Pump Configuration (Table 1)

The DOE test procedure for pumps includes calculation-based and testing-based options that apply based on pump configuration (including style of motor and control) as distributed in commerce. *See* appendix A, Table 1. The calculation-based options rely on a bare pump test, whereas the testing-based options rely on a ''wire-to-water'' test. The calculation-based options may reduce test burden by allowing a manufacturer to test a sample of bare pumps and use that data to rate multiple pump configurations using calculation-based methods. On the other hand, wire-to-water testing may more accurately represent pump, motor, and control performance.

In order to further assess opportunity for reducing burden, DOE requested additional information on how manufacturers are implementing Table 1 of appendix A. Specifically, DOE sought comment on the extent to which pumps sold with multiple motor and control configurations are evaluated multiple times using physical testing-based methods (rather than a calculation-based approach); the extent to which pumps sold with single-phase motors are being rated as bare pumps (using a calculation-based approach); and the extent to which pumps sold with motors (other than inverter-only motors) are having their efficiency being evaluated using a calculation-based approach as opposed to a testing-based approach. 86 FR 20075, 20082. DOE also requested comment on whether any revisions to Table 1 of appendix A could be considered to maintain or improve the information derived from the test procedure while reducing burden with no impact on the PEI rating for currently regulated pumps. *Id.*

HI stated that testing burdens typically cause manufacturers to calculate losses based on the standard motor efficiency and that approximately 1 percent of pumps are wire-to-water tested according to section IV of the test procedure. HI stated that no products were reported with wire-to-water testing on induction motors with controls per section VI of the test procedure. (HI, No. 20 at p. 5) HI stated that a majority of pumps with single-phase motors use the

bare pump PEI_{CL} value; however, there are a small number of these products that were wire-to-water tested. *Id.* Grundfos stated that it utilized calculated methods wherever it was allowed, given what Grundfos characterized as the overly burdensome testing required to qualify the most efficient products running inverter-only motors. Grundfos stated that it conducted no testing using Section IV or Section VI for any product using an induction motor and reported all single-phase equipment using Section III. (Grundfos, No. 17 at p. 5) Summit stated that it filed its certification reports using only Section III, as they saw only minimal PEI improvement with section V, and using section IV for ESCC pumps would be burdensome. (Summit, No. 16 at p. 5)

NEEA encouraged DOE to ensure the information derived from the test procedure is maintained when considering possible changes to Table 1 to reduce burden. Specifically, NEEA recommended against DOE removing options for wire-to-water testing as a way to reduce burden and asserted that wire-to-water testing may result in more accurate ratings. NEEA also recommended that DOE not require wire-to-water testing but keep the option to use calculation-based or wire-to-water testing approaches. (NEEA, No. 21 at p. 10–11)

HI recommended amending Table I to allow use of section IV for pumps + single-phase induction motor and to require section VI for pumps + single-phase induction motor + continuous or non-continuous controls. (HI, No. 20 at pp. 5–6). HI also recommended amending Table 1 to require section IV for pump + motor + controls other than continuous or non-continuous controls (*e.g.,* ON/OFF switches). (HI, No. 20 at pp. 5–6) Grundfos supported the edits to Table 1 as recommended by HI. (Grundfos, No. 17 at p. 5–6) Grundfos additionally stated that because single-phase motors are not completely regulated (currently only open drip-proof motors are regulated), using section III for pump + motors should remain, and section IV should be optional but not mandatory. Grundfos commented that section VI testing for single-phase product using a variable frequency drive (''VFD'') should be mandatory. (Grundfos, No. 17 at p. 9)

DOE has reviewed the ways in which manufacturers are utilizing the various options in Table 1 as well as the recommended edits to Table 1. In response to NEEA, DOE is not proposing to remove wire-to-water testing options from Table 1. In response to HI and Grundfos, DOE agrees that Table 1 would benefit from providing more explicit instruction, particularly by moving information out of footnotes and into the table itself. However, DOE does not agree with the specific changes requested. Specifically, commenters provided no reason that a ''pump + motor + controls,'' other than continuous or non-continuous controls, must use a test method rather than a calculation method, or why single-phase products using a VFD must use a test method rather than the bare pump calculation method. Neither of these constraints are currently included in appendix A Table 1. DOE maintains that the existing allowances to use a calculation method for these products are appropriate and consistent with stakeholders' general desire to use calculation methods where possible. In particular, controls other than continuous or non-continuous controls—such as ON/OFF switches—would not be expected to impact the results of the test method. As such, the calculation method should adequately represent performance. Similarly, the current procedure permits single-phase equipment to be tested using the bare pump method, which eliminates the possibility of penalizing this equipment for using these less efficient motors compared to pumps sold with polyphase motors. While manufacturers could choose to use a testing-based approach when evaluating pumps sold with single-phase induction motors that use continuous or non-continuous controls in order to get a better rating than a bare pump rating, this is not necessary. For these reasons, DOE is not proposing to remove the calculation-based option, but is proposing to clarify Table 1 by moving information out of footnotes and into the table itself.

NEEA encouraged DOE to consider developing a calculation-based testing approach that would apply to any new or future pump configurations not covered by the current Table 1. NEEA recommended that DOE consider a hybrid approach to testing and calculation, similar to the test method included in Appendix H of ANSI/AMCA Standard 214–21, ''Test Procedure for Calculating Fan Energy Index (FEI) for Commercial and Industrial Fans and Blowers'' (''AMCA 214''), which stipulates a one-time test of the motor at multiple load points, which can be used to determine the input power at the appropriate pump test procedure load points and then used to calculate a rating. With this method, each motor need only be tested once, and the results used for multiple pump configurations. (NEEA, No. 21 at p. 10)

The hybrid method as suggested by NEEA would require use of a test procedure that may be dependent on the type of motor. As such, DOE would be unable to implement such a method for unknown future pump configurations without specifying all possible test methods that might be appropriate for various motor types. Accordingly, DOE is declining to adopt this suggested approach. DOE addresses a similar request related to a specific motor type in section III.F.3 of this document.

Issue 25: DOE requests comment on whether manufacturers would use a hybrid mapping approach, and if so, whether manufacturers would conduct the motor tests or request the tests from their suppliers. In addition, DOE requests comment on what additional provisions would need to be added to Appendix H of AMCA 214 to make it applicable to pumps, such as speed and load corresponding to pump rating points.

In relation to Table 1, Grundfos asked DOE to clarify how manufacturers are expected to report pumps using single-phase motors. Grundfos commented that these are sold as a pump + motor but reported using section III data, and that it was unclear whether they should be reported as a bare pump. (Grundfos, No. 17 at p. 5)

Under the current scope, actual pump configuration should be certified for pumps sold with single-phase motors. These pumps should not be certified as a bare pump.

1. Calculation Method for Pumps Sold With Induction Motors and Controls

In the April 2021 RFI, DOE noted that while its test procedure for pumps incorporates by reference HI 40.6–2014, it also includes additional provisions related to measuring the hydraulic power, shaft power, and electric input power of pumps, inclusive of electric motors and any continuous or non-continuous controls. 86 FR 20075, 20081. DOE also noted the publication of the International Electrotechnical Commission (''IEC'') standard IEC 61800–9–2:2017 ''Adjustable speed electrical power drive systems—Part 9–2: Ecodesign for power drive systems, motor starters, power electronics and their driven applications—Energy efficiency indicators for power drive systems and motor starters,'' (''IEC 61800–9–2:2017''), which addresses test methods and reference losses for power drive systems, comparable to the approach in section VII of appendix A. *Id.* DOE noted that the majority of commenters responding to the

September 2020 Early Assessment RFI urged DOE to maintain the current test approach in section VII of appendix A and that substituting IEC 61800–9–2 would add burden without achieving additional energy savings. *Id.*

DOE also noted the publication of the American Movement and Control Association (''AMCA'') standard, AMCA 207–17 ''Fan System Efficiency and Fan System Input Power Calculation'' (''AMCA 207–17'') in the April 2021 RFI and requested comment on the applicability of the VFD/motor efficiencies in AMCA 207–17 to pumps, and whether DOE should consider replacing the calculations in section VII of appendix A with those in AMCA 207–17. 86 FR 20075, 20081. DOE additionally requested comment on whether adoption of the AMCA 207–17 approach would be representative for pumps, and whether such a change would impact PEI ratings, manufacturer testing burden, or manufacturer pump designs. *Id.* Finally, DOE requested comment on whether it should consider incorporating any aspect of ISO/ASME 14414 ''Pumps System Energy Assessment'' (''ISO ASME 14414'') into its test procedure for pumps, and if so, which aspects and why. *Id.*

As stated previously, the DOE test procedure for pumps includes calculation-based and testing-based options that apply based on pump configuration (including style of motor and control) as distributed in commerce. *See* appendix A, Table 1. The calculation-based options rely on a bare pump test, whereas the testing-based options rely on a wire-to-water test. Section VII of appendix A provides the calculation-based testing method for pumps sold with motors and continuous controls—specifically polyphase motors covered by DOE's electric motor energy conservation standards or submersible motors. Section VII includes four separate algorithms for determining part-load losses of the motor and continuous controls together. These algorithms account for part-load losses of the motor as well as additional losses that result from continuous control inefficiencies and from increased inefficiencies in the speed-controlled motor due to harmonic distortion as a function of motor horsepower.

HI stated that the current calculation methodology should remain consistent, but that HI would provide recommendations for updates to coefficients that would not increase testing burden on pump manufacturers. (HI, No. 20 at p. 4) HI additionally commented that ISO/ASME 14414 is a pump system assessment standard and is not applicable to individual bare pumps or pumps sold with motors and/or controls. (HI, No. 20 at p. 5) Grundfos stated that there is no need to modify or replace the Section VII calculation method. Grundfos supported the HI recommendation to use updated coefficients in section VII for induction equipment. (Grundfos, No. 17 at p. 4)

NEEA recommended that DOE continue using the current motor loss calculation approach, including the motor and drive loss equation and required test points for pump manufacturers. NEEA stated that the AMCA 207–17 approach would result in an average 3 to 6 percent reduction in calculated motor and drive losses, and also PEI_{VL}, in comparison to the current DOE pumps test procedure. NEEA also commented that, while the AMCA 207–17 approach could be considered more representative of typical losses in comparison to test data, AMCA 207–17 was developed specifically for fans. NEEA added that IEC 61800–9–2 results in a similar change in motor and drive losses and appears to be achieving wider adoption in the industry. NEEA suggested that if DOE were to consider updating the motor and drive losses in the test procedure, NEEA would support aligning with IEC 61800–9–2 (and the embedded standard IEC 60034–2, ''Rotating electrical machines—part 2–3: Specific test methods for determining losses and efficiency of converter-fed AC motors''). NEEA stated that updating the loss calculations to reference AMCA 207–2017 or IEC 61800–9–2 would require manufacturers to re-rate pumps for a difference in PEI_{VL} of only about 0.01. Instead, NEEA recommended that if DOE elects to pursue updates to the losses, DOE should do so by updating the coefficients or the calculations and make no changes to pump, motor, or drive testing. NEEA stated that it is important that the calculation-based approach result in conservative ratings so that manufacturers are not disincentivized from testing equipment, which provides a more accurate result, and are not able to overstate product performance based on the calculation-based approach. (NEEA, No. 21 at pp. 7–8)

The CA IOUs stated that cost of wire-to-water testing can result in the use of the calculation method for some efficient products, even though the calculated PEI would be reduced via this method, creating a market distortion in which efficient products are scored with PEIs worse than would be representative. The CA IOUs commented that this highlights the need for a calculation method to be as representative as possible, while requiring some conservativeness in the calculation methodology to prevent scores higher than wire-to-water testing of conventional products. The CA IOUs stated that the actual motor drive system performance is approximately 3 to 14 percent better in practice than estimated with the current methodology and encouraged DOE to make adjustments to the calculation method to improve the representativeness and align across industries. (CA IOUs, No. 19 at p. 2)

The CA IOUs expressed support for the use of AMCA 207–17, stating that it was designed for predictions based solely on variable-torque curves, which apply to pumps, that it provides accurate and somewhat conservative default losses, and that it has been directly or indirectly adopted by various industry consensus standards. The CA IOUs stated that the adoption of the AMCA 207–17 method would result in manufacturers reporting lower PEIs without actually improving the efficiency of the pump, but that they believe it is more important that DOE adopt a loss calculation method that is representative and can be used across all product lines that employ VFD power drive systems. The CA IOUs included a figure comparing the percent PER improvement with AMCA 207 losses compared to DOE losses, with PER improvements ranging between 6 and 14 percent. (CA IOUs, No. 19 at pp. 2–4)

The CA IOUs also commented that industry stakeholders highlighted IEC 61800–9–2 as a potential framework that could apply motor VFD losses in an industry and product independent manner, and stated that they provided a spreadsheet comparing this method, the AMCA 207 method, and the existing DOE methods.[33] The CA IOUs also stated that IEC 61800–9–2 provides high reference VFD losses that they expect to be dealt with in the International Energy Agency Round Robin of Converter Losses, Phase 2.[34] (CA IOUs, No. 19 at pp. 4–7).

In a subsequent submission, HI stated that the current coefficients for induction motors provide incremental losses well below the values in IEC 60034–31, and that the percent of incremental losses were up to 4 times more than what IEC provides (primarily above 50 hp). HI stated that it developed recommended coefficients using the delta between the IEC and current motor incremental losses, and that the

[33] The docketed spreadsheet only includes a comparison of the DOE method and the AMCA 207 method. (CA IOUs, No. 19, attachment).

[34] For information on the International Energy Agency Round Robin of Converter Losses, see: *www.iea-4e.org/emsa/news/global-round-robin-test-program-for-converter-losses/*.

modified coefficients provide more accurate, but still conservative, PEI values for induction products. HI also recommended a separate set of coefficients for the 50 to 100 hp range in order to provide more accurate losses. (HI, No. 22 at p. 3)

HI also provided a table showing the delta PEI as a function of horsepower with the proposed induction motor loss coefficients as well as a limited data set of Section VI wire-to-water testing results compared to the proposed Section VII induction motor loss calculations. For three tested pumps, the calculation method was equivalent to or more conservative than the wire-to-water test results. (HI, No. 22 at p. 4)

Since ISO/ASME 14414 is a pump system assessment standard and is not applicable to individual bare pumps or pumps sold with motors and/or controls, DOE has tentatively determined that this industry standard is not relevant to the DOE test procedure for pumps. DOE has reviewed the industry standards mentioned by NEEA, the CA IOUs, and HI, including AMCA 207–17, IEC 61800–9–2:2017, IEC 60034–2–3:2020 and IEC 60034–31:2021 (''Rotating Electrical Machines—Part 31: Selection of Energy-Efficient Motors Including Variable Speed Applications—Application Guidelines''). IEC 60034–2–3 is a method of test and does not provide information related to motor and control part-load losses, and as such DOE did not evaluate this method further. AMCA 207–17 is specific to fans and includes a more complicated model with more than three coefficients, resulting in efficiency rather than losses. IEC 60034–31:2021 is a technical specification document that gives technical and economical guidelines for the use of energy-efficient motors in constant speed and variable-speed operations in different applications. Annex A (informative) to this standard further provides typical efficiency values and losses of motors and controls. IEC 61800–9–2:2017 is an international standard and provides test methods and efficiency classification provisions for controls and for motors and controls. Annex A (normative) to this standard further provides losses for reference motors and controls used to develop the efficiency classifications.

DOE has also reviewed the coefficients provided by HI, which HI stated were designed to provide incremental motor losses similar to the values in IEC 60034–31 when comparing an induction motor operated without controls and with controls. (HI, No. 22 at p. 3) Based on a subsequent submission, DOE understands that the intent of HI's recommended coefficients is to better match the full-load losses that would result from starting with motor-only full-load losses and adding incremental harmonic losses of 15 percent for motors up to 90 kW and adding incremental harmonic losses of 25 percent for motors over 90 kW, as specified in section A.3 of IEC 60034–31, as well as adding an assumed VFD efficiency penalty [35] of 2 percent. (HI, No. 23 at p. 1)

Figures III–1 through III–3 [36] show example plots for a 1 hp, 10 hp, and 25 hp power drive system (*i.e.,* motor and controls), with the efficiency plotted as a function of motor load for the existing DOE loss model, HI's suggested loss model, AMCA 207, IEC 61800–9–2 (Annex A), and IEC 60034–31 (Annex A).[37] In addition, DOE has included AHRI Standard 1210, ''Standard for Performance Rating of Variable Frequency Drives,'' (''AHRI 1210'') certified data from 2016, 2020, and 2021 for specific power drive systems to provide a point of comparison, noting that this is a different test method and may not be directly comparable to the other standards. DOE has developed these plots for other horsepower drive systems, although the AHRI 1210 data do not go above 75 hp.[38]

DOE notes that on February 28, 2022, the National Electric Manufacturers Association (''NEMA'') released NEMA MG 1011–2022, ''Power Index Calculation Procedure—Standard Rating Methodology for Power Drive Systems and Complete Drive Modules.'' While this NEMA methodology does not addresses the default losses that are core to DOE's pumps test procedure method, and, accordingly, would not be considered within the context of the current rulemaking at hand, data based on MG 1011–2022's methodology could prove useful in supplementing already-collected data regarding part-load losses. To the extent that information and data using MG 1011–2022 are available, DOE invites interested parties to provide feedback and comment regarding their respective experience with this NEMA testing standard.[39]

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[35] Decrease in efficiency, in percentage points due to the addition of a VFD.

[36] Color versions of Figures 1–3 are available at Docket No. EERE–2020–BT–TP–0032–0025.

[37] In the IEC standards, the losses are a function of torque and speed, not load. Load equals torque times speed; as such there are multiple results at the same load depending on the torque/speed point, and the average of those results is plotted.

[38] Color versions of Figures III.1–III.3 are available at Docket No. EERE–2020–BT–TP–0032–0025.

[39] NEMA MG 1011–2022 defines a rating system for power drive systems that is similar to PEI, although it is exclusive of the driven load (*i.e.,* pump, fan, compressor). The direct measurement approach in the NEMA testing method relies on testing in accordance with Section 7.7.1 or 7.7.2 of IEC 61800–9–2; the testing standard also offers a calculation-based approach which includes default losses for a premium efficiency motor, but not default losses for a combined power drive system, as are needed for DOE's test procedure for pumps. However, DOE recognizes the possibility that industry use of this testing standard could encourage the collection of part-load performance data, including part-load losses, for power drive systems applied in pumping applications. These data could be used in the future to supplement the AHRI 1210-certified data displayed in Figures III.1–III.3 and help DOE better tailor potential energy conservation standards for the pumps addressed by the current test procedure rulemaking.

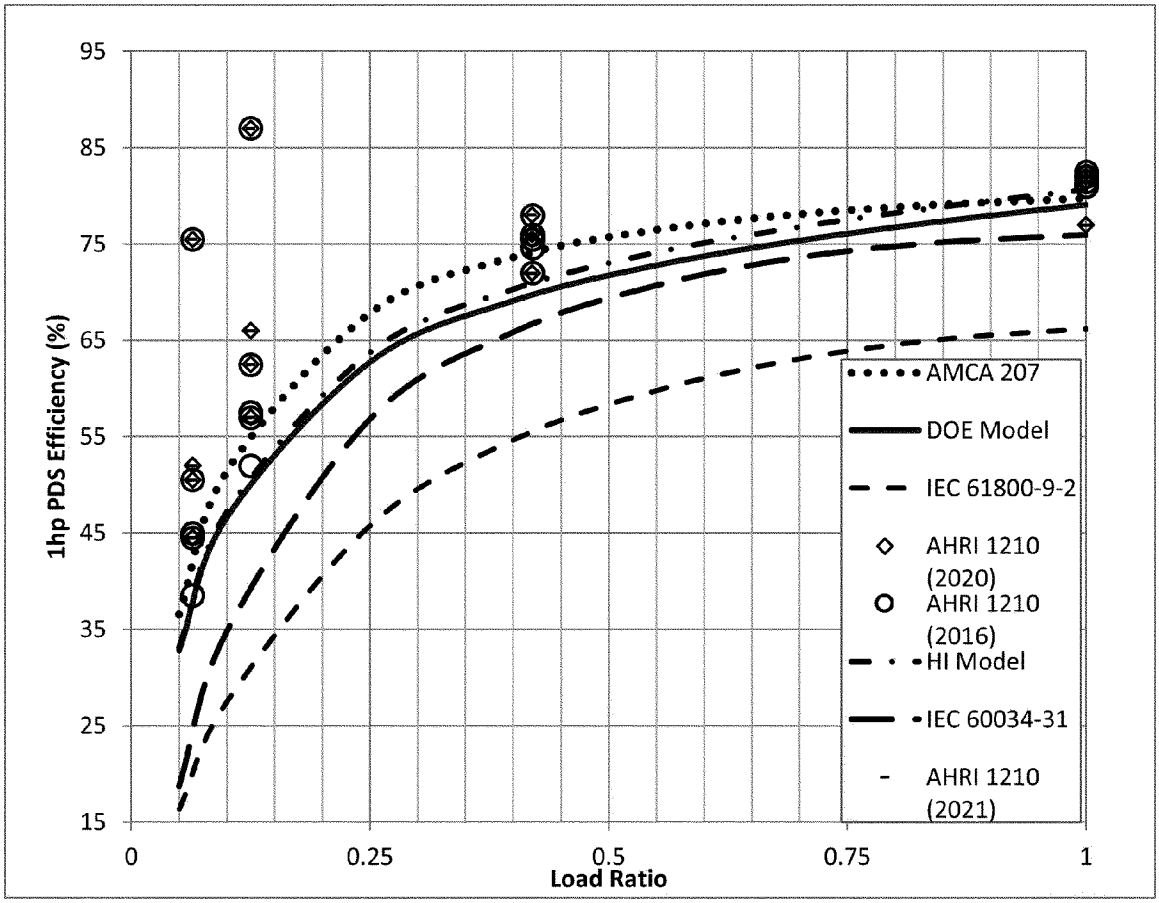

Figure III-1: Efficiency plotted as a function of load ratio for a 1 hp drive system. Comparison of DOE's loss model, HI's proposed loss model, AMCA 207 losses, IEC 61800-9-2 (Annex A), and IEC 60034-31 (Annex A), in addition to AHRI 1210 data from 2016, 2020, and 2021.

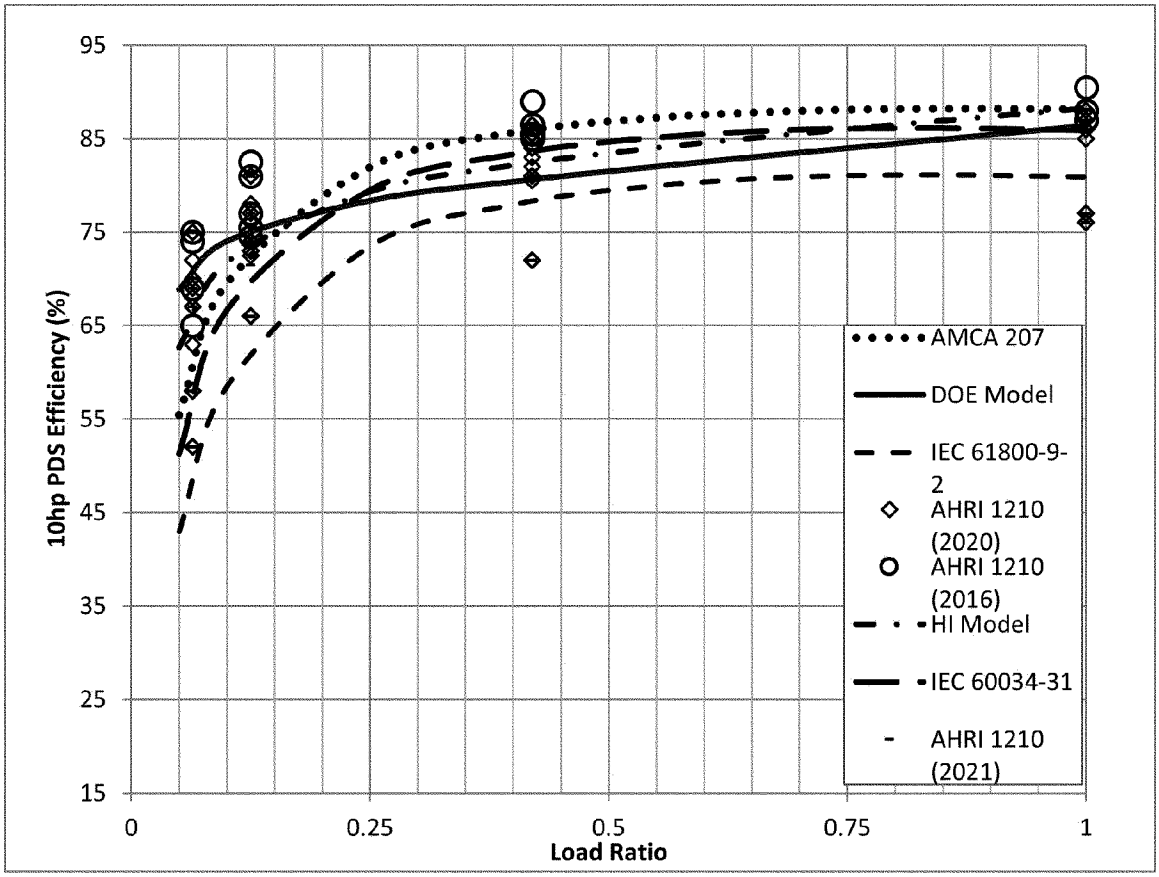

Figure III-2: Efficiency plotted as a function of load ratio for a 10 hp drive system. Comparison of DOE's loss model, HI's proposed loss model, AMCA 207 losses, IEC 61800-9-2 (Annex A), and IEC 60034-31 (Annex A), in addition to AHRI 1210 data from 2016, 2020, and 2021.

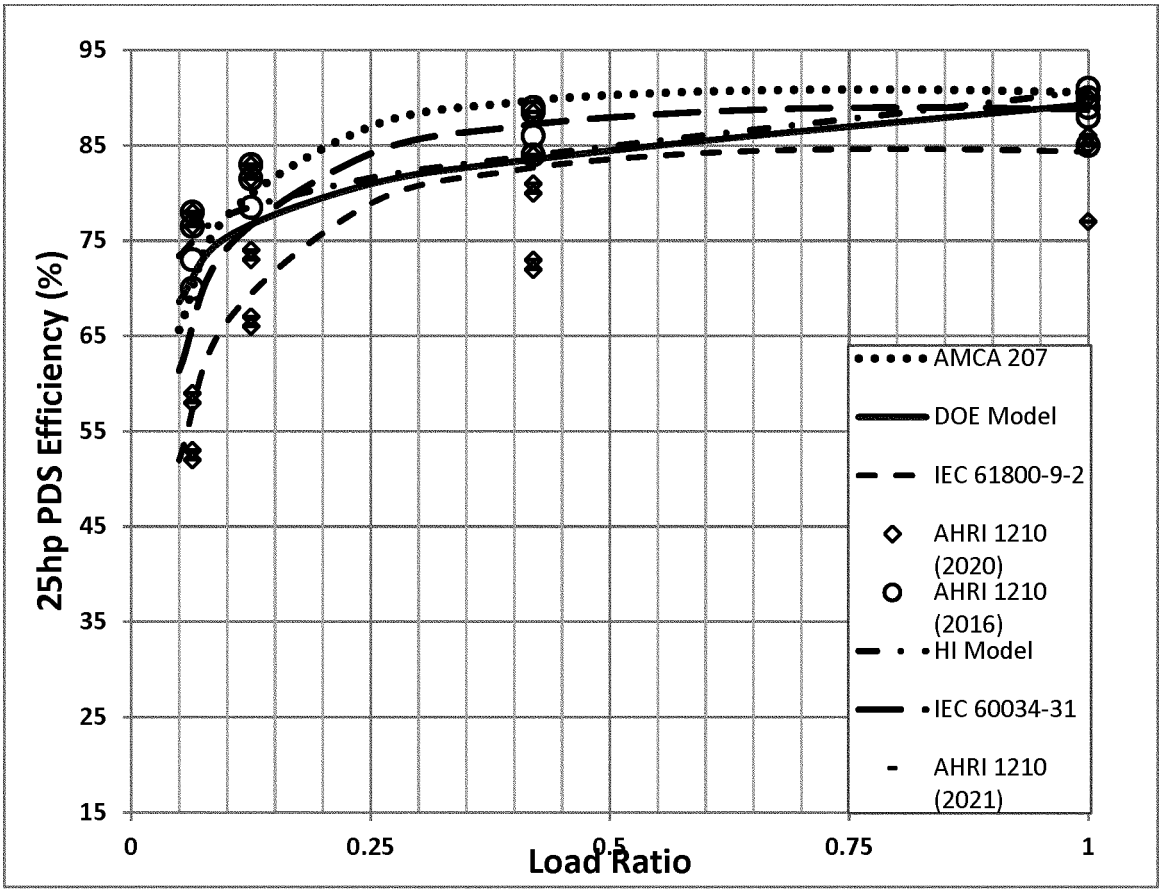

Figure III-3: Efficiency plotted as a function of load ratio for a 25 hp drive system. Comparison of DOE's loss model, HI's proposed loss model, AMCA 207 losses, IEC 61800-9-2 (Annex A), and IEC 60034-31 (Annex A), in addition to AHRI 1210 data from 2016, 2020 and 2021.

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DOE's current test procedure provides a calculation method for pumps sold with motors and controls in order to reduce testing burden compared to wire-to-water testing. However, DOE did not intend for the calculation method to be used for overrating pumps. None of the commenters provided justification for their statements that actual motor drive system performance is better than that assumed by the DOE coefficients. At 1 hp, the DOE model seems to appropriately capture motor drive system performance of the systems represented by the AHRI 1210 data (*i.e.,* none of the systems represented would likely be overrated using this model). However, while DOE based its model using results relying on AHRI 1210–2011 testing to establish the maximum values of the ratio of VFD and motor losses to the motor full-load losses,[40] current AHRI 1210 data for 10 hp to 50 hp motors show that the current DOE model may be overstating motor drive system performance across all loads. The curves for AMCA 207, IEC 60034–31, and HI's proposed coefficients result in better motor drive system performance compared to the DOE model at higher motor loads (with the exception of IEC 60034–31 at 1 hp). However, some curves result in worse motor drive system performance at lower motor loads compared to the DOE model since the DOE model tends to be flatter than the other curves, particularly in the 10–25 hp range. The relative efficiency difference between the DOE model and the suggested model with the highest efficiency (*i.e.,* the AMCA 207 curve) across the majority of the curve is 4 percent, averaged across all horsepower sizes and loads.

DOE notes that the motor load points do not necessarily correspond to the pump test points in appendix A; if motors were sized such that 100 percent BEP flow represented 100 percent motor load, the points would be relatively close. However, the current test procedure for bare pumps assumes that motor sizing is based on 120 percent BEP flow, which DOE understands to be more representative of typical use. Furthermore, a recent DOE motor study shows that only three percent of commercial sector motor system electricity consumption and six percent of industrial motor system electricity consumption operate below 40 percent load factor.[41] For these reasons, DOE expects that typical motor load points for pumps would tend to be higher than those tested according to AHRI 1210, and the higher load points represent a larger contribution to the average measured power under the test procedure. As such, DOE has tentatively determined that it is more important for the selected model to accurately capture performance at higher loads. Nevertheless, the best model that would be representative across all loads without overrating efficiency depends

[40] 80 FR 17586, 17621 (April 1, 2015)

[41] Prakash Rao et al., ''U.S. Industrial and Commercial Motor System Market Assessment Report Volume 1: Characteristics of the Installed Base,'' Prepared for the U.S. Department of Energy, January 12, 2021, *https://doi.org/10.2172/1760267.* (p. 173)

on the performance of the motor drive systems associated with the pumps being evaluated. DOE does not have these specific data.

DOE notes that AMCA 207 is specific to fans. IEC 60034–31 is based on ''typical'' values, which would be expected to overstate the performance of at least some motor drive systems. Section 7.7 of that testing standard states that Annex A may not be a good approximation of loads less than 50 percent, which DOE notes may be a significant portion of loads based on the pumps test procedure. Finally, HI's proposed induction coefficients are based on typical harmonic losses and typical VFD efficiency penalties. DOE believes that, at a minimum, the VFD efficiency penalty may be understated and it is also not clear if the typical harmonic losses associated with IE3 [42] motors are applicable to the U.S. market. Furthermore, HI's proposed inverter-only coefficients, discussed in section III.F.2, result in a lower PEI than a tested PEI in at least one instance (*i.e.* slightly overstate motor drive system performance), and given that those coefficients were based on HI's proposed induction coefficients and an assumed incremental efficiency improvement between induction and inverter-only motors, DOE expects that HI's proposed induction coefficients may also overstate motor drive system performance. As seen in Figure III–1, IEC 61800–9–2 represents coefficients least likely to overstate motor drive system performance; however, DOE understands that these coefficients are undergoing IEC review.

Based on its review of available coefficients and part-load loss data, DOE has tentatively determined that without further data indicating that its current coefficients overstate motor drive system losses for pumps, it will retain its current loss model for motors less than 50 hp. DOE's current coefficients correspond to about 30 percent added harmonic losses and a 3 percent VFD efficiency penalty. DOE would consider revising its coefficients below 50 hp in accordance with the method suggested by HI, or to harmonize with fans (AMCA 207) or with international standards (IEC 60034–31 or IEC 61800–9–2), given appropriate data specific to pumps. To ensure that the calculation method does not overrate pumps while balancing stakeholders' requests for representativeness, DOE is proposing to allow use of an AEDM, as discussed in section III.I.2 of this document.

Issue 26: DOE requests: (1) Data indicating whether AHRI 1210-certified data is applicable to pumps as well as any other applicable part-load loss data; (2) data indicating whether 15 percent and 25 percent incremental losses, which are specified as part of IE3 ratings that are not commonly used in the U.S., are applicable to the U.S. and do not overstate performance, and if not, what incremental losses would be appropriate to apply, and (3) data indicating an appropriate VFD efficiency penalty by hp.

Given HI's statement that losses are especially overstated in the 50 hp to 100 hp range, DOE has reviewed its existing coefficients and found that they result in a dip in full-load efficiency at 75 hp, which would not be expected. In addition, the AHRI 1210-certified data is limited to a maximum of 75 hp and does not exist at higher hp. Furthermore, DOE's current coefficients in the 50 hp to 100 hp range correspond to about 60 percent added harmonic losses and a 3 percent VFD penalty, and, based on previous discussion of typical losses, DOE has tentatively determined that these losses are too high.

In light of this situation, DOE proposes to update its coefficients for motors rated at 50 hp and above. DOE has determined that HI's approach is relatively reasonable, although the 2 percent VFD penalty may be too low. To adjust its coefficients for motors 50 hp and above, DOE started with the current DOE default losses for the motor-only at full-load and added 15 to 25 percent losses, as applicable, as well as a VFD efficiency penalty of 3 percent. DOE then adjusted the current DOE default losses for the motor and control at 100 percent to match the result of adding the incremental harmonic losses and VFD penalty and applied the same adjustment factor to all load points. Table III.1 includes DOE's proposal for the induction motor and control part-load loss coefficients.

Table III.1 Proposed Induction Motor and Control Part Load Loss Factor Equation Coefficients

Motor Horsepower (hp)	Coefficients for Induction Motor and Control part Load Loss Factor (z_i)		
	a	b	c
≤ 5	-0.4658	1.4965	0.5303
> 5 and ≤ 20	-1.3198	2.9551	0.1052
> 20 and ≤ 50	-1.5122	3.0777	0.1847
> 50 and ≤ 100	-0.6629	2.1452	0.1952
> 100	-0.7583	2.4538	0.2233

Issue 27: DOE requests comment on its proposed part-load loss factors for induction motors and controls greater than 50 hp.

2. Calculation Method for Pumps Sold With Inverter-Only Motors (With or Without Controls)

For pumps sold with motors or with motors and continuous or noncontinuous controls that are rated using the calculation-based approach, the nominal full-load motor efficiency used in determining the PER_{CL} or PER_{VL} will be the value that is certified to DOE as the nominal full-load motor efficiency in accordance with the standards and test procedures for electric motors at 10 CFR part 431, subpart B. Use of the certified motor efficiency is available only for motors that are subject to DOE's test procedure for electric motors and only pumps sold with motors subject to DOE's electric motor test procedure and energy conservation standards are able to utilize the calculation-based approach.

Inverter-only motors are currently not subject to DOE's electric motor energy conservation standards, and as such, based on Table 1 in appendix A, pumps with inverter-only motors currently require wire-to-water testing. DOE

[42] ''IE3'' is the IEC designation for premium efficiency motors. IE3, NEMA premium and Energy Independence and Security Act (''EISA'') 2007 standards for electric motors are often considered equivalent efficiency requirements, although the actual values differ depending on pole/hp/enclosure.

requested information and feedback on the categories of motors for which DOE should consider allowing the application of the calculation-based method in the April 2021 RFI. 86 FR 20075, 20082. Specifically, DOE requested information on the categories of inverter-only motors (*e.g.,* electronically commutated motors (''ECMs''), permanent magnet alternative current motors (''PMACs''), or other alternative current (''AC'') induction motors) for which DOE should consider allowing the application of the calculation-based method. *Id.* DOE also sought feedback on the general approach for including default values and equations to represent inverter-only motor performance. *Id.* DOE also requested data and information to support the development of default values for inverter-only motors (similar to the values developed for submersible motors in Table 2 of appendix A) as well as equations that would represent the part-load efficiency or losses of these motors (similar to the equations developed for certain motor and drive combinations in Table 4 of appendix A). *Id.* To the extent DOE should consider a different approach, DOE requested information on the methodology it should consider in addition to supporting data. *Id.* Finally, DOE requested information on the percentage of pumps sold with inverter-only motors without controls (which would be impacted by a change in rating from PEI_{CL} to PEI_{VL}). *Id.*

HI stated that all inverter-only (synchronous) motors should have a calculation method with similar methodology to ST pumps, but with updated full-load motor efficiencies and loss coefficients. (HI, No. 20 at p. 6) Grundfos supported the creation of a calculation method for inverter-only [43] equipment that covers IE4 and IE5 [44] motors and controls. (Grundfos, No. 17 at p. 4) Additionally, Grundfos supported HI's efforts to create a calculation-based method for inverter-only motors with part-load loss coefficients specifically designed for inverter-only products. Grundfos stated that the final proposal should include both IE4 and IE5 calculation-based methods to reduce testing burden. (Grundfos, No. 17 at p. 6)

NEEA commented that inverter-only motors are increasing in popularity because many inverter-only motors are represented as having higher efficiencies than induction motors, especially at reduced speeds, and that the variable-speed capabilities make them a compelling choice in variable load pumping applications. (NEEA, No. 21 at p. 8) NEEA also stated that while ECM motors are particularly common, there is no technical limitation to other inverter-only motor types such as permanent magnet and synchronous reluctance motors being used in clean water applications. (NEEA, No. 21 at p. 8)

NEEA stated that while they supported wire-to-water testing as the most accurate way to rate a pump and motor (and drive), the calculation method of test is a conservative but economical option, and the inability to rely on the calculation method may discourage manufacturers from selling or developing these more efficient pump systems. Therefore, NEEA recommended that DOE include a calculation test method for inverter-only motors. NEEA stated that motor efficiencies consistent with an IE4 efficiency level would be appropriate for pumps. (NEEA, No. 21 at p. 8–9)

The CA IOUs supported calculation approaches for inverter-only motor drive systems, provided that the calculation methodology can reliably generate representative, but slightly conservative motor drive system losses, in order to minimize potential market distortion. (CA IOUs, No. 19 at p. 7) Additionally, the CA IOUs commented that, unlike submersible motors, inverter-only motors are found in numerous industries, sectors, and applications, so the motor losses table must be aligned with other DOE and industry treatments of these motors. (CA IOUs, No. 19 at p. 8) The CA IOUs stated that ECM performance between products and manufacturers is likely similar enough to performance variance typical of conventional induction motors that a loss table could be developed with manufacturer-submitted data. The CA IOUs commented that typical ECM motors will be using surface permanent magnet architectures, while permanent magnet power drive systems will use internal permanent magnet architectures, and that while these differences may eventually result in diverging performance, at the moment a single losses table may be sufficient. The CA IOUs recommended that DOE verify this single losses table assumption. (CA IOUs, No. 19 at p. 8)

The CA IOUs recommended developing a conventional-efficiency branch and a high-efficiency branch of a calculation method, for example by referring to IEC 60034–30–2 and assigning conventional product losses to products with an IE4 motor-drive system rating and efficient product losses to products with an IE5 motor drive system rating. (CA IOUs, No. 19 at p. 8) For permanent magnet inverter-only motors with a non-integrated controller sold with a choice of controller, the CA IOUs cautioned against the use of a losses table due to variance in performance between drive units (as opposed to induction motors, which are relatively uninfluenced by choice of drive unit) and instead recommended this subset use a hybrid power drive system mapping procedure. The CA IOUs stated that this does not apply to ECM products that typically have the drive embedded. (CA IOUs, No. 19 at pp. 8–9) Ultimately, the CA IOUs recommended that DOE consider a hybrid testing approach similar to that detailed in appendix F of AMCA 214, in which a motor drive system is mapped at several test points, with interpolation allowed between test points, which could be applied to any pumps that would be connected to that power drive system. The CA IOUs estimated that this approach would reduce test time compared to a wire-to-water pump test. The CA IOUs suggested that manufacturers could choose to use the calculation method or the hybrid mapping test method. (CA IOUs, No. 19 at pp. 9–10)

In a subsequent submittal responding to the April 2021 RFI, HI stated that it developed coefficients and calculation modifications for inverter-only motors by establishing the incremental loss delta between power drive systems operating with induction motors and power drive systems operating with inverter-only motors.[45] HI commented that it used actual motor data from multiple manufacturers to calculate these coefficients. The coefficients developed by HI would require using either IE4 or IE5 minimum efficiencies (IEC 60034–30–2) in the Section VII calculation for the equipped motor efficiency in appendix A. As suggested by HI, IE3 efficiency would be used to calculate PER_{STD}. (HI, No. 22 at pp. 1–2) HI also provided limited comparisons of the recommended inverter-only calculation method to test data for IE5 products. In five out of six cases, the calculation method resulted in a PEI

[43] Grundfos referenced induction-only motors, which DOE understands to have been intended to be a reference to inverter-only motors.

[44] The International Electrotechnical Commission (''IEC'') standards IEC 60034–30 for variable-speed electric motors establishes an efficiency classification system for these motors. Efficiency classes are designated as IE1, IE2, IE3, IE4, and IE5. IE4 is an approximation of super premium efficiency motors and IE5 is the IEC designation for ultra-premium efficiency motors.

[45] HI provided the incremental loss delta values in a subsequent submission. (HI, No. 23 at p. 1)

equivalent to or higher than the test method.[46] (HI, No. 22 at p. 2)

After reviewing the comments, DOE understands stakeholder references to ''inverter-only motors'' to mean inverter-only electric motors that are synchronous electric motors. DOE's current definition of ''inverter-only motor'' at 10 CFR 431.12 also includes AC induction motors.[47]

In the December 17, 2021, Electric Motors TP NOPR (''Motors TP NOPR''), DOE describes a ''synchronous electric motor'' as an electric motor in which the average speed of the normal operation is exactly proportional to the frequency of power supply to which it is connected, regardless of load. 86 FR 71710, 71726. DOE proposed to include within the scope of its electric motors test procedure synchronous electric motors with specific characteristics, inclusive of synchronous electric motors that are inverter-only electric motors. 86 FR 71710, 71727.

As stated, only pumps sold with motors subject to DOE's electric motor test procedure and energy conservation standards can be used to conduct the calculation-based approach. The current electric motors test procedures and standards apply only to induction electric motors, and the ''induction motor'' criteria exclude synchronous electric motors from scope. 10 CFR 431.25(g)(1). In this NOPR, DOE proposes that, to the extent that DOE adopts a definition, test procedure, and energy conservation standard for synchronous electric motors that are inverter-only electric motors, DOE would reference such regulations in the pumps test procedure, allowing for the use of the calculation method by pumps sold with synchronous electric motors that are inverter-only electric motors.

In the Motors TP NOPR, DOE proposed to test inverter-only synchronous electric motors (inclusive of the inverter) that include an inverter in accordance with Section 7.7.2 of IEC 61800–9–2:2017, using the test provisions specified in section 7.7.3.5 and testing conditions specified in section 7.10. 86 FR 71710, 71742. DOE proposed to test inverter-only synchronous electric motors that do not include an inverter in the same manner and to specify that testing must be performed using an inverter as recommended in the manufacturer's catalogs or offered for sale with the electric motor. *Id.* In response to comments from HI, Grundfos, NEEA, and CA IOUs, rather than referencing IE4 and IE5 motor efficiencies in the proposed calculation method for pumps sold with inverter-only synchronous electric motors, DOE proposes to require use of the nameplate efficiency of the inverter-only synchronous electric motors tested in accordance with any relevant test procedure in subpart B to part 431 if available, or if none available, in accordance with the DOE test procedure, should it be finalized. DOE notes that this nameplate efficiency, as proposed, would be representative of the motor + inverter efficiency rather than just the motor efficiency.

As proposed in the Motors TP NOPR, manufacturers of synchronous electric motors would not be required to test according to the DOE test procedure, if finalized, until the compliance date of energy conservation standards. 86 FR 71710, 71716. Accordingly, should DOE finalize a test procedure for these motors, there may be a period of time in which motor manufacturers would not be required to publish efficiency information for these motors. However, since the proposed electric motors test procedure is an IEC test procedure, if DOE's proposal is finalized, the tested efficiency of the synchronous inverter-only electric motors + inverters would likely already be available.

Issue 28: DOE requests comment on whether inverter-only motors used by pump manufacturers are typically tested in accordance with IEC 61800–9–2:2017.

With respect to HI's proposal to use IE3 efficiency to calculate PER_{STD}, DOE maintains that the appropriate denominator for pumps sold with inverter-only synchronous electric motors is the same as for other pumps sold with motors (with or without controls)—*i.e.,* the efficiency standards for NEMA Design B motors in 10 CFR 431.25 is comparable to the PEI metric when comparing pumps across a common baseline. Consequently, DOE is not proposing a revision to the calculation of PER_{STD} for these pumps.

With respect to part-load losses, while DOE does not have data to evaluate the model quantitatively, DOE has plotted HI's suggested model and preliminarily finds the resulting trends in losses to be reasonable in relation to the expected loss differences between induction and synchronous electric motors. Specifically, the suggested model shows inverter-only motors to be more efficient at part-load when compared to DOE's loss model for induction motors. Further, HI's suggested model shows higher efficiency at full-load compared to DOE's loss model for induction motors—an expected outcome given that induction motor efficiency is set at a NEMA Premium level, whereas inverter-only efficiency is Super Premium.

DOE notes that the HI-provided comparison of wire-to-water test data with results from the calculation method using the recommended coefficients did result in one case in which the calculation method would result in a slightly lower PEI rating than the test method. In addition, HI's proposed coefficients were based on a delta between induction motors and inverter-only motors, and DOE is not proposing to adopt HI's proposed induction motor coefficients. Finally, HI's coefficients were developed to be applicable to motor-only efficiency, while DOE's proposed test procedure for inverter-only motors results in efficiency for the motor + inverter combined. Therefore, DOE proposes to make slight modifications to the inverter-only coefficients proposed by HI. Specifically, DOE started with the revised proposed DOE induction motor and control coefficients, then applied the deltas provided by HI (the difference in efficiency points between a synchronous motor + control versus induction motor + control at different load points and different hp ranges),[48] and then normalized to the motor + control losses (rather than the motor only losses). Table III.2 shows the proposed inverter-only motor and control part-load loss factor coefficients. These coefficients result in slightly higher losses than the HI model across all hp.

[46] While the final column of Table 2 shows that in all six cases, the calculation method resulted in a PEI equivalent to or higher than the tested PEI, in one case the actual delta calculated from columns three and five results in one case where the calculation method results in a lower PEI than the test method.

[47] DOE defines ''inverter-only electric motor'' in 10 CFR 431.12 as an electric motor that is capable of rated operation solely with an inverter, and is not intended for operation when directly connected to polyphase, sinusoidal line power.

[48] HI provided the delta values in a subsequent comment submission. (HI, No. 23 at p. 1)

Table III.2 Proposed Inverter-Only Motor and Control Part Load Loss Factor Equation Coefficients

Motor Horsepower (hp)	Coefficients for Induction Motor and Control part Load Loss Factor (z_i)		
	a	b	c
≤ 5	-0.0898	1.0251	0.0667
> 5 and ≤ 20	-0.1591	1.1683	-0.0085
> 20 and ≤ 50	-0.4071	1.4028	0.0055
> 50 and ≤ 100	-0.3341	1.3377	-0.0023
> 100	-0.0749	1.0864	-0.0096

Issue 29: DOE requests comment on its proposed inverter-only part-load loss coefficients. DOE specifically requests comment on the appropriateness of the delta used to derive these coefficients as well as any other available comparable motor data with which DOE could vet these coefficients.

In response to the suggestion by the CA IOUs that DOE investigate whether a single table of part-load loss factors would be suitable for both ECM and permanent magnet motors, as well as for both conventional-efficiency and high-efficiency motors, DOE has no efficiency data for ECM and permanent magnet motors with which to perform such an analysis at this time. DOE acknowledges that permanent magnet inverter-only motors sold without a controller may perform differently based on the inverter with which it is paired. However, DOE does not expect that the use of a hybrid mapping approach would provide the burden reduction intended by the use of the calculation method. While the hybrid mapping approach would be less burdensome than multiple wire-to-water tests, it would likely be significantly more burdensome than a calculation-based approach based on a bare pump test, as it would require physical tests of all motors with which the bare pump would be paired. Furthermore, DOE tentatively concludes that the calculation-based approach is sufficient to generate appropriately representative values for this equipment—and with the option to allow for a testing-based approach, or an AEDM as discussed in section III.I.2, a manufacturer is free to refine accuracy of the values for specific equipment.

Issue 30: DOE requests comment on the merits of using a hybrid mapping approach for inverter-only motors and whether it would reduce or increase manufacturer burden compared to the current proposals.

In the April 2021 RFI, DOE requested information on the percentage of pumps sold with inverter-only motors without controls (and thus would be impacted by a change in rating from PEI_{CL} to PEI_{VL}). 86 FR 20075, 20082.

HI stated that pumps sold with inverter-only motors without controls constitute a small percentage of the market, but that such pumps should be labeled with a PEI_{VL} since they cannot be operated without the inverter and are variable-speed capable. (HI, No. 20 at p. 7) Grundfos stated that products with inverter-only motors cannot operate without a controller and should not be required to have a PEI_{CL} on the nameplate if sold without a controller. Grundfos suggested that DOE allow a PEI_{VL} on any product sold with an inverter-only motor (whether PM or PM+ controller). Grundfos also stated that the PEI will be valid regardless of the controller used by the end user. (Grundfos, No. 17 at pp. 6–7)

DOE agrees with the positions presented by commenters and proposes that to the extent that the calculation-based method would be applicable to pumps sold with synchronous electric motors that are inverter-only electric motors, such provision would apply to pumps sold with inverter-only synchronous electric motors both with and without controls. DOE also proposes that pumps sold with inverter-only motors with or without controls would apply the testing-based approach in section VI of appendix A (for pumps sold with motors and controls) rather than in section IV of appendix A (for pumps sold with motors), given that section VI results in PEI_{VL}, and DOE assumes that such pumps, even if sold without an inverter, would be tested with an inverter.

Issue 31: DOE requests comment on its proposal to apply PEIVL to pumps sold with inverter-only synchronous motors without controls, including application of the testing method in section VI of appendix A and the calculation method in section VII of appendix A.

3. Pumps Sold With Submersible Motors

For pumps sold with submersible motors, the calculation of PER_{STD}, the test procedure for bare pumps, the calculation-based approach for pumps sold with motors, and the calculation-based approach for pumps sold with motors and controls all include reference to Table 2 of appendix A, which includes default nominal full-load submersible motor efficiency values. These motor efficiency values were developed to allow for pumps sold with submersible motors to be rated using calculation-based methods despite the fact that submersible motors are not included in DOE's current motor regulations. In the Motors TP NOPR, DOE proposed a test procedure for submersible motors based on Section 34.4 of NEMA MG1–2016 with its 2018 Supplements. 86 FR 71725, 71749–71750. DOE notes that it has not established energy conservation standards for submersible motors. Were DOE to establish a test procedure for submersible motors, such motors would not be required to be tested according to the DOE test procedure until such time that compliance with any energy conservation standards that DOE may establish is required.

DOE proposes that for the calculation-based approaches for submersible pumps sold with motors (with or without controls), for determination of PER_{CL} and PER_{VL}, the default efficiency values in Table 2 would be used until compliance with an energy conservation standard for submersible motors is required, should such a standard be established. At such time, calculation of the pump efficiency for submersible pumps would rely on the motor efficiency rating marked on the nameplate and tested in accordance with the relevant DOE test procedure. DOE further proposes that if DOE finalizes a test procedure for submersible pumps, prior to any required compliance with an energy conservation standard that DOE may establish for these pumps, a manufacturer may rely on the motor efficiency represented by the motor manufacturer, if such a representation were made, or the default values in Table 2.

DOE also proposes that when determining PER_{STD} using the calculation-based approach for bare pumps, before the compliance date of

any future standards for submersible electric motors that publishes after January 1, 2021, the default efficiency values in Table 2 would be used. After the compliance date of any standards for submersible electric motors that publishes after January 1, 2021, any standards applicable to submersible motors in appendix B of part 431 would be used.

Issue 32: DOE requests comment on its proposal for the calculation-based approach for pumps sold with submersible pumps to require use of the rated motor efficiency marked on the nameplate that has been tested in accordance with the relevant DOE test procedure after such time as compliance is required with an energy conservation standard for submersible motors, should such a standard be established.

G. Test Procedure for SVIL Pumps

As discussed, DOE is proposing to expand the scope of the test procedure to include SVIL pumps. DOE reviewed the general pumps test procedure in appendix A to determine if any modifications were necessary to accommodate SVIL pumps. The current general pumps test procedure established in appendix A is based on the test methods contained in HI 40.6–2014, with certain modifications. As discussed in section III.C.1, DOE is proposing to update this reference to HI 40.6–2021, which DOE has tentatively determined also applies to SVIL pumps.

As discussed in section III.F, the general pumps test procedure also contains methods to determine the appropriate PEI using either calculation-based methods or testing-based methods. DOE has tentatively determined that these calculation- and testing-based methods are applicable to SVIL pumps just as they are applicable to IL pumps, based on the configuration in which the pump is being sold. Since SVIL pumps are sold as pumps with motors or pumps with motors and controls, the test methods established in the January 2016 Final Rule would apply to SVIL pumps. Additionally, the determination of pump performance in the general pumps test procedure, and as proposed to be updated in this proposed rule, would be appropriate for SVIL pumps.

The primary differences between SVIL and IL pumps affecting the application of DOE's general pumps test procedure are the size and certain characteristics of the motor with which the SVIL pumps are rated. Specifically, the general pumps test procedure establishes that the testing-based methods apply to all pump configurations, while the calculation-based methods apply only to (1) pumps sold without a motor or controls (*i.e.,* a bare pump), (2) pumps sold with motors that are subject to DOE's energy conservation standards for electric motors, as defined pursuant to 10 CFR 431.25(g), (with or without continuous controls), and (3) pumps sold with submersible motors (with or without continuous controls). This distinction exists because the calculation-based test methods presume motor efficiency and motor or motor and drive loss values based on the performance characteristics of motors that are subject to DOE's current electric motor energy conservation standards detailed in 10 CFR 431.25. These standards apply to electric motors, including partial electric motors, that satisfy the following criteria:

1. Are single-speed, induction motors;
2. Are rated for continuous duty (MG 1) operation or for duty type S1 (IEC);
3. Contain a squirrel-cage (MG 1) or cage (IEC) rotor;
4. Operate on polyphase alternating current 60-hertz sinusoidal line power;
5. Are rated 600 volts or less;
6. Have a 2-, 4-, 6-, or 8-pole configuration,
7. Are built in a three-digit or four-digit NEMA frame size (or IEC metric equivalent), including those designs between two consecutive NEMA frame sizes (or IEC metric equivalent), or an enclosed 56 NEMA frame size (or IEC metric equivalent),
8. Produce at least 1 hp (0.746 kW) but not greater than 500 hp (373 kW), and
9. Meet all of the performance requirements of one of the following motor types: A NEMA Design A, B, or C motor or an IEC Design N or H motor.

10 CFR 431.25(g)

DOE notes that SVIL pumps, which this NOPR proposes to define as pumps having shaft input power less than 1 hp, may be paired with motors that are less than 1 hp and, as such, are not subject to DOE's electric motor regulations specified at 10 CFR 431.25. However, some motors with less than 1 hp are subject to DOE's small electric motor regulations specified at 10 CFR 431.446.

The current general pumps test procedure established in the January 2016 Final Rule allows pumps sold with single-phase motors to apply the test procedure for bare pumps. 10 CFR 431.464 and appendix A. DOE specified this approach because the nominal full-load motor efficiency values and part-load motor loss curves developed in the January 2016 Final Rule that describe the minimally-compliant pump (*i.e.,* PER_{STD}) are based on the performance and minimum efficiency requirements for NEMA B polyphase induction motors. 81 FR 4086, 4104. In the January 2016 Final Rule, DOE noted, and interested parties agreed, that such an approach was equitable and appropriate, since the majority of pumps in the scope of that TP rulemaking are sold with polyphase induction motors and, to the extent that pumps within the scope of the proposed test procedure are distributed in commerce with single-phase motors, most of these pumps are offered for sale with either single-phase or polyphase induction motors of similar size, depending on the power requirements of customers. *Id.* However, SVIL pumps are much more commonly sold with single-phase induction motors, and DOE regulations at 10 CFR 431.446 include efficiency standards for single-phase capacitor-start capacitor-run (''CSCR'') and capacitor-start induction-run (''CSIR'') motors.

In the May 2021 Circulator Pumps RFI, DOE requested comment on the recommendation to test SVIL pumps with the test methods from the general pumps test procedure in conjunction with additional provisions to account for the differences in size and characteristics of SVIL pump motors. In particular, DOE requested comment on the potential extension of the nominal full-load motor efficiency values to reference DOE's small electric motor regulations, including certain single-phase motors, and the need for an exception for SVIL pumps so that those sold with single-phase motors do not have to be rated as bare pumps. DOE also requested comment on the prevalence of SVIL pumps sold with single-phase versus three-phase motors, and the prevalence of SVIL pumps sold with motors not covered by DOE's small electric motors and electric motors energy conservation standards for either single- or three-phase motors. 86 FR 24516, 24527.

HI stated that the small motor regulation does not cover the full scope of motors (*e.g.,* single-phase, totally enclosed, fan-cooled (''TEFC''), and permanent split capacitor (''PSC'')) used with SVILs and that efficiencies for non-covered motors would need to be addressed, similar to submersible motors in appendix A, to reduce test burden and number of basic models to report. (HI, Docket No. EERE–2016–BT–STD–0004–112, at pp. 5–6) HI stated that data reported by four manufacturers of SVIL pumps indicated that between 70% and 75% are single-phase products. (HI, Docket No. EERE–2016–BT–STD–0004–112 at p. 6) HI added that many of these are custom special purpose motors specific to each manufacturer and may not be covered under the current motor efficiency regulations. (HI, Docket No. EERE–2016–BT–STD–0004–0112, at p. 6)

Grundfos stated that the test method for general pumps is appropriate for SVIL pumps, but that SVIL pumps would require a new pump category and should be limited to variable load products only. Grundfos stated that incorporating the small [electric] motor rule is appropriate to facilitate calculations in section VII of appendix A but commented that this regulation does not cover TEFC products and that DOE must ensure TEFC motors can utilize the same calculation methods. (Grundfos, Docket No. EERE–2016–BT–STD–0004–0113 at p. 5) Grundfos stated that 70% of its SVIL pumps are sold as single-phase (in both constant- and variable-speed equipment) and 30% are sold with 3-phase motors. They added that nearly all SVIL pumps are sold with TEFC motors that are not covered by DOE's small [electric] motor regulation. (Grundfos, Docket No. EERE–2016–BT–STD–0004–0113 at p. 5) Grundfos suggested that SVILs may be removed from the market and replaced by equivalent circulator products but was not explicit as to reason for such a change. (Grundfos, Docket No. EERE–2016–BT–STD–0004–0113 at p. 5)

DOE motor regulations at 10 CFR 431.446 exclude TEFC and certain other motors considered non-general purpose motors. However, in the Motors TP NOPR, DOE proposed adding such motors to the scope of electric motors coverage under the term small non-small electric motor electric motors (''SNEMs''). Specifically, DOE has proposed to define SNEMs as agnostic to enclosure and topology, affirmatively stating that the proposed test procedure would apply to general-purpose, definite-purpose, and special-purpose motors. As proposed, SNEMs would include fractional horsepower motors as low as 0.25 hp. 86 FR 71710, 71721–71725. The Motors TP NOPR also proposed testing instructions specific to these motors. 86 FR 71710, 71739. DOE notes that it has not established energy conservation standards for SNEMs. Were DOE to establish a test procedure for SNEMs, such motors would not be required to test according to the DOE test procedure until such time as compliance with any energy conservation standards be required, should such standards be established. Under DOE's Motors TP NOPR, any definitions, test procedures, and standards finalized for SNEMs would be in found in subpart B of part 431.

DOE expects that the proposed definition and test procedure for SNEMs, as well as the proposed test procedure for inverter-only synchronous electric motors, as discussed in section III.F.2, would encompass the additional types of motors discussed by HI and Grundfos that are not currently covered by the standards at 10 CFR 431.446. Therefore, DOE proposes that where the calculation-based test methods refer to the ''represented nominal full-load motor efficiency (*i.e.,* nameplate/DOE-certified value),'' the nominal full-load motor efficiency for an SVIL pump would be determined in accordance with the applicable test procedure in 10 CFR 431.444 or in subpart B of part 431.

DOE is also proposing that for SVIL pumps, the determination of PER_{STD} would reference DOE's small electric motor regulations at 10 CFR 431.446 rather than the electric motor regulations at 10 CFR 431.25, and would be the minimum efficiency of the energy conservation standards for polyphase or single-phase (CSIR/CSCR) for the relevant number of poles and motor horsepower. As noted, the single-phase standards only apply to CSCR and CSIR but this proposal would apply the efficiency values found at 10 CFR 431.446 when determining an SVIL pump's PER_{STD}. DOE believes that these values represent an appropriate default for the SVIL market. However, DOE would also consider application of efficiency values found for specific SNEMs in subpart B of part 431, if the relevant proposed amendments contained in the Motors TP NOPR are finalized. While DOE's information does not indicate that SVIL pumps are sold as bare pumps, as discussed in section III.B.4, if stakeholders identify such models, DOE would include these same provisions in the calculation method for bare pumps.

Issue 33: DOE seeks comment on whether the efficiency standards found at 10 CFR 431.446 are appropriate for use in the determination of PERSTD for SVILs, whether certain motor topologies that would be classified as SNEM are more prevalent and significantly less efficient, and whether the minimum efficiency of the polyphase and CSCR/CSIR standards for the relevant number of poles and motor horsepower is appropriate or whether there should be differences depending on the phase of the motor with which the pump is sold.

DOE's market research indicates that the vast majority of SVILs are sold with motors with a nominal horsepower of 0.25 hp or greater. However, DOE has identified some models with horsepower closer to 0.125 hp. Such motors are not subject to the standards in 10 CFR 431.446 and are not proposed to be subject to any test procedure in the Motors TP NOPR. DOE proposes that for determination of PER_{STD} for SVILs sold with a motor nominal horsepower of less than 0.25 hp, the full-load efficiency values in Table III.3 would be used. DOE has scaled these values from the standards for 0.25 hp pumps (3.9 efficiency point decrease, comparable to the most common decrease from 0.33 to 0.25 hp) and taken the minimum value across polyphase and CSCR/CSIR motors. DOE also proposes that the nominal full-load motor efficiency for SVILs would be determined in accordance with the applicable test procedure in 10 CFR 431.444 or in subpart B of part 431, although such test procedure is not required for those motors. DOE may consider alternate methods of determining motor efficiency for motors less than 0.25 hp, or if there is no appropriate test procedure, DOE may consider requiring SVILs sold with such motors to use a testing-based approach.

Table III.3 Average Full Load Efficiency for SVILs Less than 0.25 hp

Motor Horsepower	Average Full-Load Efficiency		
	Open Motors (Number of Poles)		
	6	4	2
< 0.25	58.3	64.6	61.7

Issue 34: DOE seeks comment on: (1) How many models of SVILs are sold with motors with a nominal horsepower less than 0.25 hp, (2) whether such motors could be tested in accordance with the relevant test procedures in 10 CFR 431.446 or proposed in the Motors TP NOPR, and if not, how such motors are tested, and (3) whether the efficiency values in Table III.3 are appropriate for such motors, and if not, how those values should be determined.

DOE expects that the existing regulations for small electric motors at 10 CFR 431.446, as well as any finalized regulations for SNEMs and inverter-only synchronous electric motors, would account for the vast majority of motors sold with SVIL pumps. However, DOE proposes that any SVIL pumps that are distributed in commerce with motors that are not regulated by DOE's electric motor regulations at 10 CFR 431.25, DOE's small electric motor regulations at 10 CFR 431.466, or any electric motor regulations in subpart B to part 431 established after January 1, 2022, as applicable, would need to apply the testing-based methods currently specified in sections IV and VI of appendix A and as proposed to be modified in this proposed rule. Given that DOE is proposing for PER_{STD} to reference motor efficiencies relevant to SVIL pumps, DOE is proposing not to have an option for SVIL pumps sold with single-phase motors to be rated as bare pumps.

If regulations for SNEMs and inverter-only synchronous electric motors are not set, DOE may consider allowing an option for SVIL pumps sold with single-phase motors to be rated as bare pumps. In this case, DOE would reference the efficiency values in 10 CFR 431.446 to determine bare pump performance.

Issue 35: DOE seeks comment on its proposal to require testing of SVIL pumps distributed in commerce with motors not regulated by DOE's current electric motor regulations or any motor regulations finalized after January 1, 2022. DOE also seeks comment on whether it should allow such pumps to be rated as bare pumps only if any motor regulations finalized after January 1, 2022, do not include SNEMs and inverter-only synchronous electric motors.

As stated in section III.F.1, the general pumps test procedure includes calculation-based methods that specify part-load loss curves for pumps sold with motors, accounting for the part-load losses of the motor at each load point, as well as part-load loss curves for pumps sold with motors and continuous controls, which account for additional losses.

Both the motor and combined motor and drive loss curves were developed for the general pumps test procedure based on data from NEMA and from manufacturers of motors and drives, as well as data from DOE's own testing, for motors and drives from 1 to 250 hp gathered during the general pumps test procedure rulemaking. Since these losses were based on data for motors and drives from 1 to 250 hp, the nominal motor losses derived for the general pumps test procedure may not be appropriate for SVIL pumps, given the lower hp ratings of the motors used in these applications. In the May 2021 Circulator Pumps RFI, DOE requested comment on whether the equations used to establish the part-load motor and drive losses in the general pumps test procedure are appropriate for SVIL pumps under one hp—and if inappropriate, DOE requested data supporting the generation of alternative loss curves. 86 FR 24516, 24527.

HI stated that current loss coefficients would not be valid for smaller motors and that DOE should investigate since this data is not available in the public domain. As noted previously, HI added that many of these are custom special purpose motors specific to each manufacturer and may not be covered under the current motor efficiency regulations. (HI, Docket No. EERE–2016–BT–STD–0004–0112 at p. 6) Grundfos stated that it did not believe that current part-load loss calculations apply to fractional horsepower motors and that DOE must engage with motor manufacturers and NEMA to determine appropriate part-load loss calculations. (Grundfos, Docket No. EERE–2016–BT–STD–0004–0013 at p. 5)

DOE understands that part-load loss curves (*i.e.,* the variation in efficiency as a function of load) do not vary significantly between 1 hp motors and drives and motors and drives that are less than 1 hp. DOE did not receive any newer data in response to this RFI or any indication that the SVIL market has changed such that data collected in 2017 would no longer be applicable. As stated previously, DOE is not proposing to revise its part-load loss curves for motors and drives less than 5 hp. Therefore, DOE proposes to apply the existing motor and combined motor and drive part-load loss curves that are applicable to 1 hp motors and drives to the fractional horsepower motors and drives with which SVIL pumps may be sold. DOE notes that IEC standards do not include motors below ¾ kw (1 hp), and that many SVIL pumps may use integrated packages rather than separate motors and drives—and as noted by HI, may be specific to each manufacturer. Consequently, there may be more variation in losses across manufacturers or models compared to larger hp motors and drives. As discussed in section III.I.2, DOE is proposing to allow use of AEDMs for pumps. In cases where a manufacturer wishes to use an alternative to the part-load loss coefficient method, it may choose to perform wire-to-water testing of SVILs or employ an AEDM under DOE's proposal.

Issue 36: DOE seeks comment on whether the market for SVIL pumps has changed such that the data collected by DOE in 2017 would no longer be applicable, and whether the use of AEDM would address concerns related to part-load loss curves specific to low-horsepower motors.

H. Test Procedure for Other Expanded Scope Pumps

DOE reviewed the general pumps test procedure in appendix A, including the amendments proposed in this NOPR, to determine if any modifications were necessary to accommodate BB, RSH, and VT pumps, as well as pumps designed to operate with 6-pole induction motors and pumps designed to operate with non-induction motors with an operating range that includes speeds of rotation between 960 rpm and 1,440 rpm (''pumps tested with a nominal speed of 1,200 rpm''). Specifically, the general pumps test procedure established in appendix A is based on the test methods contained in HI 40.6–2014, with certain modifications. As discussed in section III.C.1, DOE is proposing to update this reference to HI 40.6–2021, which DOE has tentatively determined is also applicable to BB, RSH, and VT pumps, as well as to pumps tested with a nominal speed of 1,200 rpm.

As discussed in section III.F, the general pumps test procedure also contains methods to determine the appropriate PEI using either calculation-based methods and/or testing-based methods. DOE tentatively determined that these calculation- and testing-based methods are applicable to BB, RSH, and VT pumps, as well as pumps tested with a nominal speed of 1,200 rpm just as they apply to other general pumps, based on the configuration in which the pump is being sold. Since BB, RSH, and VT pumps, as well as pumps tested with a nominal speed of 1,200 rpm are sold as bare pumps, pumps with motors, or pumps with motors and controls, the test methods established in the January 2016 Final Rule would be applicable to BB, RSH, and VT pumps, as well as pumps tested with a nominal speed of 1,200 rpm pumps. Additionally, the determination of pump performance in the current general pumps test procedure, and as proposed to be updated in this document, would be applicable to BB, RSH, and VT pumps, as well as pumps tested with a nominal speed of 1,200 rpm.

DOE understands that the motors paired with BB, RSH, and VT pumps are typically similar to those paired with the existing scope of general pumps. As such, DOE tentatively determined that

Table 1 and the relevant test and calculation options are appropriate for these expanded scope pumps and that no modifications are needed.

Issue 37: DOE requests comment on whether the proposed test procedure is appropriate for BB, RSH, and VT pumps.

Issue 38: DOE seeks comment on whether BB, RSH, and VT pumps are typically sold with motors not subject to the energy conservation standards in 10 CFR 431.25 or synchronous inverter-only electric motors, and if so, what kind of motors they are sold with, and what calculation modifications would be needed to accommodate such motors.

For pumps tested at a nominal speed of 1,200 rpm, DOE tentatively determined that the existing test procedure references to 10 CFR 431.25 for the appropriate number of poles, and the part-load loss factors in Table 4, and as proposed in this document, would be appropriate. The current requirements at 10 CFR 431.25 and 10 CFR 431.446 include energy efficiency standards for 6-pole motors. In addition, part-load losses are a relative factor that is agnostic to pole configuration. As a result, DOE is not proposing to revise these references and factors. DOE notes that Table 2, the default efficiency values for submersible pumps, does not currently have values for 6-pole motors. DOE is proposing to expand Table 2 to include such values. The proposed values were developed at the same time as the existing values in Table 2 but were not included in the 2016 test procedure at that time because the original scope did not include pumps tested at a nominal speed of 1,200 rpm. DOE notes that, as discussed in section III.F.3, Table 2 may be replaced with energy conservation standard values for submersible motors, if such standards are developed and adopted.

Issue 39: DOE requests comment and data on the proposed default submersible motor efficiency values for 6-pole motors.

I. Sampling Plan, AEDMs, Enforcement Provisions, and Basic Model

1. Sampling Plan for Determining Represented Values

DOE currently provides sampling plans for all covered equipment that manufacturers must use when certifying their equipment as compliant with the relevant standards and when making written representations of energy consumption and efficiency. (*See generally* 10 CFR parts 429 and 431) DOE expects that SVIL pumps would have the same testing uncertainty and manufacturing variability as larger IL pumps, as they are similar in construction and design to IL pumps and would apply the same test procedure under DOE's proposal. Similarly, RSH pumps would have the same testing uncertainty and manufacturing variability as RSV pumps, as they are similar in construction and design to RSV pumps and would use the same test procedure under this proposal. DOE has tentatively determined that BB pumps would have the same testing uncertainty and manufacturing variability as large, currently covered, end-suction pumps, as they are reasonably similar in construction and design to BB pumps and would apply the same test procedure as end-section pumps. VT pumps would also likely have the same testing uncertainty and manufacturing variability as large, currently covered, ST pumps, as they are reasonably similar in construction and design to VT pumps and use the same test procedure as VT pumps. Additionally, DOE has tentatively determined that pumps tested at a nominal speed of 1,200 rpm would have the same testing uncertainty and manufacturing variability as pumps that are currently regulated and tested at nominal speeds of 1,800 and 3,600. Therefore, DOE proposes to adopt the same statistical sampling plans that are already in place for commercial industrial pumps and apply them to those pumps that DOE is proposing to include as part of its expanded test procedure scope (*i.e.,* SVIL, BB, RSH, VT, and 1,200 rpm pumps.).

Issue 40: DOE request comment on its tentative determinations that SVIL, BB, RSH, VT, and pumps tested at a nominal speed of 1,200 rpm have the same testing uncertainty and manufacturing variability as currently regulated pumps. DOE also requests comment on its proposal to adopt the same statistical sampling plans which are currently in place for commercial industrial pumps for SVIL, BB, RSH, VT, and pumps tested at a nominal speed of 1,200 rpm.

Under this proposal, for purposes of certification testing, determining whether a basic model complies with the applicable energy conservation standard would be based on testing conducted using the proposed DOE test procedure and sampling plan. The general sampling requirement currently applicable to all covered products and equipment provides that a sample of sufficient size must be randomly selected and tested to ensure compliance and that, unless otherwise specified, a minimum of two units must be tested to certify a basic model as compliant. 10 CFR 429.11 This minimum is implicit in the requirement to calculate a mean—an average—which requires at least two values.

DOE proposes to apply this minimum requirement to the pump categories addressed in this proposed expansion of the test procedure's scope. Manufacturers may need to test a sample of more than two units depending on the variability of their sample, as provided by the statistical sampling plan.

Additionally, DOE's certification requirements state that other performance parameters derived from the test procedure must be reported, but no sampling plan provisions are provided for such other parameters, which include: pump total head in feet at BEP and nominal speed, volume per unit time (*i.e.,* flow rate) in gallons per minute at BEP and nominal speed, and calculated driver power input at each load point (*i.e.,* corrected to nominal speed in horsepower). 10 CFR 429.59(b)(2). In the April 2021 RFI, DOE sought input on whether it should specify an approach for determining how to determine represented values for parameters other than PEI, and sought comment on using the mean of the value for each tested unit in the sample as the represented value. 86 FR 20075, 20083.

HI and Grundfos recommended that if the sample size is greater than one, the arithmetic mean should be used for reported parameters other than PEI (HI, No. 20 at p.7; Grundfos, No. 17 at p. 7).

Regarding representative values other than PEI and PER, DOE is proposing that if more than one unit is tested for a given sample, represented values (other than PEI and PER) would be determined using the arithmetic mean of the individual units. For example, if three units are tested for a given sample, and pump total head at BEP is measured at 99.1 ft, 96.2 ft, and 97.3 ft, the reported values for head would be the sum of the three values divided by three (*i.e.,* 97.5 ft). This proposal would apply to both the existing and proposed expanded scope of pumps that would be addressed by the general pumps test procedure.

Issue 41: DOE requests comment on the proposed statistical sampling procedures and certification requirements.

2. Alternative Efficiency Determination Methods

a. Background

Pursuant to the requirements of 10 CFR 429.70, DOE may permit use of an AEDM in cases where actual testing of regulated equipment may present considerable burdens to a manufacturer

and use of that AEDM can reasonably predict the equipment's energy efficiency performance. Although specific requirements vary by product or equipment, use of an AEDM entails development of a mathematical model that estimates energy efficiency or energy consumption characteristics of the basic model, as would be measured by the applicable DOE test procedure. The AEDM must be based on engineering or statistical analysis, computer simulation or modeling, or other analytic evaluation of performance data. A manufacturer must validate an AEDM by demonstrating that its predicted efficiency performance of the evaluated equipment agrees with the performance as measured by actual testing in accordance with the applicable DOE test procedure. The validation procedure and requirements, including the statistical tolerance, number of basic models, and number of units tested vary by product.

Once developed, an AEDM may be used to certify the performance of untested basic models in lieu of physical testing. However, use of an AEDM for any basic model is always at the option of the manufacturer. One potential advantage of AEDM use is that it may free a manufacturer from the burden of physical testing—but this advantage must be weighed against the potential risk that an AEDM may not perfectly predict performance and could result in a finding that the equipment has an invalid rating and/or that the manufacturer has distributed a noncompliant basic model. The manufacturer, by using an AEDM, bears the responsibility and risk of the validity of the ratings, including cases where the manufacturer receives and relies on performance data for certain components from a component manufacturer.

Given stakeholder requests for the calculation methods to be more representative, and to balance the risk of allowing overrating through calculation methods, DOE proposes to accommodate the application of AEDMs to determine performance ratings for pumps. DOE expects that the use of AEDMs would allow manufacturers to rate equipment that performs better than the assumptions in DOE's calculation method with less burden than if physical testing were required for each basic model. Manufacturers could still choose to use the calculation method where they were satisfied that it resulted in appropriate representations of model performance. DOE proposes regulatory language that is consistent with most other commercial and industrial equipment that have AEDM provisions. The specific details are discussed in sections III.I.2.b through III.I.2.f of this document.

b. Basic Criteria Any AEDM Must Satisfy

A manufacturer may not use an AEDM to determine the values of metrics unless the following three criteria are met:

(1) The AEDM is derived from a mathematical model that estimates the energy efficiency or energy consumption characteristics of the basic model as measured by the applicable DOE test procedure;

(2) The AEDM is based on engineering or statistical analysis, computer simulation or modeling, or other analytic evaluation of performance data; and

(3) The manufacturer has validated the AEDM, in accordance with the applicable validation requirements for such equipment (discussed in section III.I.2.c of this document).

c. Validation

Validation is the process by which a manufacturer demonstrates that an AEDM meets DOE's requirements for use as a certification tool by physically testing a certain number and style of pump models and comparing the test results to the output of the AEDM. Before using an AEDM, a manufacturer must validate the AEDM's accuracy and reliability as follows:

A manufacturer must select a minimum number of basic models from each validation class to which the AEDM applies.[49] To validate an AEDM, the specified number of basic models from each validation class must be tested in accordance with the DOE test procedure and sampling plan in effect at the time those basic models used for validation are distributed in commerce. Testing may be conducted at a manufacturer's testing facility or a third-party testing facility. The resulting rating is directly compared to the result from the AEDM to determine the AEDM's validity. A manufacturer may develop multiple AEDMs per validation class, and each AEDM may span multiple validation classes; however, the minimum number of basic models must be validated per validation class for every AEDM that a manufacturer chooses to develop. An AEDM may be applied to any basic model within the applicable validation classes at the manufacturer's discretion. All documentation of testing, the AEDM results, and subsequent comparisons to the AEDM would be required to be maintained as part of both the test data underlying the certified rating and the AEDM validation package pursuant to 10 CFR 429.71.

DOE is proposing to include general pumps validation classes at 10 CFR 429.70(i) and to require that two basic models per validation class be tested using the relevant proposed test procedure. This number of basic models is consistent with the number for basic models required for most DOE-regulated equipment that utilize AEDMs. Additionally, DOE proposes that the AEDM-predicted result would be applied to the PEI metric and would be greater than or equal to 95 percent of the tested results for that same model. Additionally, the predicted PEI for each basic model calculated by applying the AEDM must meet or exceed the applicable federal energy conservation standard that applies.

DOE's proposed validation classes for general pumps are listed below:

- Constant Load End-suction Closed-Coupled Pumps and Constant Load End-suction Frame-Mounted Pumps
- Variable Load End-suction Closed-Coupled Pumps and Variable Load End-suction Frame-Mounted Pumps
- Constant Load Inline Pumps and Constant Load Small Volute Inline Pumps
- Variable Load Inline Pumps and Variable Load Small Volute Inline Pumps
- Constant Load Radially-Split Multi-Stage Vertical Pumps and Constant Load Radially-Split Multi-Stage Horizonal Pumps
- Variable Load Radially-Split Multi-Stage Vertical Pumps and Variable Load Radially-Split Multi-Stage Horizontal Pumps
- Constant Load Submersible Turbine Pumps and Constant Load Vertical Turbine Pumps
- Variable Load Submersible Turbine Pumps and Variable Load Vertical Turbine Pumps
- Constant Load Between-Bearing Pumps
- Variable Load Between-Bearing Pumps

d. Records Retention Requirements

Consistent with provisions for other commercial and industrial equipment, DOE also proposes requirements regarding retention of certain information related to validation and use of an AEDM to certify equipment. Specifically, any manufacturer using an AEDM to generate representative values must provide on request records showing: (1) The AEDM itself, and any

[49] ''Validation classes'' are groupings of products based on the equipment classes used for validating an AEDM.

mathematical modeling, engineering or statistical analysis, and/or computer simulation or modeling that forms the AEDM's basis; (2) regarding tested units that were used to validate the AEDM pursuant to section III.I.2.b, all relevant equipment information, complete test data, AEDM calculations, and statistical comparisons ; and (3) for each basic model to which the AEDM has been applied, all relevant equipment information and AEDM calculations.

e. Additional AEDM Requirements

Consistent with provisions for other commercial and industrial equipment, DOE proposes to require that, if requested by DOE, a manufacturer must perform at least one of the following activities: (1) Conduct a simulation before a DOE representative to predict the performance of particular basic models of the equipment to which the AEDM was applied; (2) provide analysis of previous simulations conducted by the manufacturer; or (3) conduct certification testing of basic model(s) selected by DOE.

In addition, DOE notes that when making representations of values other than PEI based on the output of an AEDM, all other representations regarding PER, pump efficiency, overall efficiency, flow, head, driver power input and pump power output would be required to be based on the same AEDM results used to generate the represented value of PEI.

f. AEDM Verification Testing

Consistent with provisions for certain other commercial and industrial equipment, DOE proposes including in 10 CFR 429.70 provisions related to AEDM verification testing for pumps, including: (1) Selection of units from retail if available, or otherwise from a manufacturer, (2) independent, third-party testing if available, or otherwise at a manufacturer's facility, (3) testing performed without manufacturer representatives on-site, (4) testing in accordance with the DOE test procedure, any active test procedures, any guidance issued by DOE, and lab communication with the manufacturer only if DOE organizes it, (5) notification of manufacturer if a model tests worse than its certified rating by an amount exceeding a 5 percent tolerance with opportunity for the manufacturer to respond, (6) potential finding of the rating for the model to be invalid, and (7) specifications regarding when a manufacturer's use of an AEDM may be restricted due to prior invalid represented values and how a manufacturer could regain the privilege of using an AEDM for rating.

DOE is also proposing conforming changes to 10 CFR 429.59 to allow use of AEDMs for general pumps in lieu of testing.

Issue 42: DOE requests feedback regarding all aspects of its proposal to permit use of an AEDM for general pumps, and any data or information comparing modeled performance with the results of physical testing. DOE specifically seeks comment on its proposed validation classes, and whether groupings should be considered where performance variation between two equipment classes or nominal speeds is well established. In addition, DOE requests comment on whether the calculation-based methods would still be necessary if manufacturers were permitted to use AEDMs in addition to physical testing.

3. Enforcement Provisions

Enforcement provisions govern the process DOE would follow when performing an assessment of basic model compliance with standards, as described under subpart C of part 429. Specifically, subpart C of part 429 describes the notification requirements, legal processes, penalties, specific prohibited acts, and testing protocols related to testing covered equipment to determine or verify compliance with standards.

DOE proposes to apply the same general enforcement provisions contained in subpart C of part 429 to the proposed expanded scope of pumps.

Additionally, given that DOE is proposing to allow the use of AEDMs, DOE is also proposing in the product specific enforcement provisions in 10 CFR 429.134 that if the model of pump unit was rated using an AEDM, DOE may conduct enforcement testing using either a testing approach or calculation approach.

Issue 43: DOE requests comment on its proposal related to enforcement provisions.

4. Basic Model Definition

This section discusses the definition of basic model as it relates to the existing general pumps scope. DOE will make any proposals related to the basic model definition for its proposed expanded scope in any energy conservation standards rulemaking for pumps. DOE's regulations for pumps at 10 CFR 429.59 require that the represented values for each basic model be determined through testing in accordance with the sampling provisions specified in that section. As applied to pumps, DOE defines the term ''basic model'' in 10 CFR 431.462.

In the April 2021 RFI, DOE stated that pump manufacturers may elect to group similar individual pump models within the same equipment class into the same basic model to reduce testing burden, provided all representations regarding the energy use of pumps within that basic model are identical and based on the most consumptive unit 86 FR 20075, 20083). Accordingly, manufacturers may pair a given bare pump with several different motors (or motor and controls) and can include all combinations under the same basic model if the certification of energy use and all representations made by the manufacturer are based on the most consumptive bare pump/motor (or motor and controls) combination for each basic model and all individual models are in the same equipment class. 86 FR 20075, 20083–20084.

In the case of pumps, the term ''basic model'' means all units of a given class of pump manufactured by one manufacturer, having the same primary energy source, and having essentially identical electrical, physical, and functional (or hydraulic) characteristics that affect energy consumption, energy efficiency, water consumption, or water efficiency; and, in addition, for pumps that are subject to the standards specified in § 431.465(b), the following provisions also apply:

(1) All variations in numbers of stages of bare RSV and ST pumps must be considered a single basic model;

(2) Pump models for which the bare pump differs in impeller diameter, or impeller trim, may be considered a single basic model; and

(3) Pump models for which the bare pump differs in number of stages or impeller diameter and which are sold with motors (or motors and controls) of varying horsepower may only be considered a single basic model if:

(i) For ESCC, ESFM, IL, and RSV pumps, each motor offered in the basic model has a nominal full load motor efficiency rated at the Federal minimum (see the current table for NEMA Design B motors at § 431.25) or the same number of bands above the Federal minimum for each respective motor horsepower (see Table 3 of appendix A to subpart Y of this part); or

(ii) For ST pumps, each motor offered in the basic model has a full load motor efficiency at the default nominal full load submersible motor efficiency shown in Table 2 of appendix A to subpart Y of this part or the same number of bands above the default nominal full load submersible motor efficiency for each respective motor horsepower (see Table 3 of appendix A to subpart Y of this part).

10 CFR 431.462.

Clauses (1) and (2) of the basic model definition, which are applicable to pumps that are subject to the standards specified in 10 CFR 431.465(b), align the scope of the ''basic model'' definition for pumps with the requirements that testing be conducted at a certain number of stages for RSV and ST pumps and at full impeller diameter. (10 CFR 431.462.) Clause (3) of the definition, which is applicable to pumps that are subject to the standards specified in 10 CFR 431.465(b), addresses basic models inclusive of pump models for which the bare pump differs in number of stages or impeller diameter. (*Id.*) Specifically, variation in motor sizing (*i.e.,* variation in the horsepower rating of the paired motor as a result of different impeller trims or stages within a basic model) is not a basis for requiring units to be rated as unique basic models. However, variation in motor sizing may also be associated with variation in motor efficiency, which is a performance characteristic; typically, larger motors are more efficient than smaller motors. 86 FR 20075, 20084.

In order to group pumps sold with motors into a single basic model, clause (3)(i) provides that for basic models inclusive of pump models for which the bare pump differs in number of stages or impeller diameter, each motor offered in a pump included in that basic model must have a full-load efficiency at the Federal minimum efficiency level for NEMA Design B electric motors (found in 10 CFR 431.25) or the same number of efficiency bands above the Federal minimum for each respective motor horsepower as described in Table 3 of appendix A.[50] (*Id.*) Clause (3)(ii) provides a similar allowance for submersible turbine pumps, where, in order to group pumps sold with motors into a single basic model, each motor offered in a pump included in that basic model must have a full-load motor efficiency at the default nominal full-load submersible motor efficiency shown in Table 2 of appendix A, or the same number of bands above the default nominal full-load submersible motor efficiency for each respective motor horsepower as described in Table 3 of appendix A. (*Id.*) DOE requested comment on how manufacturers are currently making use of the basic model grouping provisions when rating their pumps, and whether any general clarifications or modifications are needed. 86 FR 20075, 20084.

HI and Grundfos stated there are no modifications or clarifications needed for basic model except to modify the language to reduce testing burden by allowing manufacturers to group inverter-only motors into a single basic model (HI, No. 20 at p. 8; Grundfos, No. 17 at p. 8), which DOE discusses later. Summit stated that all pumps are reported using basic model grouping of ''bare pump'' as defined in Section III, regardless of whether the pump is sold with a motor. (Summit Pump, No. 16 at p. 6)

Summit requested clarification on whether ''most consumptive'' refers to the highest power consumption or least efficient and requested clarification on the phrase ''same number of bands above federal minimum.'' Summit also requested examples for reporting a bare pump with different motor powers. (Summit, No. 16 at p. 6)

In response to Summit, ''most consumptive'' would refer to the highest PEI, given that lower numbers of PEI are better. The phrase ''same number of bands above federal minimum'' means that the manufacturer should: (1) Identify the motor efficiency of the motor in question, (2) find the Federal minimum for the relevant horsepower/pole combination NEMA Design B electric motors in 10 CFR 431.25, (3) find both of those values in Table 3 of appendix A, and (4) count how many rows the motor efficiency is above the federal minimum. This process would be repeated for the other motors that the manufacturer may seek to group into the basic model to ensure that the motor efficiency for each motor is the same number of rows (''bands'') above the relevant Federal minimum in each case. Regarding Summit's request for examples of reporting a bare pump with different motor powers, DOE understands Summit to be referring to the case where a bare pump with varying number of stages or impeller diameters is sold with motors of varying horsepower. In this case, the manufacturer may choose to group those combinations into a single basic model, if all the motors are the ''same number of bands above [the] federal minimum'' as described in the process above. If so, the manufacturer would report the performance of that basic model following the steps in 10 CFR 429.59(b). The performance of the basic model would be based on the specific motor tested with the bare pump (using a testing-based approach or calculation-based approach) in accordance with 10 CFR 429.59(a). The manufacturer would report the basic model number as well as the individual model numbers for the bare pump and for all motors of varying horsepower that the manufacturer elected to group into a single basic model, in accordance with 10 CFR 429.59(c). Alternatively, the manufacturer could choose to report each of the bare pump + motor combinations as separate basic models.

In the April 2021 RFI, DOE stated that it received several inquiries related to the application of the basic model definition to pumps sold with VFDs of varying phase, voltage, and/or efficiency; pumps sold with inverter-only motors such as PMAC motors; and pumps sold with both single-phase and polyphase motors. 86 FR 20075, 20084.

For pumps sold with motors, when determining how to group models within a basic model, manufacturers must consider clause (3), which currently allows the grouping of models to be based on the number of bands above ''nominal full-load motor efficiency rated at the Federal minimum (see the current table for NEMA Design B electric motors at § 431.25),'' or for submersible turbine pumps, the number of bands above the default nominal full-load submersible motor efficiency. DOE stated that it may consider inclusion of explicit language that applies this clause to pumps sold with specific kinds of motors, or to pumps sold with VFDs. For example, inverter-only motors may have a rated efficiency (*i.e.,* nameplate efficiency) that exceeds the Federal minimum for NEMA Design B electric motors (10 CFR 431.25) (based on hp, poles, and enclosure construction of that motor), as might certain single-phase motors subject to the energy efficiency standards in 10 CFR 431.446 and tested in accordance with 10 CFR 431.444. DOE also noted that stakeholders have recommended that DOE develop default nominal full-load efficiency values for inverter-only motors, which could also provide a baseline for grouping pumps sold with those motors. 86 FR 20075, 20084.

DOE noted that for motors not currently subject to the DOE test procedure for electric motors, it is not clear how manufacturers would determine the full-load efficiency of a given motor, or specifically, determine the number of bands above the Federal minimum or, for submersible pumps, above the default efficiency. For inverter-only motors, DOE noted that the IEC recently published an industry test procedure that provides test methods for measuring the efficiency of these motors: IEC 60034–2–3:2020, ''Rotating electrical machines—Part 2–3: Specific test methods for determining losses and efficiency of converter-fed

[50] The efficiency bands in Table 3 of appendix A are derived from Tables 12–10 and 12–12 of NEMA MG1–2016, with 2018 supplements. Each higher incremental level of nominal full-load efficiency represents a loss reduction of approximately 10 percent or one ''NEMA Band.''

AC motors'' (''IEC 60034'') and IEC 61800–9–2:2017 (discussed in section III.F.1 of this RFI). DOE requested comment on whether to amend clause (3) in the basic model definition for pumps to provide additional detail regarding pumps sold with inverter-only motors, single-phase motors, or other non-NEMA Design B electric motors. DOE requested comment on which motor categories not currently subject to DOE's test procedure and standards are commonly combined with pumps, as well as their relative efficiency compared to regulated NEMA Design B electric motors, and which corresponding industry test procedure (if any) should be used to establish their ''rated'' efficiency. Finally, DOE requested comment on how VFDs are typically paired with pumps and motors; for example, whether motors of various sizes are paired with the same VFD. DOE also sought comment on whether a pump manufacturer would know which VFD commonly paired with its pumps would result in the most consumptive rating. 86 FR 20075, 20084.

Summit stated that the majority of supplied motors are covered. (Summit, No. 16 at p. 6) Grundfos stated that their inverter-only motors are IE5 compliant as defined in IEC TS 60034–30–2 and tested according to IEC 60034–2–3. (Grundfos, No. 17 at p. 8) HI stated that IEEE 114 applies for efficiency testing of single-phase induction motors and IEC 60034–2–3 applies for efficiency testing of inverter-only motors. (HI, No. 20 at p. 8) NEEA provided a list of all test procedures applicable to all motor technologies that DOE considered in the 2017 Electric Motors test procedure RFI and stated that in particular they supported consideration of IEC 61800–9:2017 and 60034–2–3:2020, which appear to be applicable to all inverter-fed motors. (NEEA, No. 21 at p. 9–10)

HI recommended modifying the language of the basic model definition to reduce testing burden by allowing manufacturers to group inverter-only motors into a single basic model as long as all motors had an efficiency above the Federal minimum for each respective motor horsepower for NEMA Design B motors at 10 CFR 431.25, or above the default for submersible motors. (HI, No. 20 at p. 8) Grundfos supported HI's comment on modifying the ''Band Rule'' requirements to allow for all inverter-only motors [51] to be grouped in a single basic model for purposes of testing, regardless of how many bands above the Federal minimum efficiency standard each motor of a given hp rating may be. Grundfos noted that this would remove burdensome testing requirements when products meet IE4 and IE5 efficiency levels but the number of bands can vary greatly due to inconsistent efficiency levels in the Federal minimum. (Grundfos, No. 17 at p. 8)

Grundfos stated that it sells products with VFDs in two configurations: (1) For products with integrated inverter-only motors, the VFD is specifically designed for the motor hp it is paired with, and (2) for external Grundfos VFDs, the VFD is designed for a specific hp motor. Grundfos also noted that VFDs can be used on differing hp motors where the kVA rating of the VFD is not exceeded. Finally, Grundfos noted that products can be used by end users with many different VFDs with which they are not sold, and so Grundfos could not determine the most consumptive of the entire market. (Grundfos, No. 17 at p. 9) HI stated that in many cases VFDs and pumps are purchased separately, but where manufacturers include VFDs with pumps, the test procedure is sufficient for determining a basic model and testing. (HI, No. 20 at p. 8)

As discussed in section III.F.1 and III.F.2, DOE proposed as part of its Motors TP NOPR to address single-phase induction motors (SNEMs) and inverter-only motors. As such, DOE does not need to reference external test procedures as part of the basic model definition. In addition, DOE proposed that PER_{STD} for inverter-only motors would still be based on DOE's standards for NEMA Design B motors. In regard to the issue Grundfos raised with the difference in number of bands between IE4 or IE5 efficiency levels and Federal minimums across hp for inverter-only motors, DOE proposes to amend clause (3) so that the current band rule does not apply and instead the grouping can be based on anything above the Federal minimum for NEMA Design B motors as long as the rating is based on the lowest number of bands above the minimum.

With regard to addressing VFDs in the basic model definition, HI stated that the test procedure is sufficient for determining a basic model, and Grundfos stated that it would be unable to determine which VFD was most consumptive. (HI, No. 20 at p. 8; Grundfos, No. 17 at p. 9) As such, DOE has tentatively determined that there is no viable option to more explicitly address VFDs in the basic model definition and that it does not need to change the basic model definition to address VFDs.

In the April 2021 RFI, DOE noted that to group pumps sold with both single-phase motors and pumps sold with polyphase motors into a single basic model, manufacturers would need to utilize a testing-based approach on the most consumptive configuration, as pumps sold with polyphase motors cannot be rated as bare pumps, and pumps sold with single-phase motors cannot be rated using a calculation-based approach (see Table 1 to appendix A). DOE requested comment on whether allowing such a grouping under the same basic model for pumps sold with both single-phase and polyphase motors would require more explicit direction in 10 CFR part 431. 86 FR 20075, 20084.

Grundfos stated that grouping single-phase products with polyphase product would not meet the definition of basic model because the characteristics that affect energy consumption are not ''essentially identical.'' Grundfos stated that if the intention of this grouping is to reduce testing burden, this is not accomplished because testing is still required on both versions to determine whether the single-phase or polyphase equipment would be ''most consumptive,'' unless DOE clearly states in the regulation what method(s) DOE determines to be valid to determine ''most consumptive'' before actual testing. Grundfos does not believe grouping single-phase with polyphase equipment should be allowed. (Grundfos, No. 17 at p. 9) HI stated that attempting to include regulated single-phase equipment would be limited because the current DOE regulation only includes general purpose open drip proof products. (HI, No. 20 at p. 8) HI recommended that pumps sold with single-phase and polyphase motors not be combined into a single basic model and recommended that DOE continue to allow pumps sold with single-phase motors to be rated with section III for bare pumps. (HI, No. 20 at p. 8)

Following consideration of HI and Grundfos' comments, DOE is not proposing to allow the grouping of single-phase and polyphase products into a single basic model. Instead, DOE proposes to require that pumps sold with single-phase motors can continue to be rated as bare pumps (with the exception of SVIL as discussed in section III.G).

Issue 44: DOE requests comment on the proposed amendments to the definition of basic model.

[51] The comment uses the term ''induction-only motors''; however, DOE believes this to be referring to ''inverter-only'' motors since this comment was in response to Issue 25, which requested detail about inverter-only motors. Additionally, the HI comment referenced by Grundfos also specified inverter-only motors.

J. Representations of Energy Use and Energy Efficiency

DOE understands manufacturers often make representations (graphically or in numerical form) of energy use metrics, including pump efficiency, overall (wire-to-water) efficiency, bowl efficiency, driver power input, pump power input (brake or shaft horsepower), and/or pump power output (hydraulic horsepower). Manufacturers often make these representations at multiple impeller trims, operating speeds, and number of stages for a given pump. DOE proposes to allow manufacturers to continue making these representations. To ensure consistent and standardized representations across the pump industry and to ensure such representations are not in conflict with the reported PEI for any given pump model, DOE proposes to establish optional testing procedures for these parameters that are part of the DOE test procedure. DOE also proposes that, to the extent manufacturers wish to make representations regarding the performance of commercial and industrial pumps using these additional metrics, they would be required to do so based on testing in accordance with the DOE test procedure.

DOE notes that overall (wire-to-water) efficiency, driver power input, and/or pump power output (hydraulic horsepower) are already parameters that are described in HI 40.6–2021, which DOE proposes to incorporate by reference in the DOE test procedure (section III.C.1). DOE expects that further specification is not necessary regarding the determination of these parameters.

Issue 45: DOE requests comment on its proposal to adopt optional test provisions for the measurement of several other circulator pump metrics, including overall (wire-to-water) efficiency, driver power input, and/or pump power output (hydraulic horsepower).

Issue 46: DOE also requests comment on its understanding that HI 40.6–2021 contains all the necessary methods to determine overall (wire-to-water) efficiency, driver power input, and/or pump power output (hydraulic horsepower) and that further specification is not necessary.

K. Labeling Requirements

DOE specifies labeling requirements for pumps at 10 CFR 431.466. DOE requires that the permanent nameplate must be marked clearly with the following information: (A) For bare pumps and pumps sold with electric motors but not continuous or non-continuous controls, the rated pump energy index—constant load (PEI_{CL}), and for pumps sold with motors and continuous or non-continuous controls, the rated pump energy index—variable load (PEI_{VL}); (B) The bare pump model number; and (C) If transferred directly to an end-user, the unit's impeller diameter, as distributed in commerce. Otherwise, a space must be provided for the impeller diameter to be filled in. 10 CFR 431.466(a)(1)(i).

DOE also specifies that all orientation, spacing, type sizes, typefaces, and line widths to display this required information must be the same as or similar to the display of the other performance data on the pump's permanent nameplate. DOE also specifies the form in which PEI_{CL}, PEI_{VL}, model number, and impeller diameter must be identified. 10 CFR 431.466(a)(1)(ii).

Regarding disclosure of efficiency information in marketing materials, DOE requires that the same information that must appear on a pump's permanent nameplate must also be prominently displayed on each page of a catalog that lists the pump; and in other materials used to market the pump. 10 CFR 431.466(a)(2)(i).

In the April 2021 RFI, DOE requested comment on whether the test procedure should explicitly specify how to determine the information required to be marked on a label in accordance with 10 CFR 431.466, and if so, how. 86 FR 20075, 20085.

Summit stated that labeling requirements seem straightforward but requested clarification on who is considered the manufacturer. (Summit, No. 16 at p. 6) DOE notes that 10 CFR 431.2 defines the term ''manufacturer'' as ''any person who manufactures industrial equipment . . .'' and defines manufacture as ''to manufacture, produce, assemble, or import.'' *See also* 42 U.S.C. 6311(5) (defining ''manufacturer''), 42 U.S.C. 6311(7) (referencing the definition for ''manufacture'' under 42 U.S.C. 6291) *and* 42 U.S.C. 6291(10) (defining ''manufacture'').

Grundfos stated that individual model numbers should be the only data mandated by DOE on labels and marketing materials, and that basic models should not be mandated on product nameplates since they are only a reference with the manufacturers and DOE. (Grundfos, No. 17 at p. 9) HI requested that DOE clarify that only the individual model number and PEI need to be on the nameplate and marketing materials. (HI, No. 20 at p. 9)

Grundfos stated that mandating the actual impeller diameter on the nameplate of a product serves no purpose with respect to the regulation, EPCA, or consumers referencing this information. Grundfos added that there is also ample evidence from consumers that marking the ''actual impeller diameter'' on the product causes confusion because the PEI on the label is based on full impeller diameter. Grundfos recommended that the impeller diameter mandate for nameplates and marketing materials be removed to reduce substantial burden for global products. (Grundfos, No. 17 at p. 9–10) HI recommended that DOE not mandate that the impeller diameter appear on the pump nameplate or marketing materials, asserting that this requirement has no impact on EPCA and increases manufacturer burden for global products. (HI, No. 20 at p. 9)

DOE agrees that if the pump is sold only as a unit including motor (with or without controls) and is not sold as a bare pump, then using the manufacturer's individual model number on the label rather than the bare pump model number would be appropriate. DOE also notes that in the current regulations, impeller diameter does not have to be provided if the pump is not transferred directly to an end user. However, DOE will address these comments and consider proposals related to them in a separate rulemaking.

DOE also requested comment on whether the term ''full impeller diameter'' should be modified to explicitly address pumps with multiple stages and varying impeller diameters, and if so, how. 86 FR 20075, 20085.

Grundfos and HI stated that the definition of ''full impeller diameter'' is sufficient for testing purposes but could be clarified to ensure that multi-stage products are properly included by a slight modification to the definition by adding an ''(s)'' to the phrase ''maximum diameter impeller.'' (Grundfos, No. 17 at p. 10) HI offered a similar solution, suggesting that the definition be modified as to refer to ''the maximum diameter impeller or *impellers (in the case of multistage pumps)* with which a given pump basic model is distributed in commerce.'' (HI, No. 20 at p. 9 (emphasis added)) Summit stated that it had no issue with the definition of ''full impeller diameter'' and did not request any changes. (Summit, No. 16 at p. 6)

After considering the submitted comments, DOE proposes to revise the definition of full impeller diameter to mean ''the maximum impeller diameter(s) with which a given pump

basic model is distributed in commerce.'' DOE notes that where a pump includes different-sized impellers for different stages, manufacturers may include the largest impeller size only, as well as sufficient identifying information in the individual model number to identify inclusion of reduced impeller sizes.

L. Test Procedure Costs and Harmonization

1. Test Procedure Costs and Impact

In this NOPR, DOE proposes to amend the existing test procedure at appendix A for pumps by: (1) Expanding the scope to include SVIL pumps; (2) expanding the scope to include other specified clean water pumps; (3) reducing the pump bowl diameter restriction to include more ST pumps; (4) changing the definitions of ESFM and ESCC pumps to cover all end-suction pumps; (5) incorporating a nominal speed of 1,200 rpm, in addition to 1,800 rpm and 3,600 rpm; (6) providing a calculation method for pumps sold with inverter-only motors; and (7) updating the part-load loss coefficients for pumps sold with induction motors. DOE has tentatively determined that the test procedure as proposed in this NOPR will not be unduly burdensome for manufacturers to conduct. Further discussion of the cost impacts of the test procedure amendments are presented in the following paragraphs.

As discussed in the April 2021 RFI, DOE received comments from stakeholders in response to the September 2020 Early Assessment RFI regarding costs to test pumps to the DOE test procedure. 86 FR 20075, 20082. Specifically, DOE noted HI's statement that, based on a survey of HI members, industry testing costs significantly exceeded DOE's estimates, and that wire-to-water testing represented 20 percent of total industry testing. *Id.* Comments from Grundfos were also noted by DOE in which Grundfos stated that approximately 45 percent of its testing was wire-to-water testing—specifically, for pumps sold with motors that can only operate when driven by an inverter (*i.e.,* inverter-only motors). *Id.* In response to the April 2021 RFI, DOE received additional comments specific to cost and burden of the current DOE pumps test procedure. Summit stated that testing cost has the largest impact to small businesses since the time that employees spend testing products is time that cannot be used to support the business in other ways (*i.e,* testing has high opportunity cost), but also stated that DOE has generally managed test burden for pumps well. (Summit, No. 16 at p. 7) HI stated that DOE's estimates of testing costs in the January 2016 Final Rule were too low based on data from HI member surveys. (HI, No. 20 at p. 1) HI also stated that some manufacturers have not been able to provide additional features due to testing requirements. (HI, No. 20 at p. 9)

Issue 47: DOE requests comment on the details of the pump features which have been limited due to the burdens imposed by DOE's current test procedure, including, but not limited to, the nature of the features that manufacturers have had to forego providing, the extent of the limits that manufacturers have had to place, and the manner in which manufacturers have had to apply these limits—such as on the basis of intended markets (*e.g.,* higher-end vs. budget-end). DOE also seeks information regarding how these burdens may be mitigated to reduce the likelihood of manufacturers from having to limit the inclusion of features with their pumps.

DOE notes that pump manufacturers must comply with the energy conservation standards that were established in 2016 and required beginning on January 27, 2020. 81 FR 4368 (January 26, 2016) (''January 2016 ECS Final Rule''). First-time compliance costs associated with meeting those energy conservation standards included testing costs, potential capital costs, and other one-time manufacturer costs associated with developing a testing and certification protocol. DOE also recognizes that the current test procedure does not provide a calculation method for pumps sold with motors that do not have a DOE energy efficiency standard; therefore, for pumps that rely on such motors, wire-to-water testing is required for each basic model. Finally, DOE notes that for all pumps currently subject to the energy conservation standards, the applicable energy efficiency values must be determined for all basic models according to the DOE test procedure, which includes the calculation method for certain pumps.

DOE notes that HI's response to the September 2020 Early Assessment RFI, included an estimate of the overall industry cost ($8.76 million) to test general pumps to certify compliance with the energy conservation standards established in the January 2016 ECS Final Rule. (HI, No. 6, at p. 2) Using its Compliance Certification Management System (''CCMS'') database, DOE estimates that a total of 2,745 basic models have been certified using the testing-based approach. Assuming that two individual pumps are tested to rate a basic model (the minimum as specified in 10 CFR 429.11, the number of pumps tested is 5,490. This results in an estimated per unit test cost of $1,600.[52]

A total of 6,645 basic models are included in DOE's CCMS database, which means that 3,900 basic models, or 59 percent, were certified using the calculation-based approach. DOE estimates that it will take a mechanical engineer two hours to calculate and determine a rating for each basic model. Assuming a fully burdened engineering hourly wage of $65.07,[53] DOE estimates the labor cost to perform the pump calculation method to be $130.14 per basic model. These cost estimates apply to the discussion in the following sections.

DOE has tentatively determined that the test procedure amendments proposed in this NOPR would impact testing costs as discussed in the following sections.

a. Scope Expansions

As stated previously, DOE is proposing to expand the scope of this test procedure to include SVIL pumps, other specified clean water pumps, ST pumps with bowl diameters greater than 6 inches, currently uncovered end-suction pumps, and pumps designed to operate with a 6-pole induction motor or with a non-induction motor with an operating range that includes speeds of rotation between 960 and 1,440 rpm. As these pumps would also be newly regulated equipment, DOE currently has no test procedures or standards for the equipment. The proposed test procedure and metrics would be consistent with the requirements established in the January 2016 Final Rule. DOE also assumed a sampling plan consistent with that for pumps currently subject to the test procedure, which requires a sample size of at least two units per pump basic model be tested when determining representative values of PEI, as well as other pump performance metrics.

[52] $8,784,000 (total testing costs) ÷ 5,490 (total number of pumps tested) = $1,600 (per pump tested).

[53] DOE used the mean hourly wage of $45.94, taken from BLS's ''Occupational Employment and Wages, May 2020'' using the Occupation Profile of ''Mechanical Engineers'' (17–2141). *See: www.bls.gov/oes/current/oes172141.htm.* Last accessed on December 8, 2021.

Additionally, DOE used data from the ''Employer Costs for Employee Compensation—June 2021'' to estimate that a Private Industry Worker's wages and salary are 70.6% of an employee's total compensation. *See: www.bls.gov/news.release/archives/ecec_09162021.pdf.* Last accessed on December 8, 2021.

Therefore, total employer hourly cost is $65.07 = $45.94 ÷ 0.706.

DOE recognizes that some manufacturers of these newly-covered pump categories may not manufacture general pumps, and therefore may not be currently testing pumps to the DOE test procedure. Manufacturers may opt to test their products either in-house or at a third-party laboratory. To estimate the test burden for newly-covered pumps as proposed in this TP NOPR, DOE assumed that manufacturers will test pumps in-house. In order to test a pump in-house, each manufacturer may have to undertake the construction and maintenance of a test facility that is capable of testing pumps in compliance with the test procedure, including acquisition and calibration of any necessary measurement equipment. DOE also assumed that manufacturers have a pump test facility available but may not have the equipment required to conduct the DOE test procedure and that the cost of purchasing such equipment is approximately $4,000 based on a review of available testing equipment on the market.

DOE assumes that for pump manufacturers who are member companies of HI or who conduct testing in accordance with the January 2016 Final Rule for other product offerings, these manufacturers already conduct testing in accordance with HI 40.6–2014 and would not incur any additional capital expenditures to be able to conduct the proposed DOE pump test procedure.

Pump manufacturers who are not members of HI may need to purchase electrical measurement equipment with ±2.0 percent accuracy to conduct the proposed pump test procedure. DOE estimates that calibrating the flowmeter, torque sensor, power quality meter, pressure transducer, and laser tachometer, together, will cost a manufacturer about $1,250 per year.

Issue 48: DOE requests comment on its assumptions and understanding of the anticipated impact and potential costs to pump manufacturers if DOE expands the scope of the general pumps test procedure. Additionally, DOE requests comment on any potential cost manufacturers may incur, if any, from this NOPR's proposed scope expansion.

b. Calculation Method for Testing Pumps With Inverter-Only Motors

In this NOPR, DOE is proposing a calculation method for testing pumps with inverter-only motors. The current test procedure does not include a calculation method for motors that do not have a DOE efficiency standard; therefore, manufacturers are required to conduct wire-to-water testing for pumps sold with these (*i.e.,* inverter) motors. Aside from the proposed calculation approach, the test procedure, metrics, and sampling plan for general pumps remains consistent with the requirements established in the January 2016 Final Rule and, among other things, require a sample size of at least two units per pump basic model be tested when determining representative values of PEI, as well as other pump performance metrics.

For general pumps already certified, DOE would not expect any additional costs to manufacturers. DOE has tentatively determined that the calculation method for inverter-only motors proposed in this NOPR would provide results that are conservative as compared to results from wire-to-water testing—consequently, DOE does not expect manufacturers will need to rerate their basic models. For new basic models where the bare pump is already certified (*i.e.,* the only change is in the inverter-only motor sold with the pump), DOE expects a manufacturer's cost to be the labor required to run the calculations (*i.e.,* $130.14 per basic model), providing an estimated savings of $3,070 per basic model (*i.e.,* test cost savings).[54] DOE expects that there would be no change in test cost for new bare pump basic models paired with an inverter-only motor, since the bare pump would need to be tested.

Issue 49: DOE requests comment on its assumptions and understanding of the anticipated impact and potential cost savings to manufacturers of pumps sold with inverter-only motors if DOE adopts the proposed calculation method. Additionally, DOE requests comment on any potential costs or savings that manufacturers may incur, if any, from this proposal.

c. Updated Calculation Method for Testing Pumps With Induction Motors

In this NOPR, DOE is proposing an updated calculation method for testing pumps with induction motors. The updated calculation method provides less conservative part-load loss coefficients than those provided in the current test procedure; however, DOE has tentatively determined that the proposed coefficients would still be conservative relative to wire-to-water testing. Aside from the proposed updated part-load motor coefficients, the test procedure, metrics, and sampling plan for general pumps remains consistent with the requirements established in the January 2016 Final Rule and, among other things, require a sample size of at least two units per pump basic model be tested when determining representative values of PEI, as well as other pump performance metrics.

For general pumps already certified, DOE would not expect any additional costs to manufacturers since the current calculation method provides the most conservative results. DOE expects that there will be no change in test cost for new bare pump basic models paired with an inverter-only motor, since the bare pump will need to be tested.

Issue 50: DOE requests comment on its assumptions and understanding that there will be no cost impact to manufacturers if DOE adopts the proposed updated coefficients for part-load motor losses. Additionally, DOE requests comment on any potential costs or savings that manufacturers may incur, if any, from this proposal.

d. Additional Amendments

DOE does not anticipate that the remaining amendments proposed in this NOPR, listed below, would impact test costs.

(1) Incorporate by reference HI 40.6–2021 into 10 CFR 431.463;

(2) Remove the incorporations by reference of ANSI/HI 1.1–1.2–2014 and ANSI/HI 2.1–2.2–2014;

DOE has tentatively determined that manufacturers would be able to rely on data generated under the current test procedure should any of these additional proposed amendments be finalized.

2. Harmonization With Industry Standards

DOE's established practice is to adopt relevant industry standards as DOE test procedures unless such methodology would be unduly burdensome to conduct or would not produce test results that reflect the energy efficiency, energy use, water use (as specified in EPCA) or estimated operating costs of that product during a representative average use cycle or period of use. *See* 10 CFR part 430, subpart C, appendix A, section 8(c). In cases where the industry standard does not meet EPCA's statutory criteria for test procedures, DOE will make modifications through the rulemaking process to these testing standards as needed to adopt the procedure as the DOE test procedure.

The test procedures for pumps at subpart Y incorporates by reference FM Class Number 1319, ANSI/HI 1.1–1.2–2014, ANSI/HI 2.1–2.2–2014, HI 40.6–2014, NFPA 20–2016, ANSI/UL 448–2013, and ANSI/UL 1081–2016. FM Class Number 1319, ANSI/HI 1.1–1.2–

[54] As previously stated, DOE estimated that the per unit test cost is $1,600 and at least two units need to be tested. Therefore, the calculation method is estimated to save approximately $3,070 = ($1,600 × 2) − $130.14.

2014, ANSI/HI 2.1–2.2–2014, NFPA 20–2016, ANSI/UL 448–2013, and ANSI/UL 1081–2016 all provide definitions for 10 CFR 431.462. HI 40.6–2014 provides test methods for the determinations of the energy efficiency of pumps. The industry standard DOE proposes to incorporate by reference via amendments described in this document are discussed in further detail in section IV.M of this document.

Issue 51: DOE requests comments on the benefits and burdens of the proposed updates and additions to industry standards referenced in the test procedure for pumps.

M. Compliance Date

EPCA prescribes that, if DOE amends a test procedure, all representations of energy efficiency and energy use, including those made on marketing materials and product labels, must be made in accordance with that amended test procedure, beginning 180 days after publication of such a test procedure final rule in the **Federal Register**. (42 U.S.C. 6314(d)(1)) To the extent the modified test procedure proposed in this document is required only for the evaluation and issuance of updated efficiency standards, use of the modified test procedure, if finalized, would not be required by manufacturers until the compliance date of any amended standards that DOE may set. 10 CFR 431.4; 10 CFR part 430, subpart C, appendix A, section 8(e).

Manufacturers of commercial and industrial pumps newly-covered under the proposed scope of the DOE pump test procedure, if finalized, would not be required to test such pumps to the proposed test procedure, if made final, until such time as compliance were required with energy conservation standards was required, should such standards be established. However, to the extent manufacturers choose to make voluntary representations as to the energy efficiency of such pumps, beginning 180 days following publication of the final test procedure, if finalized, any such representations would be required to be based on testing of the pumps in accordance with the finalized test procedure and such representation must fairly discloses the results of such testing. (42 U.S.C. 6314(d))

If DOE were to publish an amended test procedure, EPCA provides an allowance for individual manufacturers to petition DOE for an extension of the 180-day period if the manufacturer may experience undue hardship in meeting the deadline. (42 U.S.C. 6314(d)(2)) To receive such an extension, petitions must be filed with DOE no later than 60 days before the end of the 180-day period and must detail how the manufacturer will experience undue hardship. (*Id.*)

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866 and 13563

Executive Order (''E.O.'') 12866, 58 FR 51735 (Oct. 4, 1993), ''Regulatory Planning and Review,'' as supplemented and reaffirmed by E.O. 13563, ''Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 21, 2011), requires agencies, to the extent permitted by law, to (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public. DOE emphasizes as well that E.O. 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, the Office of Information and Regulatory Affairs (''OIRA'') in the Office of Management and Budget (''OMB'') has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. For the reasons stated in the preamble, this proposed regulatory action is consistent with these principles.

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

B. Review Under the Regulatory Flexibility Act

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

The following sections detail DOE's IRFA for this test procedure rulemaking:

1. Descriptions of Reasons Why Action Is Being Considered

DOE is proposing to amend the existing DOE test procedures for commercial and industrial pumps. DOE shall amend test procedures with respect to covered equipment, if the Secretary determines that amended test procedures would more accurately produce test results which measure energy efficiency, energy use, or estimated annual operating cost of a covered equipment during a representative average use cycle or period of use. (42 U.S.C. 6314(a)(2)) This proposed rulemaking is in accordance with DOE's obligations under EPCA.

2. Objectives of, and Legal Basis for, Rule

DOE is required to review existing DOE test procedures for all covered equipment every 7 years. (42 U.S.C. 6314(a)(1))

3. Description and Estimate of Small Entities Regulated

DOE has recently conducted a focused inquiry into small business manufacturers of the equipment covered by this proposed rulemaking. DOE used the SBA's small business size standards to determine whether any small entities would be subject to the requirements of

the rule. The size standards are listed by North American Industry Classification System (''NAICS'') code as well as by industry description and are available at *www.sba.gov/document/support—table-size-standards.* Manufacturing commercial and industrial pumps is classified under NAICS 333914, ''measuring, dispensing, and other pumping equipment manufacturing.'' The SBA sets a threshold of 750 employees or fewer for an entity to be considered as a small business for this category. DOE used available public information to identify potential small manufacturers. DOE accessed the Compliance Certification Database [55] to create a list of companies that import or otherwise manufacture the equipment covered by this proposal. Once DOE created a list of potential manufacturers, DOE used market research tools to determine whether any met the SBA's definition of a small entity, based on the total number of employees for each company including parent, subsidiary, and sister entities.

Based on DOE's analysis, 46 companies potentially selling commercial and industrial pumps covered by this proposed test procedure were identified. DOE screened out companies that do not meet the small entity definition and additionally screened out companies that are largely or entirely foreign owned and operated. Of the 46 companies, 21 were further identified as a small business. Based on a review of publicly available model databases, DOE estimated the number of models currently covered by the test procedure for each small business, excluding four small businesses not reflected in the model databases. DOE attributes a total of 779 unique basic models of covered pumps to small businesses, ranging from one model to 503 models for an average of approximately 46 models per small business. DOE was able to find revenue estimates for all 21 small businesses.

4. Description and Estimate of Compliance Requirements

DOE estimates that this proposed test procedure would not require any manufacturer to incur any additional testing burden associated with the proposed test procedure. If finalized, DOE recognizes that commercial and industrial pump energy conservation standards may be proposed or promulgated in the future and pump manufacturers would then be required to test all covered pumps in accordance with the proposed test procedures. (*See* Docket No. EERE–2020–BT–STD–0013) Therefore, although such is not yet required, DOE is presenting the costs associated with testing equipment and procedure consistent with the requirements of the proposed test procedure, as would be required to comply with any future energy conservation standards for pumps. Additionally, since the list of small businesses was drawn from manufacturers with products covered by the current test procedure, DOE assumes that each noted small business already possesses the necessary equipment for testing under the proposed test procedure. Impacts for each test procedure amendment are reviewed below:

SVIL Product Class Scope Expansion

DOE examined the websites and, when available, product catalogs of all previously identified 21 potential small businesses for listings of SVIL pumps. DOE identified three small businesses manufacturing SVIL pumps—producing an estimated total of 73 basic models, with one small business producing nine basic models, another producing as many as 56 basic models, and other small business producing eight basic models. DOE estimated that it would cost approximately $1,600 per unique basic model tested. Accordingly, all small businesses combined would incur costs of approximately $116,800—with the first small business incurring a cost of $14,400, the second incurring a cost of $89,600, and the third incurring a cost of $12,800.

DOE was able to find revenue estimates for both small businesses. Testing costs for newly-covered SVIL pumps would represent significantly less than one percent of estimated annual revenue for both small businesses.

Other Clean Water Pump Scope Expansion

DOE examined the websites and, when available, product catalogs of all previously identified 21 potential small businesses for listings of any of the clean water pumps that would be newly-covered under this proposed test procedure, if finalized. DOE identified five small businesses manufacturing clean water pumps potentially covered by this rulemaking that are not covered by the current test procedure. Although a newly-covered model count estimate was not possible for two small businesses, the remaining three small businesses produce an estimated total of 255 newly-covered basic models, with the first small business producing 189 basic models, the second producing 13 basic models, and the third producing 53 basic models. For the first small business, DOE conservatively estimated 65 newly-covered models of between-bearing pumps, 27 models of newly-covered vertical turbine pumps, and 97 models covered by the 1200 RPM scope expansion—excluding models also covered by the other scope expansions. The second small business produces approximately 13 models that would fall under the 1200 RPM scope expansion. For the third small business, approximately one-third of newly-covered unique basic models are submersible pumps and two-thirds are vertical turbine pumps, several of which also fall under the 1200 RPM scope expansion. DOE estimated that it would cost approximately $1,600 per unique basic model tested. Accordingly, the three small businesses combined would incur costs of approximately $408,000—with the first incurring a cost of $302,400, the second incurring accost of $20,800, and the third incurring a cost of $84,800. The first and second small businesses produce both SVIL pumps and newly-covered clean water pumps and would incur an approximate total testing cost of $315,200 and $35,200 respectively.

DOE was able to find revenue estimates for both small businesses. Testing costs for newly-covered clean water pumps would represent significantly less than one percent of estimated annual revenue for both small businesses.

Calculation Method Changes

Because, relative to the amended test procedure calculations, the proposed calculation changes are conservative, manufacturers would not have to recalculate or re-rate existing models. Accordingly, DOE does not anticipate that updating the part-load loss coefficients for pumps sold with induction motors or providing a calculation method for pumps sold with inverter-only motors would impose any costs on small businesses if the amended test procedures are adopted. Likewise, permitting the use of AEDMs in lieu of the calculation-based test is not expected to result in additional costs for affected small businesses, as they will continue to be able to employ the calculation-based test.

DOE requests comment on the number of small businesses DOE identified; the estimated number of covered models these small businesses manufacture; the per testing costs and total testing costs DOE estimated small businesses may incur to test models to appendix A; and any other potential

[55] U.S. Department of Energy Compliance Certification Database, available at: *www.regulations.doe.gov/certification-data.*

costs small businesses may incur due to the proposed amended test procedures, if finalized.

5. Duplication, Overlap, and Conflict With Other Rules and Regulations

DOE is not aware of any rules or regulations that duplicate, overlap, or conflict with the proposed rule being considered today.

6. Significant Alternatives to the Rule

As previously stated in this section, DOE is required to review existing DOE test procedures for all covered products and equipment every 7 years. Additionally, DOE shall amend test procedures with respect to any covered equipment, if the Secretary determines that amended test procedures would more accurately produce test results which measure energy efficiency, energy use, or estimated annual operating cost of a covered equipment type during a representative average use cycle or period of use. (42 U.S.C. 6314(a)(1)) DOE has initially determined that the proposed amendments for the existing DOE test procedure for commercial and industrial pumps would more accurately produce test results to measure the efficiency of this equipment.

DOE has tentatively determined that there are no better alternatives than the proposed amendments in terms of meeting the agency's objectives to measure energy efficiency more accurately and to reduce burden on manufacturers. Therefore, DOE is proposing in this NOPR to amend the existing DOE test procedure for commercial and industrial pumps.

Additional compliance flexibilities may be available through other means. Notably, section 504 of the Department of Energy Organization Act, 42 U.S.C. 7194, provides authority for the Secretary to adjust a rule issued under EPCA in order to prevent ''special hardship, inequity, or unfair distribution of burdens'' that may be imposed on that manufacturer as a result of such rule. Manufacturers should refer to 10 CFR part 430, subpart E, and part 1003 for additional details.

C. Review Under the Paperwork Reduction Act of 1995

Under the procedures established by the Paperwork Reduction Act of 1995 (''PRA''), a person is not required to respond to a collection of information by a Federal agency unless that collection of information displays a currently valid OMB Control Number.

OMB Control Number 1910–1400, Compliance Statement Energy/Water Conservation Standards for Appliances, is currently valid and assigned to the certification reporting requirements applicable to covered equipment, including pumps.

DOE's certification and compliance activities ensure accurate and comprehensive information about the energy and water use characteristics of covered products and covered equipment sold in the United States. Manufacturers of all covered products and covered equipment must submit a certification report before a basic model is distributed in commerce, annually thereafter, and if the basic model is redesigned in such a manner to increase the consumption or decrease the efficiency of the basic model such that the certified rating is no longer supported by the test data. Additionally, manufacturers must report when production of a basic model has ceased and is no longer offered for sale as part of the next annual certification report following such cessation. DOE requires the manufacturer of any covered product or covered equipment to establish, maintain, and retain the records of certification reports, of the underlying test data for all certification testing, and of any other testing conducted to satisfy the requirements of 10 CFR part 429, 10 CFR part 430, and/or 10 CFR part 431. Certification reports provide DOE and consumers with comprehensive, up-to date efficiency information and support effective enforcement.

Certification data would be required for pumps that would be covered under the proposed expansion of the test procedure scope at such time compliance is required with energy conservation standards for such pumps, should such standards be established; however, DOE is not proposing certification or reporting requirements for pumps in this NOPR. Instead, DOE may consider proposals to establish certification requirements and reporting for the pumps covered under the proposed expansion of the test procedure scope under a separate rulemaking regarding appliance and equipment certification. DOE will address changes to OMB Control Number 1910–1400 at that time, as necessary.

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

D. Review Under the National Environmental Policy Act of 1969

DOE is analyzing this proposed regulation in accordance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. DOE's regulations include a categorical exclusion for rulemakings interpreting or amending an existing rule or regulation that does not change the environmental effect of the rule or regulation being amended as well as a categorical exclusion for those rulemakings that are strictly procedural. *See* 10 CFR part 1021, appendix A to subpart D, A5 and A6. In this NOPR, DOE proposes test procedure amendments that it expects will be used to develop and implement future energy conservation standards for pumps. DOE has determined that this rule falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. Specifically, DOE has tentatively determined that adopting test procedures for measuring energy efficiency of consumer products and industrial equipment is consistent with activities identified in 10 CFR part 1021, appendix A to subpart D, A5 and A6. *See also* 10 CFR 1021.410. DOE will complete its NEPA review before issuing the final rule.

E. Review Under Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (Aug. 10, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this proposed rule and has determined that it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various

levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this proposed rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297(d)) No further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

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

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (''UMRA'') requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820; also available at *www.energy.gov/gc/office-general-counsel.* DOE examined this proposed rule according to UMRA and its statement of policy and determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of $100 million or more in any year, so these requirements do not apply.

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

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This proposed rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

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

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

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

K. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

The proposed regulatory action to amend the test procedure for measuring the energy efficiency of pumps is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

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

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91; 42 U.S.C. 7101), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977. (15 U.S.C.

788; ''FEAA'') Section 32 essentially provides in relevant part that, where a proposed rule authorizes or requires use of commercial standards, the notice of proposed rulemaking must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the Attorney General and the Chairman of the Federal Trade Commission (''FTC'') concerning the impact of the commercial or industry standards on competition.

The proposed modifications to the test procedure for pumps would incorporate testing methods contained in certain sections of the following commercial standards: HI 40.6–2021. DOE has evaluated these standards and is unable to conclude whether they fully comply with the requirements of section 32(b) of the FEAA (*i.e.,* whether it was developed in a manner that fully provides for public participation, comment, and review.) DOE will consult with both the Attorney General and the Chairman of the FTC concerning the impact of these test procedures on competition, prior to prescribing a final rule.

M. Description of Materials Incorporated by Reference

In this NOPR, DOE proposes to incorporate by reference the test standard published by The Hydraulic Institute titled ''HI 40.6–2021, Methods for Rotodynamic Pump Efficiency Testing.'' HI 40.6–2021 is an industry-accepted test procedure for measuring the performance of rotodynamic pumps. The test procedure proposed in this NOPR references various sections of HI 40.6–2021 that address test setup, instrumentation, test conduct, and calculations. Copies of HI 40.6–2021 can be obtained from the Hydraulic Institute at 6 Campus Drive, First Floor North, Parsippany, NJ, 07054–4406, or by going to *www.pumps.org.*

V. Public Participation

A. Participation in the Webinar

The time and date for the webinar meeting are listed in the **DATES** section at the beginning of this document. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's website: *www.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=41.* Participants are responsible for ensuring their systems are compatible with the webinar software.

B. Procedure for Submitting Prepared General Statements for Distribution

Any person who has an interest in the topics addressed in this document, or who is representative of a group or class of persons that has an interest in these issues, may request an opportunity to make an oral presentation at the webinar. Such persons may submit to *ApplianceStandardsQuestions@ee.doe.gov.* Persons who wish to speak should include with their request a computer file in WordPerfect, Microsoft Word, PDF, or text (ASCII) file format that briefly describes the nature of their interest in this rulemaking and the topics they wish to discuss. Such persons should also provide a daytime telephone number where they can be reached.

DOE requests persons selected to make an oral presentation to submit an advance copy of their statements at least two weeks before the webinar. At its discretion, DOE may permit persons who cannot supply an advance copy of their statement to participate, if those persons have made advance alternative arrangements with the Building Technologies Office. As necessary, requests to give an oral presentation should ask for such alternative arrangements.

C. Conduct of the Webinar

DOE will designate a DOE official to preside at the webinar/public meeting and may also use a professional facilitator to aid discussion. The meeting will not be a judicial or evidentiary-type public hearing, but DOE will conduct it in accordance with section 336 of EPCA (42 U.S.C. 6306). A court reporter will be present to record the proceedings and prepare a transcript. DOE reserves the right to schedule the order of presentations and to establish the procedures governing the conduct of the webinar/public meeting. There shall not be discussion of proprietary information, costs or prices, market share, or other commercial matters regulated by U.S. anti-trust laws. After the webinar/public meeting and until the end of the comment period, interested parties may submit further comments on the proceedings and any aspect of the rulemaking.

The webinar will be conducted in an informal, conference style. DOE will present a general overview of the topics addressed in this proposed rulemaking, allow time for prepared general statements by participants, and encourage all interested parties to share their views on issues affecting this proposed rulemaking. Each participant will be allowed to make a general statement (within time limits determined by DOE), before the discussion of specific topics. DOE will permit, as time permits, other participants to comment briefly on any general statements.

At the end of all prepared statements on a topic, DOE will permit participants to clarify their statements briefly. Participants should be prepared to answer questions by DOE and by other participants concerning these issues. DOE representatives may also ask questions of participants concerning other matters relevant to this proposed rulemaking. The official conducting the webinar/public meeting will accept additional comments or questions from those attending, as time permits. The presiding official will announce any further procedural rules or modification of the above procedures that may be needed for the proper conduct of the webinar/public meeting.

A transcript of the webinar will be included in the docket, which can be viewed as described in the *Docket* section at the beginning of this document. In addition, any person may buy a copy of the transcript from the transcribing reporter.

D. Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule no later than the date provided in the **DATES** section at the beginning of this proposed rule.[56] Interested parties may submit comments using any of the methods described in the **ADDRESSES** section at the beginning of this document.

Submitting comments via www.regulations.gov. The *www.regulations.gov* web page will require you to provide your name and

[56] DOE has historically provided a 75-day comment period for test procedure NOPRs pursuant to the North American Free Trade Agreement, U.S.-Canada-Mexico (''NAFTA''), Dec. 17, 1992, 32 I.L.M. 289 (1993); the North American Free Trade Agreement Implementation Act, Public Law 103–182, 107 Stat. 2057 (1993) (codified as amended at 10 U.S.C.A. 2576) (1993) (''NAFTA Implementation Act''); and Executive Order 12889, ''Implementation of the North American Free Trade Agreement,'' 58 FR 69681 (Dec. 30, 1993). However, on July 1, 2020, the Agreement between the United States of America, the United Mexican States, and the United Canadian States (''USMCA''), Nov. 30, 2018, 134 Stat. 11 (*i.e.,* the successor to NAFTA), went into effect, and Congress's action in replacing NAFTA through the USMCA Implementation Act, 19 U.S.C. 4501 *et seq.* (2020), implies the repeal of E.O. 12889 and its 75-day comment period requirement for technical regulations. Thus, the controlling laws are EPCA and the USMCA Implementation Act. Consistent with EPCA's public comment period requirements for consumer products, the USMCA only requires a minimum comment period of 60 days. Consequently, DOE now provides a 60-day public comment period for test procedure NOPRs.

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

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

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

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

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

Include contact information each time you submit comments, data, documents, and other information to DOE. No faxes will be accepted.

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

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

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

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

E. Issues on Which DOE Seeks Comment

Although DOE welcomes comments on any aspect of this proposal, DOE is particularly interested in receiving comments and views of interested parties concerning the following issues:

Issue 1: Consistent with the Circulator Pump Working Group recommendation and based on the concerns expressed in the comments summarized above regarding SVILs being a part of the same model family as IL pumps and serving as an unregulated alternative to pumps currently subject to DOE test procedures and energy conservation standards, DOE proposes to include SVIL pumps within the test procedure's scope. DOE has tentatively determined that SVIL pumps can be tested using the current DOE pumps test procedure with certain additional modifications The proposed test procedure and metric for SVIL pumps are discussed in sections III.G and III.D of this document. Moreover, DOE expects that including SVIL pumps within the scope of the pumps test procedure would reduce confusion over which inline pumps are and are not regulated. DOE requests comment on its proposal to expand the scope of the test procedure to cover SVIL pumps.

Issue 2: DOE requests comment on its proposal to expand the current test procedure's scope to include BB pumps. Additionally, DOE requests comment on the repeatability and representativeness of testing BB pumps using the current DOE test procedure. DOE also requests comment on any additional burdens associated with testing BB pumps that are different from those burdens associated with pumps currently covered by the DOE test procedure.

Issue 3: DOE requests comment on its proposal to expand the current test procedure's scope to include VT pumps. Additionally, DOE requests comment on the repeatability and representativeness of testing VT pumps using the current DOE test procedure. DOE also requests comment on any additional burdens associated with testing VT pumps that differ from those burdens associated with pumps currently covered by the DOE test procedure.

Issue 4: DOE requests comment on its proposal to expand scope to include RSH pumps. Additionally, DOE requests comment on the repeatability and representativeness of testing RSH pumps using the current DOE test procedure. DOE also requests comment on any additional burdens associated with testing RSH pumps which are different from those burdens associated with pumps currently covered by the DOE test procedure.

Issue 5: DOE requests comment on its tentative determination that there are certain ends suction pumps excluded from the current test procedure due to the ESFM and ESCC definitions. DOE also requests comment on the number of pump models that may fall into this category and whether they are currently being tested according to the DOE test procedure.

Issue 6: DOE requests comment on its proposal to remove the 6-inch maximum bowl diameter restriction from ST pumps, including whether there are any testing limitations for larger bowl diameters.

Issue 7: DOE requests comment on its proposal to expand the scope of the test procedure to include pumps designed to operate with a 6-pole induction motor, and pumps designed to operate with non-induction motors with an operating

range that includes speeds of rotation between 960 rpm and 1,440.

Issue 8: DOE requests comment on its tentative determination that incorporating SVILs into the test procedure will largely eliminate the issue of higher speed 1 hp pumps falling out of scope when they rate at a nominal speed of 3600 rpm.

Issue 9: DOE seeks comment on its proposal to clarify the scope of the pumps test procedure with respect to design temperature. Specifically, DOE requests comment on whether 15 °F and 250 °F are more appropriate than 14 °F and 248 °F, or whether other minor adjustments could be made to the range to assist with clarity and enforceability.

Issue 10: DOE requests comment on the proposed changes to the definitions for ''in-line pump'' and ''end-suction pump'' to remove the distinction that liquid is discharged ''through a volute''.

Issue 11: DOE requests comment on the proposed changes to the definitions for ESCC, ESFM, IL, RSV, and ST pumps to remove references to ANSI/HI 1.1–1.2–2014 pump classes. Specifically, DOE requests comment on the ability of the modified definitions to clearly communicate the intended pump categories to industry stake holders.

Issue 12: DOE requests comment on the proposed change to the definition of bowl diameter to include a more specific definition of intermediate bowl instead of referring to the term as defined in ANSI/HI 1.1–1.2–2014.

Issue 13: DOE also proposes to revise the IL definition to explicitly exclude circulator pumps. DOE requests comment on its proposed definitions for ''small vertical in-line pumps'' and ''small vertical twin-head pump.''

Issue 14: DOE requests comment on the percentage of SVIL pumps, if any, that are not sold with a motor, and whether the definition of SVIL pump should be limited to those sold with a motor.

Issue 15: DOE requests comment on its proposed revision to the IL pump definition to explicitly exclude circulator pumps.

Issue 16: DOE requests comment on its proposed definition for between-bearing pumps, specifically if it is sufficient to identify the intended scope.

Issue 17: DOE request comment on the proposed definition for axially-split pump.

Issue 18: DOE requests comment on the proposed definition for vertical turbine pump.

Issue 19: DOE requests comment on the proposed definitions for RSH, RSHIL, and RSHES pumps—particularly whether they are sufficient to identify the intended scope of such pumps as discussed in section III.A.3.c of this document.

Issue 20: DOE requests comment on the proposed definitional changes to ESFM and ESCC pumps in defining both categories based on the location of the bearings which bear the axial load of the pump. Specifically, DOE seeks comment on whether these proposed changes will capture the end-suction pumps identified by stakeholders as not currently meeting the ESCC or ESFM definitions.

Issue 21: DOE requests comment on its proposal that pumps designed to operate between 960 and 1,440 rpm or with 6-pole motors be assigned a nominal speed of 1,200 rpm.

Issue 22: DOE requests comment on the proposed number of stages for testing RSH, VT, and BB pumps.

Issue 23: DOE requests comment on whether the alternate flow points for pumps with BEP at run-out should be determined with respect to expected maximum flow rate or expected BEP flow rate.

Issue 24: DOE requests comment on how manufacturers are currently performing motor sizing for bare pumps with BEP at run-out, and whether using 100 percent of the BEP flow rate is appropriate.

Issue 25: DOE requests comment on whether manufacturers would use a hybrid mapping approach, and if so, whether manufacturers would conduct the motor tests or request the tests from their suppliers. In addition, DOE requests comment on what additional provisions would need to be added to Appendix H of AMCA 214 to make it applicable to pumps, such as speed and load corresponding to pump rating points.

Issue 26: DOE requests: (1) Data indicating whether AHRI 1210-certified data is applicable to pumps; (2) data indicating whether 15 percent and 25 percent incremental losses, which are specified as part of IE3 ratings that are not commonly used in the U.S., are applicable to the U.S. and do not overstate performance, and if not, what incremental losses would be appropriate to apply, and (3) data indicating an appropriate VFD efficiency penalty by hp.

Issue 27: DOE requests comment on its proposed part-load loss factors for induction motors and controls greater than 50 hp.

Issue 28: DOE requests comment on whether inverter-only motors used by pump manufacturers are typically tested in accordance with IEC 61800–9–2:2017.

Issue 29: DOE requests comment on its proposed inverter-only part-load loss coefficients. DOE specifically requests comment on the appropriateness of the delta used to derive these coefficients as well as any other available comparable motor data with which DOE could vet these coefficients.

Issue 30: DOE requests comment on the merits of using a hybrid mapping approach for inverter-only motors and whether it would reduce or increase manufacturer burden compared to the current proposals.

Issue 31: DOE requests comment on its proposal to apply PEI_{VL} to pumps sold with inverter-only synchronous motors without controls, including application of the testing method in section VI of appendix A and the calculation method in section VII of appendix A.

Issue 32: DOE requests comment on its proposal for the calculation-based approach for pumps sold with submersible pumps to require use of the rated motor efficiency marked on the nameplate that has been tested in accordance with the relevant DOE test procedure after such time as compliance is required with an energy conservation standard for submersible motors, should such a standard be established.

Issue 33: DOE seeks comment on whether the efficiency standards found at 10 CFR 431.446 are appropriate for use in the determination of PER_{STD} for SVILs, whether certain motor topologies that would be classified as SNEM are more prevalent and significantly less efficient, and whether the minimum efficiency of the polyphase and CSCR/CSIR standards for the relevant number of poles and motor horsepower is appropriate or whether there should be differences depending on the phase of the motor with which the pump is sold.

Issue 34: DOE seeks comment on: (1) How many models of SVILs are sold with motors with a nominal horsepower less than 0.25 hp, (2) whether such motors could be tested in accordance with the relevant test procedures in 10 CFR 431.446 or proposed in the Motors TP NOPR, and if not, how such motors are tested, and (3) whether the efficiency values in Table III.3 are appropriate for such motors, and if not, how those values should be determined.

Issue 35: DOE seeks comment on its proposal to require testing of SVIL pumps distributed in commerce with motors not regulated by DOE's current electric motor regulations or any motor regulations finalized after January 1, 2022. DOE also seeks comment on whether it should allow such pumps to be rated as bare pumps only if any motor regulations finalized after January

1, 2022, do not include SNEMs and inverter-only synchronous electric motors.

Issue 36: DOE seeks comment on whether the market for SVIL pumps has changed such that the data collected by DOE in 2017 would no longer be applicable, and whether the use of AEDM would address concerns related to part-load loss curves specific to low-horsepower motors.

Issue 37: DOE requests comment on whether the proposed test procedure is appropriate for BB, RSH, and VT pumps.

Issue 38: DOE seeks comment on whether BB, RSH, and VT pumps are typically sold with motors not subject to the energy conservation standards in 10 CFR 431.25 or synchronous inverter-only electric motors, and if so, what kind of motors they are sold with, and what calculation modifications would be needed to accommodate such motors.

Issue 39: DOE requests comment and data on the proposed default submersible motor efficiency values for 6-pole motors.

Issue 40: DOE request comment on its tentative determinations that SVIL, BB, RSH, VT, and pumps tested at a nominal speed of 1,200 rpm have the same testing uncertainty and manufacturing variability as currently regulated pumps. DOE also requests comment on its proposal to adopt the same statistical sampling plans which are currently in place for commercial industrial pumps for SVIL, BB, RSH, VT, and pumps tested at a nominal speed of 1,200 rpm.

Issue 41: DOE requests comment on the proposed statistical sampling procedures and certification requirements.

Issue 42: DOE requests feedback regarding all aspects of its proposal to permit use of an AEDM for general pumps, and any data or information comparing modeled performance with the results of physical testing. DOE specifically seeks comment on its proposed validation classes, and whether groupings should be considered where performance variation between two equipment classes or nominal speeds is well established. In addition, DOE requests comment on whether the calculation-based methods would still be necessary if manufacturers were permitted to use AEDMs in addition to physical testing.

Issue 43: DOE requests comment on its proposal related to enforcement provisions.

Issue 44: DOE requests comment on the proposed amendments to the definition of basic model.

Issue 45: DOE requests comment on its proposal to adopt optional test provisions for the measurement of several other circulator pump metrics, including overall (wire-to-water) efficiency, driver power input, and/or pump power output (hydraulic horsepower).

Issue 46: DOE also requests comment on its understanding that HI 40.6–2021 contains all the necessary methods to determine overall (wire-to-water) efficiency, driver power input, and/or pump power output (hydraulic horsepower) and that further specification is not necessary.

Issue 47: DOE requests comment on the details of the pump features which have been limited due to the burdens imposed by DOE's current test procedure, including, but not limited to, the nature of the features that manufacturers have had to forego providing, the extent of the limits that manufacturers have had to place, and the manner in which manufacturers have had to apply these limits—such as on the basis of intended markets (*e.g.* higher-end vs. budget-end). DOE also seeks information regarding how these burdens may be mitigated to reduce the likelihood of manufacturers from having to limit the inclusion of features with their pumps.

Issue 48: DOE requests comment on its assumptions and understanding of the anticipated impact and potential costs to pump manufacturers if DOE expands the scope of the general pumps test procedure. Additionally, DOE requests comment on any potential cost manufacturers may incur, if any, from this NOPR's proposed scope expansion.

Issue 49: DOE requests comment on its assumptions and understanding of the anticipated impact and potential cost savings to manufacturers of pumps sold with inverter-only motors if DOE adopts the proposed calculation method. Additionally, DOE requests comment on any potential costs or savings that manufacturers may incur, if any, from this proposal.

Issue 50: DOE requests comment on its assumptions and understanding that there will be no cost impact to manufacturers if DOE adopts the proposed updated coefficients for part-load motor losses. Additionally, DOE requests comment on any potential costs or savings that manufacturers may incur, if any, from this proposal.

Issue 51: DOE requests comments on the benefits and burdens of the proposed updates and additions to industry standards referenced in the test procedure for pumps.

VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notice of proposed rulemaking and announcement of public webinar.

List of Subjects

10 CFR Part 429

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Intergovernmental relations, Reporting and recordkeeping requirements, Small businesses.

10 CFR Part 431

Administrative practice and procedure, Confidential business information, Energy conservation test procedures, Incorporation by reference, Reporting and recordkeeping requirements.

Signing Authority

This document of the Department of Energy was signed on March 17, 2022, by Kelly J. Speakes-Backman, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on March 18, 2022.

Treena V. Garrett,

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

For the reasons stated in the preamble, DOE is proposing to amend parts 429 and 431 of chapter II of title 10, Code of Federal Regulations as set forth below:

PART 429—CERTIFICATION, COMPLIANCE, AND ENFORCEMENT FOR CONSUMER PRODUCTS AND COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 429 continues to read as follows:

Authority: 42 U.S.C. 6291–6317; 28 U.S.C. 2461 note.

■ 2. Amend § 429.59 by:
■ a. Revising the introductory text of paragraph (a); and
■ b. Adding paragraphs (a)(2)(iv) and (a)(3).

The revision and additions read as follows:

§ 429.59 Pumps.

(a) *Determination of represented value.* Manufacturers must determine the represented value, which includes the certified rating, for each basic model of general purpose pump either by testing (which includes the calculation-based methods in the test procedure), in conjunction with the following sampling provisions, or by application of an AEDM that meets the requirements of § 429.70 and the provisions of this section. Manufacturers must determine the represented value, which includes the certified rating, for each basic model of dedicated-purpose pool pump by testing, in conjunction with the following sampling provisions. Manufacturers must update represented values to account for any change in the applicable motor standards in subpart B of part 431 of this chapter and certify amended values as of the next annual certification.

* * * * *

(2) * * *

(iv) *General pumps.* The representative values for pump total head in feet at BEP and nominal speed, volume per unit time in gallons per minute at BEP and nominal speed, and calculated driver power input at each load point must be the arithmetic mean of the value determined for each tested unit of general pump.

(3) Alternative efficiency determination methods. In lieu of testing, a represented value of efficiency or consumption for a basic model of pump must be determined through the application of an AEDM pursuant to the requirements of § 429.70 and the provisions of this section, where:

(i) Any represented value of energy consumption or other measure of energy use of a basic model for which consumers would favor lower values shall be greater than or equal to the output of the AEDM and less than or equal to the Federal standard for that basic model; and

(ii) Any represented value of energy efficiency or other measure of energy consumption of a basic model for which consumers would favor higher values shall be less than or equal to the output of the AEDM and greater than or equal to the Federal standard for that basic model.

* * * * *

■ 3. Amend § 429.70 by adding paragraph (i) to read as follows:

§ 429.70 Alternative methods for determining energy efficiency and energy use.

* * * * *

(i) Alternative efficiency determination method (AEDM) for general pumps—(1) *Criteria an AEDM must satisfy.* A manufacturer may not apply an AEDM to a basic model to determine its efficiency pursuant to this section, unless:

(i) The AEDM is derived from a mathematical model that estimates the energy efficiency or energy consumption characteristics of the basic model as measured by the applicable DOE test procedure;

(ii) The AEDM is based on engineering or statistical analysis, computer simulation or modeling, or other analytic evaluation of performance data; and

(iii) The manufacturer has validated the AEDM, in accordance with paragraph (i)(2) of this section.

(2) *Validation of an AEDM.* Before using an AEDM, the manufacturer must validate the AEDM's accuracy and reliability as follows:

(i) *AEDM overview.* The manufacturer must select at least the minimum number of basic models for each validation class specified in paragraph (i)(2)(iv) of this section to which the particular AEDM applies. Using the AEDM, calculate the PEI for each of the selected basic models. Test each basic model and determine the represented value(s) in accordance with § 429.63(a). Compare the results from the testing and the AEDM output according to paragraph (i)(2)(ii) of this section. The manufacturer is responsible for ensuring the accuracy and repeatability of the AEDM.

(ii) *AEDM basic model tolerances.* (A) The predicted representative PEI for each basic model calculated by applying the AEDM may not be more than five percent less than the represented PEI determined from the corresponding test of the model.

(B) The predicted constant or variable load pump energy index for each basic model calculated by applying the AEDM must meet or exceed the applicable federal energy conservation standard.

(iii) *Additional test unit requirements.* (A) Each AEDM must be supported by test data obtained from physical tests of current models; and

(B) Test results used to validate the AEDM must meet or exceed current, applicable Federal standards as specified in part 431 of this chapter; and

(C) Each test must have been performed in accordance with the applicable DOE test procedure with which compliance is required at the time the basic models used for validation are distributed in commerce.

(iv) *Pump validation classes.*

Validation class	Minimum number of distinct basic models that must be tested
Constant Load End-suction Closed-Coupled Pumps and Constant Load End-suction Frame-Mounted Pumps	2 Basic Models.
Variable Load End-suction Closed-Coupled Pumps and Variable Load End-suction Frame-Mounted Pumps	2 Basic Models.
Constant Load Inline Pumps and Constant Load Small Volute Inline Pumps	2 Basic Models.
Variable Load Inline Pumps and Variable Load Small Volute Inline Pumps	2 Basic Models.
Constant Load Radially-Split Multi-Stage Vertical Pumps and Constant Load Radially-Split Multi-Stage Horizonal Pumps	2 Basic Models.
Variable Load Radially-Split Multi-Stage Vertical Pumps and Variable Load Radially-Split Multi-Stage Horizontal Pumps	2 Basic Models.
Constant Load Submersible Turbine Pumps and Constant Load Vertical Turbine Pumps	2 Basic Models.
Variable Load Submersible Turbine Pumps and Variable Load Vertical Turbine Pumps	2 Basic Models.
Constant Load Between-Bearing Pumps	2 Basic Models.
Variable Load Between-Bearing Pumps	

(3) *AEDM Records Retention Requirements.* If a manufacturer has used an AEDM to determine representative values pursuant to this section, the manufacturer must have available upon request for inspection by the Department records showing:

(i) The AEDM, including the mathematical model, the engineering or statistical analysis, and/or computer simulation or modeling that is the basis of the AEDM;

(ii) Regarding the units tested that were used to validate the AEDM pursuant to paragraph (i)(2) of this

section, equipment information, complete test data, AEDM calculations, and the statistical comparisons; and

(iii) For each basic model to which the AEDM was applied, equipment information and AEDM calculations.

(4) *Additional AEDM requirements.* If requested by the Department, the manufacturer must:

(i) Conduct simulations before representatives of the Department to predict the performance of particular basic models of the equipment to which the AEDM was applied;

(ii) Provide analyses of previous simulations conducted by the manufacturer; and/or

(iii) Conduct certification testing of basic models selected by the Department.

(5) AEDM verification testing. DOE may use the test data for a given individual model generated pursuant to § 429.104 to verify the certified rating determined by an AEDM as long as the following process is followed:

(i) *Selection of units.* DOE will obtain units for test from retail, where available. If units cannot be obtained from retail, DOE will request that a unit be provided by the manufacturer.

(ii) *Lab requirements.* DOE will conduct testing at an independent, third-party testing facility of its choosing. In cases where no third-party laboratory is capable of testing the equipment, it may be tested at a manufacturer's facility upon DOE's request.

(iii) *Manufacturer participation.* Testing will be performed without manufacturer representatives on-site.

(iv) *Testing.* All verification testing will be conducted in accordance with the applicable DOE test procedure, as well as each of the following to the extent that they apply:

(A) Any active test procedure waivers that have been granted for the basic model;

(B) Any test procedure guidance that has been issued by DOE;

(C) If during test set-up or testing, the lab indicates to DOE that it needs additional information regarding a given basic model in order to test in accordance with the applicable DOE test procedure, DOE may organize a meeting between DOE, the manufacturer and the lab to provide such information.

(D) At no time during the process may the lab communicate directly with the manufacturer without DOE present.

(v) *Failure to meet certified rating.* If a model's test results are worse than its certified rating by an amount exceeding the tolerance prescribed in paragraph (f)(5)(vi) of this section, DOE will notify the manufacturer. DOE will provide the manufacturer with all documentation related to the test set up, test conditions, and test results for the unit. Within the timeframe allotted by DOE, the manufacturer may then present all claims regarding testing validity.

(vi) *Tolerances.* For consumption metrics, the result from a DOE verification test must be less than or equal to the certified rating × (1 + the applicable tolerance).

TABLE 4 TO PARAGRAPH (I)(5)(VI)

Equipment	Metric	Applicable tolerance (%)
General Pumps	Constant or Variable Load Pump Energy Index	5

(vii) *Invalid rating.* If, following discussions with the manufacturer and a retest where applicable, DOE determines that the testing was conducted appropriately in accordance with the DOE test procedure, the rating for the model will be considered invalid. The manufacturer must conduct additional testing and re-rate and re-certify the basic models that were rated using the AEDM based on all test data collected, including DOE's test data.

(viii) *AEDM use.* This paragraph (i)(5)(viii) specifies when a manufacturer's use of an AEDM may be restricted due to prior invalid represented values.

(A) If DOE has determined that a manufacturer made invalid ratings on two or more models rated using the same AEDM within a 24 month period, the manufacturer must take the action listed in the table corresponding to the number of invalid certified ratings. The twenty-four month period begins with a DOE determination that a rating is invalid through the process outlined above. Additional invalid ratings apply for the purposes of determining the appropriate consequences if the subsequent determination(s) is based on selection of a unit for testing within the twenty-four month period (*i.e.,* subsequent determinations need not be made within 24 months).

TABLE 5 TO PARAGRAPH (i)(5)(viii)(A)

Number of invalid certified ratings from the same AEDM [1] within a rolling 24-month period [2]	Required manufacturer actions
2	Submit different test data and reports from testing to validate that AEDM within the validation classes to which it is applied.[3] Adjust the ratings as appropriate.
4	Conduct double the minimum number of validation tests for the validation classes to which the AEDM is applied. Note, the tests required under this paragraph (i)(5)(viii) must be performed on different models than the original tests required under paragraph (i)(2) of this section.
6	Conduct the minimum number of validation tests for the validation classes to which the AEDM is applied at a third-party test facility; And Conduct additional testing, which is equal to ½ the minimum number of validation tests for the validation classes to which the AEDM is applied, at either the manufacturer's facility or a third-party test facility, at the manufacturer's discretion. Note, the tests required under this paragraph (i)(5)(viii) must be performed on different models than the original tests performed under paragraph (i)(2) of this section.

TABLE 5 TO PARAGRAPH (i)(5)(viii)(A)—Continued

Number of invalid certified ratings from the same AEDM [1] within a rolling 24-month period [2]	Required manufacturer actions
> = 8	Manufacturer has lost privilege to use AEDM. All ratings for models within the validation classes to which the AEDM applied should be rated via testing. Distribution cannot continue until certification(s) are corrected to reflect actual test data.

[1] The ''same AEDM'' means a computer simulation or mathematical model that is identified by the manufacturer at the time of certification as having been used to rate a model or group of models.

[2] The twenty-four month period begins with a DOE determination that a rating is invalid through the process outlined above. Additional invalid ratings apply for the purposes of determining the appropriate consequences if the subsequent determination(s) is based on testing of a unit that was selected for testing within the twenty-four month period (*i.e.,* subsequent determinations need not be made within 24 months).

[3] A manufacturer may discuss with DOE's Office of Enforcement whether existing test data on different basic models within the validation classes to which that specific AEDM was applied may be used to meet this requirement.

(B) If, as a result of eight or more invalid ratings, a manufacturer has lost the privilege of using an AEDM for rating, the manufacturer may regain the ability to use an AEDM by:

(*1*) Investigating and identifying cause(s) for failures;

(*2*) Taking corrective action to address cause(s);

(*3*) Performing six new tests per validation class, a minimum of two of which must be performed by an independent, third-party laboratory to validate the AEDM; and

(*4*) Obtaining DOE authorization to resume use of the AEDM.

■ 3. Section 429.134 is amended by revising paragraph (i)(1)(ii):

§ 429.134 Product-specific enforcement provisions.

* * * * *

(i) * * *

(1) * * *

(ii) DOE will test each pump unit according to the test method specified by the manufacturer in the certification report submitted pursuant to § 429.59(b); if the model of pump unit was rated using an AEDM, DOE may use either a testing approach or calculation approach.

* * * * *

PART 431—ENERGY EFFICIENCY PROGRAM FOR CERTAIN COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 4. The authority citation for part 431 continues to read as follows:

Authority: 42 U.S.C. 6291–6317; 28 U.S.C. 2461 note.

■ 5. Amend § 431.462 by:

■ a. Revising the introductory text;

■ b. Adding in alphabetical order the definition for ''Axially-split pump'';

■ c. Revising the definition for ''Basic model'';

■ d. Adding in alphabetical order the definition for ''Between-bearing pump'';

■ e. Revising the definitions for ''Bowl diameter'', ''Close-coupled pump'',

■ f. Removing the definitions for ''End suction close-coupled (ESCC) pump'', ''End suction frame mounted/own bearings (ESFM) pump'', ''End suction pump'', and adding, in their respective places, the definitions for ''End-suction close-coupled (ESCC) pump'', ''End-suction frame mounted/own bearings (ESFM) pump'', and ''End-suction pump;

■ g. Revising the definition for ''In-line (IL) pump'';

■ h. Adding in alphabetical order the definition for ''Intermediate bowl'';

■ i. Revising the definition for ''Mechanically-coupled pump'';

■ j. Adding in alphabetical order the definitions for ''Radially-split, multi-stage, horizontal, diffuser casing (RSH) pump'', ''Radially-split, multi-stage, horizontal, end-suction diffuser casing (RSHES) pump'', ''Radially-split, multi-stage, horizontal, in-line diffuser casing (RSHIL) pump'';

■ k. Removing the definition for ''Radially split, multi-stage, vertical, diffuser casing (RSV) pump'' and adding, in its place, the definition for ''Radially-split, multi-stage, vertical, diffuser casing (RSV) pump''

■ j. Adding in alphabetical order the definitions for ''Small vertical in-line (SVIL) pump''; ''Small vertical twin-head pump'';

■ k. Revising the definition for ''Submersible turbine (ST) pump''; and

■ l. Adding in alphabetical order the definition for ''Vertical turbine pump''.

The revisions and additions read as follows:

§ 431.462 Definitions.

The following definitions are applicable to this subpart, including appendices A, B, and C. In cases where definitions reference design intent, DOE will consider marketing materials, labels and certifications, and equipment design to determine design intent.

Axially-split pump means a pump with a casing that can be separated or split in a plane that is parallel to, and which contains, the axis of the impeller shaft.

* * * * *

Basic model means all units of a given class of pump manufactured by one manufacturer, having the same primary energy source, and having essentially identical electrical, physical, and functional (or hydraulic) characteristics that affect energy consumption, energy efficiency, water consumption, or water efficiency; and, in addition, for pumps that are subject to the test procedures specified in § 431.464(a), the following provisions also apply:

(1) All variations in numbers of stages of bare RSV and ST pumps must be considered a single basic model;

(2) Pump models for which the bare pump differs in impeller diameter, or impeller trim, may be considered a single basic model; and

(3) Pump models for which the bare pump differs in number of stages or impeller diameter and which are sold with motors (or motors and controls) of varying horsepower may only be considered a single basic model if:

(i) For ESCC, ESFM, IL, and RSV pumps, each motor offered in the basic model has a nominal full load motor efficiency rated at the Federal minimum (see the applicable table at § 431.25) or the same number of bands above the Federal minimum for each respective motor horsepower (*see* table 3 of appendix A to subpart Y of this part); or for pumps sold with inverter-only synchronous electric motors, any number of bands above the Federal minimum for each respective motor horsepower provided that the rating is based on the lowest number of bands; or

(ii) For ST pumps, each motor offered in the basic model has a full load motor efficiency at the default nominal full load submersible motor efficiency shown in table 2 of appendix A to subpart Y of this part or the same

number of bands above the default nominal full load submersible motor efficiency for each respective motor horsepower (*see* table 3 of appendix A to subpart Y of this part) or for inverter-only synchronous electric motors, any number of bands above the default nominal full load submersible motor efficiency provided the rating is based on the lowest number of bands.

* * * * *

Between-bearing (BB) pump means an axially-split, mechanically-coupled, one- or two-stage, dry rotor, rotodynamic pump with bearings on both ends of the rotating assembly that has a shaft input power greater than or equal to 1 hp and less than or equal to 200 hp at BEP and full impeller diameter and at the number of stages required for testing.

Bowl diameter means the maximum dimension of an imaginary straight line passing through and in the plane of the circular shape of the intermediate bowl of the bare pump that is perpendicular to the pump shaft and that intersects the outermost circular shape of the intermediate bowl of the bare pump at both of its ends.

* * * * *

Close-coupled pump means a pump in which the driver's bearings absorb the pump's axial load.

* * * * *

End-suction close-coupled (ESCC) pump means a close-coupled, dry rotor, end-suction pump that has a shaft input power greater than or equal to 1 hp and less than or equal to 200 hp at BEP and full impeller diameter and that is not a dedicated-purpose pool pump.

End-suction frame mounted/own bearings (ESFM) pump means a mechanically-coupled, dry rotor, end-suction pump that has a shaft input power greater than or equal to 1 hp and less than or equal to 200 hp at BEP and full impeller diameter and that is not a dedicated-purpose pool pump.

End-suction pump means a single-stage, rotodynamic pump in which the liquid enters the bare pump in a direction parallel to the impeller shaft and on the side opposite the bare pump's driver-end. The liquid is discharged in a plane perpendicular to the shaft.

* * * * *

In-line (IL) pump means a pump that is either a twin-head pump or a single-stage, single-axis flow, dry rotor, rotodynamic pump that has a shaft input power greater than or equal to 1 hp and less than or equal to 200 hp at BEP and full impeller diameter, in which liquid is discharged in a plane perpendicular to the shaft. Such pumps do not include circulator pumps.

* * * * *

Intermediate bowl means the enclosure within which the impeller rotates and which serves as a guide for the flow from one impeller to the next.

* * * * *

Mechanically-coupled pump means a pump in which bearings external to the driver absorb the pump's axial load.

* * * * *

Radially-split, multi-stage, horizontal, diffuser casing (RSH) pump means a horizontal, multi-stage, dry rotor, rotodynamic pump:

(1) That has a shaft input power greater than or equal to 1 hp and less than or equal to 200 hp at BEP and full impeller diameter and at the number of stages required for testing;

(2) In which liquid is discharged in a plane perpendicular to the impeller shaft;

(3) For which each stage (or bowl) consists of an impeller and diffuser; and

(4) For which no external part of such a pump is designed to be submerged in the pumped liquid.

Radially-split, multi-stage, horizontal, end-suction diffuser casing (RSHES) pump means a RSH pump in which the liquid enters the bare pump in a direction parallel to the impeller shaft and on the side opposite the bare pump's driver-end.

Radially-split, multi-stage, horizontal, in-line diffuser casing (RSHIL) pump means a single-axis flow RSH pump in which the liquid enters the pump in a plane perpendicular to the impeller shaft.

Radially-split, multi-stage, vertical, diffuser casing (RSV) pump means a vertically suspended, multi-stage, single-axis flow, dry rotor, rotodynamic pump:

(1) That has a shaft input power greater than or equal to 1 hp and less than or equal to 200 hp at BEP and full impeller diameter and at the number of stages required for testing;

(2) In which liquid is discharged in a plane perpendicular to the impeller shaft;

(3) For which each stage (or bowl) consists of an impeller and diffuser; and

(4) For which no external part of such a pump is designed to be submerged in the pumped liquid.

* * * * *

Small vertical in-line (SVIL) pump means a small vertical twin-head pump or a single stage, single-axis flow, dry rotor, rotodynamic pump that:

(1) Has a shaft input power less than 1 horsepower at its BEP at full impeller diameter; and

(2) In which liquid is discharged in a plane perpendicular to the shaft; and

(3) Is not a circulator pump.

Small vertical twin-head pump means a dry rotor, single-axis flow, rotodynamic pump that contains two equivalent impeller assemblies, each of which:

(1) Contains an impeller, impeller shaft (or motor shaft in the case of close-coupled pumps), shaft seal or packing, driver (if present), and mechanical equipment (if present); and

(2) Has a shaft input power that is less than or equal to 1 hp at BEP and full impeller diameter; and

(3) Has the same primary energy source (if sold with a driver) and the same electrical, physical, and functional characteristics that affect energy consumption or energy efficiency; and

(4) Is mounted in its own volute; and

(5) Discharges liquid through its volute and the common discharge in a plane perpendicular to the impeller shaft.

* * * * *

Submersible turbine (ST) pump means a single-stage or multi-stage, dry rotor, rotodynamic pump that is designed to be operated with the motor and stage(s) fully submerged in the pumped liquid; that has a shaft input power greater than or equal to 1 hp and less than or equal to 200 hp at BEP and full impeller diameter and at the number of stages required for testing; and in which each stage of this pump consists of an impeller and diffuser, and liquid enters and exits each stage of the bare pump in a direction parallel to the impeller shaft.

* * * * *

Vertical turbine (VT) pump means a vertically suspended, single-stage or multi-stage, dry rotor, rotodynamic pump:

(1) That has a shaft input power greater than or equal to 1 hp and less than or equal to 200 hp at BEP and full impeller diameter and at the number of stages required for testing;

(2) For which no external part of such pump is designed to be submerged in the pumped liquid;

(3) That has a single pressure containing boundary (*i.e.,* is single casing), which may consist of, but is not limited, to bowls, columns, and discharge heads; and

(4) That discharges liquid through the same casing in which the impeller shaft is contained.

* * * * *

■ 6. Section 431.463 is amended by:

■ a. Revising paragraph (a);

■ b. Removing paragraphs (d)(1) and (2);

■ c. Redesignating paragraphs (d)(3) and (4) as paragraphs (d)(2) and (1), respectively; and.
■ d. Revising newly redesignated paragraph (d)(2).

The revisions read as follows:

§ 431.463 Materials incorporated by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, DOE must publish a document in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at DOE and at the National Archives and Records Administration (NARA). Contact DOE at the U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, Sixth Floor, 950 L'Enfant Plaza SW, Washington, DC 20024, (202) 586–9127, *Buildings@ee.doe.gov, https://www.energy.gov/eere/buildings/building-technologies-office.* For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.* The material may be obtained from the sources in the following paragraphs of this section.

* * * * *

(d) * * *

(2) HI 40.6–2021, ''Methods for Rotodynamic Pump Efficiency Testing'', IBR approved for appendix A to this subpart.

* * * * *

■ 7. Section 431.464 is amended by:
■ a. Revising the introductory text of paragraph (a)(1)(i);
■ b. Redesignating paragraphs (a)(1)(ii) and (iii) as (a)(1)(iii) and (iv);
■ c. Adding new paragraph (a)(1)(ii); and
■ d. Revising newly redesignated paragraph (a)(1)(iii).

The revisions and addition read as follows:

§ 431.464 Test procedure for measuring and determining energy consumption of pumps.

(a) * * *

(1) * * *

(i) The following categories of clean water pumps that have the characteristics listed in paragraph (a)(1)(iii) of this section.

* * * * *

(ii) The additional following categories of clean water pumps that have the characteristics listed in paragraph (a)(1)(iii) of this section:

(A) Between-bearing (BB);

(B) Radially-split, multi-stage, horizontal, end-suction diffuser casing (RSHES);

(C) Radially-split, multi-stage, horizontal, in-line diffuser casing (RSHIL);

(D) Small vertical in-line (SVIL); and

(E) Vertical Turbine (VT).

(iii) Pump characteristics:

(A) Flow rate of 25 gpm or greater at BEP and full impeller diameter;

(B) Maximum head of 459 feet at BEP and full impeller diameter and the number of stages required for testing (*see* section 1.2.2 of appendix A of this subpart);

(C) Design temperature range wholly or partially in the range of 15 to 250 °F;

(D) Designed to operate with either:

(*1*) A 2- or 4- or 6-pole induction motor, or

(*2*) A non-induction motor with a speed of rotation operating range that includes speeds of rotation between 2,880 and 4,320 revolutions per minute (rpm) and/or 1,440 and 2,160 rpm and/or 960 and 1,440 revolutions per minute, and in each case, the driver and impeller must rotate at the same speed; and

(E) For ESCC and ESFM pumps, a specific speed less than or equal to 5,000 when calculated using U.S. customary units.

* * * * *

■ 8. Appendix A to subpart Y of part 431 is amended by:
■ a. Revising the note to the beginning of the appendix;
■ b. Revising Section I;
■ c. In section II,
■ i. Revising paragraphs A.1, A.2, B.1.2.1.2, B.1.2.1.2.1., and B.1.2.1.2.2; and
■ ii. Adding paragraph B.1.2.1.2.3;
■ d. In Section III, revising paragraphs A through D, E.1.2.1.2, E.1.2.1.2.1., and E.1.2.1.2.2.;
■ e. In Section IV, revising paragraphs A through D;
■ f. In Section V, revising paragraphs A through D, E.1.1, E.1.2.1.1, E.1.2.1.1.1. and E.1.2.1.1.2.;
■ g. In Section VI, revising paragraphs A through D;
■ h. In Section VII,
■ i. Revising paragraphs A through D, the definition of L_{full} in paragraph E.1.2, paragraphs E.1.2.1, E.1.2.1.1, E.1.2.1.1.1, and E.1.2.1.1.2,
■ ii. Adding E.1.2.1.1.3; and
■ iii. Revising paragraph E.1.2.2;
■ i. Revising Tables 2 and 4; and
■ j. Adding Table 5.

The revisions and additions read as follows:

Appendix A to Subpart Y of Part 431—Uniform Test Method for the Measurement of Energy Consumption of Pumps

Note: Prior to [*date 180 days after publication of final rule*], representations with respect to the energy use or efficiency (including compliance certifications) of pumps specified in § 431.464(a)(1)(i), excluding pumps listed in § 431.464(a)(1)(iv), must be based on testing conducted in accordance with the applicable provisions of this appendix as they appeared in the January 1, 2022 edition of the Code of Federal Regulations of subpart Y of part 431 in 10 CFR parts 200 through 499.

On or after [*date 180 days after publication of final rule*], representations with respect to the energy use or efficiency (including compliance certifications) of pumps specified in § 431.464(a)(1)(i), excluding pumps listed in § 431.464(a)(1)(iv), must be based on testing conducted in accordance with the applicable provisions of this appendix.

Any representations with respect to the energy use or efficiency of pumps specified in 431.464(a)(1)(ii), excluding pumps listed in § 431.464(a)(1)(iv), made on or after [*date 180 days after publication of final rule*] must be made in accordance with the results of testing pursuant to this appendix. Manufacturers must use the results of testing under this appendix to determine compliance with any energy conservation standards established for pumps specified in § 431.464(a)(1)(ii), excluding pumps listed in § 431.464(a)(1)(iv), that are published after January 1, 2022.

I. Test Procedure for Pumps

0. Incorporation by Reference. DOE incorporated by reference in § 431.463 the entire standard for HI 40.6–2021; however, certain enumerated provisions of HI 40.6–2021, as set forth below are inapplicable. To the extent that there is a conflict between the terms or provisions of a referenced industry standard and the CFR, the CFR provisions control.

0.1 Section 40.6.1 Scope
0.2 Section 40.6.5.3 Test report
0.3 Appendix B Reporting of test results (informative)
0.3 Appendix E Testing Circulator Pumps (normative)
0.4 Appendix G DOE Compared to HI 40.6 Nomenclature

A. *General.* To determine the constant load pump energy index (PEI_{CL}) for bare pumps and pumps sold with electric motors or the variable load pump energy

index (PEI_{VL}) for pumps sold with electric motors and continuous or non-continuous controls, perform testing in accordance with HI 40.6–2021, except Section 40.6.5.3, ''Test report;'' Appendix E, ''Testing Circulator Pumps (normative)'', and Appendix G ''DOE Compared to HI 40.6 Nomenclature'' with the modifications and additions as noted throughout the provisions below. Where HI 40.6–2021 refers to ''pump,'' the term refers to the ''bare pump,'' as defined in § 431.462. Also, for the purposes of applying this appendix, the term ''volume per unit time,'' as defined in Section 40.6.2, ''Terms and definitions,'' of HI 40.6–2021 shall be deemed to be synonymous with the term ''flow rate'' used throughout that standard and this appendix. In addition, the specifications in Section 40.6.4.1 of HI 40.6–2021, ''Vertically suspended pumps'' do not apply to ST pumps and the performance of ST bare pumps considers bowl performance only.

A.1 *Scope.* Section II of this appendix applies to all pumps and describes how to calculate the pump energy index (section II.A) based on the pump energy rating for the minimally-compliant reference pump (PER_{STD}; section II.B) and the constant load pump energy rating (PER_{CL}) or variable load pump energy rating (PER_{VL}) determined in accordance with one of sections III through VII of this appendix, based on the configuration in which the pump is distributed in commerce and the applicable testing method specified in sections III through VII and as described in Table 1 of this appendix.

TABLE 1—APPLICABILITY OF CALCULATION-BASED AND TESTING-BASED TEST PROCEDURE OPTIONS BASED ON PUMP CONFIGURATION

Pump configuration	Pump sub-configuration	Applicable test methods
Bare Pump	Bare Pump OR Pump + Single-Phase Induction Motor (Excluding SVIL) OR Pump + Driver Other Than Electric Motor.	Section III: Test Procedure for Bare Pumps.
Pump + Motor OR Pump + Motor + Controls other than continuous or non-continuous controls (*e.g.,* ON/OFF switches).	Pump + Motor Listed at § 431.25(g) OR SVIL Pump + Motor Covered by DOE's Energy Conservation Standards* OR Pump + Submersible Motor.	Section IV: Testing-Based Approach for Pumps Sold with Motors OR Section V: Calculation-Based Approach for Pumps Sold with Motors.
	Pump (Including SVIL)+ Motor Not Covered by DOE's Motor Energy Conservation Standards (Except Submersible Motors)** OR Pump (Other than SVIL) + Single-Phase Induction Motor (if Section III is not used).	Section IV: Testing-Based Approach for Pumps Sold with Motors.
Pump + Motor + Continuous Controls OR Pump + Motor + Non-Continuous Controls OR Pump + Inverter-Only Synchronous Electric Motor*** (With or Without Controls).	Pump + Motor Listed at § 431.25(g) + Continuous Control OR SVIL Pump + Motor Covered by DOE's Energy Conservation Standards* + Continuous Control OR Pump + Submersible Motor + Continuous Control OR Pump + Inverter-Only Synchronous Electric Motor*** (With or Without Continuous Control).	Section VI: Testing-Based Approach for Pumps Sold with Motors and Controls OR Section VII: Calculation-Based Approach for Pumps Sold with Motors Controls.
	Pump + Motor Listed at § 431.25(g) + Non-Continuous Control OR SVIL Pump + Motor Covered by DOE's Energy Conservation Standards* + Non-Continuous Control OR Pump + Submersible Motor + Non-Continuous Control.	Section VI: Testing-Based Approach for Pumps Sold with Motors and Controls.
	Pump (Including SVIL) + Motor Not Covered by DOE's Motor Energy Conservation Standards** (Except Submersible Motors) + Continuous or Non-Continuous Controls OR Pump (Other than SVIL) + Single-Phase Induction Motor + Continuous or Non-Continuous Controls (if Section III is not used).	Section VI: Testing-Based Approach for Pumps Sold with Motors and Controls.

* All references to ''Motor Covered by DOE's Motor Energy Conservation Standards'' refer to those listed at § 431.446 or those for Small Non-Small Electric Motor Electric Motors (SNEMs) at subpart B of this part, including motors of such varieties that are less than 0.25 hp.

** All references to ''Motor Not Covered by DOE's Motor Energy Conservation Standards'' refer to motors not listed at § 431.25 or, for SVIL, not listed at either § 431.446 or in subpart B of this part (excluding motors of such varieties that are less than 0.25 hp).

*** All references to ''Inverter-Only Synchronous Electric Motor'' refer to inverter-only electric motors than are synchronous electric motors, both as defined in subpart B of this part.

A.2 Section III of this appendix addresses the test procedure applicable to bare pumps. This test procedure also applies to pumps sold with drivers other than motors and BB, ESCC, ESFM, IL, RSHES, RSHIL, RSV, ST, and VT pumps sold with single-phase induction motors.

A.3 Section IV of this appendix addresses the testing-based approach for pumps sold with motors, which applies to all pumps sold with electric motors, except for pumps sold with inverter-only synchronous electric motors, but including pumps sold with single-phase induction motors. This test procedure also applies to pumps sold with controls other than continuous or non-continuous controls (*e.g.,* on/off switches).

A.4 Section V of this appendix addresses the calculation-based approach for pumps sold with motors, which applies to:

A.4.1 Pumps sold with polyphase electric motors regulated by DOE's energy conservation standards for electric motors at § 431.25(g), and

A.4.2 SVIL pumps sold with small electric motors regulated by DOE's energy conservation standards at § 431.446 or sold with SNEMs regulated by DOE's energy conservation standards

in subpart B of this part but including motors of such varieties that are less than 0.25 hp, and

A.4.3 Pumps sold with submersible motors.

A.5 Section VI of this appendix addresses the testing-based approach for pumps sold with motors and controls, which applies to all pumps sold with electric motors (including single-phase induction motors) and continuous or non-continuous controls and to pumps sold with inverter-only synchronous electric motors with or without controls.

A.6 Section VII of this appendix discusses the calculation-based approach for pumps sold with motors and controls, which applies to:

A.6.1 Pumps sold with polyphase electric motors regulated by DOE's energy conservation standards for electric motors at § 431.25(g) and continuous controls and

A.6.2 Pumps sold with inverter-only synchronous electric motors,

A.6.3 SVIL pumps sold with small electric motors regulated by DOE's energy conservation standards at § 431.446 (but including motors of such varieties that are less than 0.25 hp) and continuous controls or with SNEMs regulated by DOE's energy conservation standards at subpart B of this part (but including motors of such varieties that are less than 0.25 hp) and continuous controls, and

A.6.4 Pumps sold with submersible motors and continuous controls.

B. *Measurement Equipment.*

B.1 Instrument Accuracy. For the purposes of measuring pump power input, driver power input to the motor or controls, and pump power output, the equipment specified in HI 40.6–2021 Appendix C necessary to measure head, speed of rotation, flow rate, temperature, torque, and electrical power must be used and must comply with the stated accuracy requirements in HI 40.6–2021 Table 40.6.3.2.3 except as noted in sections III.B, IV.B, V.B, VI.B, and VII.B of this appendix. When more than one instrument is used to measure a given parameter, the combined accuracy, calculated as the root sum of squares of individual instrument accuracies, must meet the specified accuracy requirements.

B.2 Calibration. Calibration requirements for instrumentation are specified in Appendix D of HI 40.6–2021.

C. *Test Conditions.* Conduct testing at full impeller diameter in accordance with the test conditions, stabilization requirements, and specifications of HI 40.6–2021 Section 40.6.3, ''Pump efficiency testing;'' Section 40.6.4, ''Considerations when determining the efficiency of certain pumps;'' Section 40.6.5.4 (including appendix A), ''Test arrangements;'' and Section 40.6.5.5, ''Test conditions.'' For ST pumps, head measurements must be based on the bowl assembly total head as described in Section A.5 of 40.6–2021 and the pump power input or driver power input, as applicable, must be based on the measured input power to the driver or bare pump, respectively; Section 40.6.4.1, ''Vertically suspended pumps,'' does not apply to ST pumps.

C.1 Nominal Speed of Rotation. Determine the nominal speed of rotation based on the range of speeds of rotation at which the pump is designed to operate, in accordance with sections I.C.1.1, I.C.1.2, and I.C.1.3 of this appendix, as applicable. When determining the range of speeds at which the pump is designed to operate, DOE will refer to published data, marketing literature, and other publicly-available information about the pump model and motor, as applicable.

C.1.1 For pumps sold without motors, select the nominal speed of rotation based on the speed for which the pump is designed.

C.1.1.1 For bare pumps designed for speeds of rotation including 2,880 to 4,320 revolutions per minute (rpm), the nominal speed of rotation shall be 3,600 rpm.

C.1.1.2 For bare pumps designed for speeds of rotation including 1,440 to 2,160 rpm, the nominal speed of rotation shall be 1,800 rpm.

C1.1.3 For bare pumps designed for speeds of rotation including 960 to 1,440 rpm, the nominal speed of rotation shall be 1,200 rpm.

C.1.2 For pumps sold with induction motors, select the appropriate nominal speed of rotation.

C1.2.1 For pumps sold with 6-pole induction motors, the nominal speed of rotation shall be 1,200 rpm.

C.1.2.2 For pumps sold with 4-pole induction motors, the nominal speed of rotation shall be 1,800 rpm.

C.1.2.3 For pumps sold with 2-pole induction motors, the nominal speed of rotation shall be 3,600 rpm.

C.1.3 For pumps sold with non-induction motors, select the appropriate nominal speed of rotation.

C.1.3.1 Where the operating range of the pump and motor includes speeds of rotation between 2,880 and 4,320 rpm, the nominal speed of rotation shall be 3,600 rpm.

C.1.3.2 Where the operating range of the pump and motor includes speeds of rotation between 1,440 and 2,160 rpm, the nominal speed of rotation shall be 1,800 rpm.

C.1.3.3 Where the operating range of the pump and motor includes speeds of rotation between 960 and 1,440, the nominal speed of rotation shall be 1,200 rpm.

C.2 Multi-Stage Pumps. Perform testing on the pump with two stages for BB pumps, three stages for RSH and RSV pumps, and nine stages for ST and VT pumps. If the basic model of pump being tested is only available with fewer than the required number of stages, test the pump with the maximum number of stages with which the basic model is distributed in commerce in the United States. If the basic model of pump being tested is only available with greater than the required number of stages, test the pump with the lowest number of stages with which the basic model is distributed in commerce in the United States. If the basic model of pump being tested is available with both fewer and greater than the required number of stages, but not the required number of stages, test the pump with the number of stages closest to the required number of stages. If both the next lower and next higher number of stages are equivalently close to the required number of stages, test the pump with the next higher number of stages.

C.3 Twin-Head Pumps. For twin-head pumps, perform testing on an equivalent single impeller IL or SVIL pump as applicable, constructed by incorporating one of the driver and impeller assemblies of the twin-head pump being rated into an adequate IL-style or SVIL-style, single impeller volute and casing. An adequate IL-style or SVIL-style, single impeller volute and casing means a volute and casing for which any physical and functional characteristics that affect energy consumption and energy efficiency are the same as their corresponding characteristics for a single impeller in the twin-head pump volute and casing.

D. *Data Collection and Analysis.*

D.1 Damping Devices. Use of damping devices, as described in Section 40.6.3.2.2 of HI 40.6–2021, are only permitted to integrate up to the data collection interval used during testing.

D.2 Stabilization. Record data at any tested load point only under stabilized conditions, as defined in HI 40.6–2021 Section 40.6.5.5.1, where a minimum of two measurements are used to determine stabilization.

D.3 Calculations and Rounding. Normalize all measured data to the nominal speed of rotation of 3,600 or 1,800 or 1,200 rpm based on the nominal speed of rotation selected for the pump in section I.C.1 of this appendix, in accordance with the

procedures specified in Section 40.6.6.1.1 of HI 40.6–2021. Except for the ''expected BEP flow rate,'' all terms and quantities refer to values determined in accordance with the procedures set forth in this appendix for the rated pump. Perform all calculations using raw measured values without rounding. Round PER_{CL} and PER_{VL} to three significant digits, and round PEI_{CL}, and PEI_{VL} values, as applicable, to the hundredths place (*i.e.,* 0.01).

D.4 Pumps with BEP at Run Out. Test pumps for which the expected BEP corresponds to a volume rate of flow that is within 20 percent of the expected maximum flow rate at which the pump is designed to operate continuously or safely (*i.e.,* pumps with BEP at run-out) in accordance with the test procedure specified in this appendix, but with the following exceptions:

D.4.1 Use the following seven flow points—40, 50, 60, 70, 80, 90, and 100 percent of the expected maximum flow rate for determination of BEP in sections III.D, IV.D, V.D, VI.D, and VII.D of this appendix instead of the flow points specified in those sections.

D.4.2 Use flow points of 60, 70, 80, 90, and 100 percent of the expected maximum flow rate of the pump to determine pump power input or driver power input instead of the flow points of 60, 75, 90, 100, 110, and 120 percent of the expected BEP flow rate specified in sections III.E.1.1, IV.E.1, V.E.1.1, VI.E.1, and VII.E.1.1 of this appendix.

D.4.3 To determine PER_{CL} in sections III.E, IV.E, and V.E and to determine PER_{STD} in section II.B, use load points of 65, 90, and 100 percent of the BEP flow rate determined with the modified flow points specified in this section I.D.4 of this appendix instead of 75, 100, and 110 percent of BEP flow. In section II.B.1.1, where alpha values are specified for the load points 75, 100, and 110 percent of BEP flow rate, instead apply the alpha values to the load points of 65, 90, and 100 percent of the BEP flow rate determined with the modified flow points specified in this section I.D.4 of this appendix. However, in sections II.B.1.1.1 and II.B.1.1.1.1 of this appendix, use 100 percent of the BEP flow rate as specified to determine $\eta_{pump,STD}$ and Ns as specified. To determine motor sizing for bare pumps in sections II.B.1.2.1.1 and III.E.1.2.1.1 of this appendix, use a load point of 100 percent of the BEP flow rate instead of 120 percent.

E. *Determination of Additional Performance Parameters.*

E.1 To determine overall (wire-to-water) efficiency, driver power input, and/or pump power output (hydraulic horsepower), conduct testing in accordance with HI 40.6–2021.

II. Calculation of the Pump Energy Index

A. * * *

A.1. For pumps rated as bare pumps or pumps sold with motors (other than inverter-only synchronous electric motors), determine the PEI_{CL} using the following equation:

$$PEI_{CL} = \frac{PER_{CL}}{PER_{STD}}$$

Where:

PEI_{CL} = the pump energy index for a constant load (hp),

PER_{CL} = the pump energy rating for a constant load (hp), determined in accordance with either section III (for bare pumps; BB, ESCC, ESFM, IL, RSHES, RSHIL, RSV, ST or VT pumps sold with single-phase induction motors; and pumps sold with drivers other than electric motors), section IV (for pumps sold with motors and rated using the testing-based approach), or section V (for pumps sold with motors and rated using the calculation-based approach) of this appendix, and

PER_{STD} = the PER_{CL} for a pump that is minimally compliant with DOE's energy conservation standards with the same flow and specific speed characteristics as the tested pump (hp), as determined in accordance with section II.B of this appendix.

A.2 For pumps rated as pumps sold with motors and continuous controls or non-continuous controls (including pumps sold with inverter-only synchronous electric motors with or without controls), determine the PEI_{VL} using the following equation:

$$PEI_{VL} = \frac{PER_{VL}}{PER_{STD}}$$

PEI_{VL} = the pump energy index for a variable load (hp),

PER_{VL} = the pump energy rating for a variable load (hp), determined in accordance with section VI (for pumps sold with motors and continuous or non-continuous controls rated using the testing-based approach) or section VII of this appendix (for pumps sold with motors and continuous controls rated using the calculation-based approach), and

PER_{STD} = the PER_{CL} for a pump that is minimally compliant with DOE's energy conservation standards with the same flow and specific speed characteristics as the tested pump (hp), as determined in accordance with section II.B of this appendix.

B. * * *

B.1.2.1.2 Determine the default nominal full load motor efficiency as described in section II.B.1.2.1.2.1 of this appendix for BB, ESCC, ESFM, IL, RSHES, RSHIL, RSV, and VT pumps; section II.B.1.2.1.2.2 of this appendix for ST pumps; and section II.B.1.2.1.2.3 for SVIL pumps.

B.1.2.1.2.1. For BB, ESCC, ESFM, IL, RSHES, RSHIL, RSV, and VT pumps, the default nominal full load motor efficiency is the minimum of the nominal full load motor efficiency standards (open or enclosed) from the table containing the current energy conservation standards for NEMA Design B motors at § 431.25, with the number of poles relevant to the speed at which the pump is being tested (see section I.C.1 of this appendix) and the motor horsepower determined in section II.B.1.2.1.1 of this appendix.

B.1.2.1.2.2. For ST pumps, prior to the compliance date of any energy conservation standards for submersible motors in subpart B of this part, the default nominal full load motor efficiency is the default nominal full load submersible motor efficiency listed in table 2 of this appendix, with the number of poles relevant to the speed at which the pump is being tested (see section I.C.1 of this appendix) and the motor horsepower determined in section II.B.1.2.1.1 of this appendix. Starting on the compliance date of any energy conservation standards for submersible motors in subpart B of this part, the default nominal full load motor efficiency shall be the minimum of any nominal full load motor efficiency standard from the table containing energy conservation standards for submersible motors in subpart B of this part, with the number of poles relevant to the speed at which the pump is being tested (see section I.C.1 of this appendix) and the motor horsepower determined in section II.B.1.2.1.1 of this appendix.

B.1.2.1.2.3. For SVIL pumps, the default nominal full load motor efficiency is the minimum full load motor efficiency standard from the tables containing the current energy conservation standards for polyphase or CSCR/CSIR small electric motors at § 431.446, with the number of poles relevant to the speed at which the pump is being tested (see section I.C.1 of this appendix) and the motor horsepower determined in section II.B.1.2.1.1 of this appendix, or for SVIL pumps sold with motors less than 0.25 hp, the default nominal full load motor efficiency is 58.3% for 6-pole, 64.6% for 4-pole, and 61.7% for 2-pole motors.

* * * * *

III. Test Procedure for Bare Pumps

A. Scope. This section III applies only to:

A.1 Bare pumps,

A.2 Pumps sold with drivers other than electric motors, and

A.3 BB, ESCC, ESFM, IL, RSHES, RSHIL, RSV, ST, and VT pumps sold with single-phase induction motors.

B. Measurement Equipment. The requirements regarding measurement equipment presented in section I.B of this appendix apply to this section III. In addition, when testing pumps using a calibrated motor, electrical measurement equipment shall meet the requirements of Section C.4.3 of HI 40.6–2021 and motor power input shall be determined according to Section 40.6.3.2.3 of HI 40.6–2021 and meet the requirements in Table 40.6.3.2.3 of HI 40.6–2021.

C. Test Conditions. The requirements regarding test conditions presented in section I.C of this appendix apply to this section III. In addition, when testing pumps using a calibrated motor, the conditions in Section C.4.3.1 of HI 40.6–2021 shall be met.

D. Testing BEP for the Pump. Determine the best efficiency point (BEP) of the pump as follows:

D.1. Adjust the flow by throttling the pump without changing the speed of rotation of the pump and conduct the test at a minimum of the following seven flow points: 40, 60, 75, 90, 100, 110, and 120 percent of the expected BEP flow rate of the pump at the nominal speed of rotation, as specified in Section 40.6.5.5.1 of HI 40.6–2021.

D.2. Determine the BEP flow rate as the flow rate at the operating point of maximum pump efficiency on the pump efficiency curve, as determined in accordance with Section 40.6.6.3 of HI 40.6–2021, where the pump efficiency is the ratio of the pump power output divided by the pump power input, as specified in Table 40.6.2 of HI 40.6–2021, disregarding the calculations provided in Section 40.6.6.2.

* * * * *

E.1.2.1.2 Determine the default nominal full load motor efficiency as described in section III.E.1.2.1.2.1 of this appendix for BB, ESCC, ESFM, IL, RSHES, RSHIL, RSV, and VT pumps; or section III.E.1.2.1.2.2. of this appendix for ST pumps.

E.1.2.1.2.1. For BB, ESCC, ESFM, IL, RSHES, RSHIL, RSV, and VT pumps, the default nominal full load motor efficiency is the minimum of the nominal full load motor efficiency standards (open or enclosed) from the table containing the current energy conservation standards for NEMA Design B motors at § 431.25, with the number of poles relevant to the speed at which the pump is being tested (see section I.C.1 of this appendix) and the motor horsepower determined in section III.E.1.2.1.1 of this appendix.

E.1.2.1.2.2. For ST pumps, prior to the compliance date of any energy conservation standards for submersible motors in subpart B of this part, the default nominal full load motor efficiency is the default nominal full load submersible motor efficiency listed in table 2 of this appendix, with the number of poles relevant to the speed at which the pump is being tested (see section I.C.1 of this appendix) and the motor horsepower determined in section III.E.1.2.1.1 of this appendix. Starting on the compliance date of any energy conservation standards for submersible motors in subpart B of this part, the default nominal full load motor efficiency is the minimum of any nominal full load motor efficiency standard from the table containing energy conservation standards for submersible motors in subpart B of this part, with the number of poles relevant to the speed at which the pump is being tested (see section I.C.1 of this appendix) and the motor horsepower determined in accordance with section III.E.1.2.1.1 of this appendix.

* * * * *

IV. Testing-Based Approach for Pumps Sold With Motors

A. Scope. This section IV applies only to pumps sold with electric motors (excluding pumps sold with inverter-only synchronous electric motors), including single-phase induction motors.

B. Measurement Equipment. The requirements regarding measurement equipment presented in section I.B of this appendix apply to this section IV. In addition, when testing pumps using a calibrated motor, electrical measurement equipment shall meet the requirements of Section C.4.3 of HI 40.6–2021 and motor power input shall be determined according to Section 40.6.3.2.3 of HI 40.6–2021 and meet the requirements in Table 40.6.3.2.3 of HI 40.6–2021.

C. *Test Conditions.* The requirements regarding test conditions presented in section I.C of this appendix apply to this section IV. In addition, when testing pumps using a calibrated motor, the conditions in Section C.4.3.1 of HI 40.6–2021 shall be met.

D. *Testing BEP for the Pump.* Determine the best efficiency point (BEP) of the pump as follows:

D.1. Adjust the flow by throttling the pump without changing the speed of rotation of the pump and conduct the test at a minimum of the following seven flow points: 40, 60, 75, 90, 100, 110, and 120 percent of the expected BEP flow rate of the pump at the nominal speed of rotation, as specified in Section 40.6.5.5.1 of HI 40.6–2021.

D.2. Determine the BEP flow rate as the flow rate at the operating point of maximum pump efficiency on the pump efficiency curve, as determined in accordance with Section 40.6.6.3 of HI 40.6–2021, where the pump efficiency is the ratio of the pump power output divided by the pump power input, as specified in Table 40.6.2 of HI 40.6–2021, disregarding the calculations provided in Section 40.6.6.2 of HI 40.6–2021.

* * * * *

V. Calculation-Based Approach for Pumps Sold With Motors

A. *Scope.* This section V can only be used in lieu of the test method in section IV of this appendix to calculate the index for pumps sold with motors listed in section V.A.1, V.A.2, or V.A.3 of this appendix.

A.1 Pumps sold with motors subject to DOE's energy conservation standards for polyphase electric motors at § 431.25(g),

A.2 SVIL pumps sold with small electric motors regulated by DOE's energy conservation standards at § 431.446 or with SNEMs regulated by DOE's energy conservation standards in subpart B of this part but including motors of such varieties that are less than 0.25 hp, and

A.3. Pumps sold with submersible motors.

A.4. Pumps sold with motors not listed in sections V.A.1, V.A.2, or V.A.3 of this appendix cannot use this section V and must apply the test method in section IV of this appendix.

B. *Measurement Equipment.* The requirements regarding measurement equipment presented in section I.B of this appendix apply to this section V. In addition, when testing pumps using a calibrated motor, electrical measurement equipment shall meet the requirements of Section C.4.3 of HI 40.6–2021 and motor power input shall be determined according to Section 40.6.3.2.3 of HI 40.6–2021 and meet the requirements in Table 40.6.3.2.3 of HI 40.6–2021.

C. *Test Conditions.* The requirements regarding test conditions presented in section I.C of this appendix apply to this section V. In addition, when testing pumps using a calibrated motor, the conditions in Section C.4.3.1 of HI 40.6–2021 shall be met.

D. *Testing BEP for the Pump.* Determine the best efficiency point (BEP) of the pump as follows:

D.1. Adjust the flow by throttling the pump without changing the speed of

rotation of the pump and conduct the test at a minimum of the following seven flow points: 40, 60, 75, 90, 100, 110, and 120 percent of the expected BEP flow rate of the pump at the nominal speed of rotation, as specified in Section 40.6.5.5.1 of HI 40.6–2021.

D.2. Determine the BEP flow rate as the flow rate at the operating point of maximum pump efficiency on the pump efficiency curve, as determined in accordance with Section 40.6.6.3 of HI 40.6–2021, where the pump efficiency is the ratio of the pump power output divided by the pump power input, as specified in Table 40.6.2 of HI 40.6–2021, disregarding the calculations provided in Section 40.6.6.2.

* * * * *

E.1.1 Determine the pump power input at 75, 100, and 110 percent of the BEP flow rate by employing a least squares regression to determine a linear relationship between the pump power input at the nominal speed of rotation of the pump and the measured flow rate at the following load points: 60, 75, 90, 100, 110, and 120 percent of the expected BEP flow rate. Use the linear relationship to determine the pump power input at the nominal speed of rotation for the load points of 75, 100, and 110 percent of the BEP flow rate.

* * * * *

E.1.2.1.1 For pumps sold with motors other than submersible motors, determine the represented nominal full load motor efficiency as described in section V.E.1.2.1.1.1 of this appendix. For pumps sold with submersible motors, determine the default nominal full load submersible motor efficiency as described in section V.E.1.2.1.1.2 of this appendix.

E.1.2.1.1.1 For pumps sold with motors other than submersible motors, the represented nominal full load motor efficiency is that of the motor with which the given pump model is being tested, as determined in accordance with the DOE test procedure for electric motors at § 431.16 or, for SVIL, the DOE test procedure for small electric motors at § 431.444, or the DOE test procedure for SNEMs in subpart B to this part, as applicable (including for motors less than 0.25 hp), and if available, applicable representation procedures in 10 CFR part 429 and this part.

E.1.2.1.1.2 For pumps sold with submersible motors, prior to the compliance date of any energy conservation standards for submersible motors in subpart B of this part, the default nominal full load submersible motor efficiency is that listed in table 2 of this appendix, with the number of poles relevant to the speed at which the pump is being tested (see section I.C.1 of this appendix) and the motor horsepower of the pump being tested, or if a test procedure for submersible motors is provided in subpart B to this part, the represented nominal full load motor efficiency of the motor with which the given pump model is being tested, as determined in accordance with the applicable test procedure in subpart B to this part and applicable representation procedures in 10 CFR part 429 and this part, may be used instead. Starting on the compliance date of any energy conservation standards for submersible motors in subpart B of this part, the default nominal full load submersible motor efficiency may no longer be used. Instead, the represented nominal full load motor efficiency of the motor with which the given pump model is being tested, as determined in accordance with the applicable test procedure in subpart B of this part and applicable representation procedures in 10 CFR part 429 and this part, must be used.

* * * * *

VI. Testing-Based Approach for Pumps Sold With Motors and Controls

A. Scope. This section VI applies only to pumps sold with electric motors, including single-phase induction motors, and continuous or non-continuous controls, as well as to pumps sold with inverter-only synchronous electric motors (with or without controls). For the purposes of this section VI, all references to ''driver input power'' in this section VI or HI 40.6–2021 refer to the input power to the continuous or non-continuous controls.

B. *Measurement Equipment.* The requirements regarding measurement equipment presented in section I.B of this appendix apply to this section VI. In addition, when testing pumps using a calibrated motor, electrical measurement equipment shall meet the requirements of Section C.4.3 of HI 40.6–2021 and motor power input shall be determined according to Section 40.6.3.2.3 of HI 40.6–2021 and meet the requirements in Table 40.6.3.2.3 of HI 40.6–2021.

C. *Test Conditions.* The requirements regarding test conditions presented in section I.C of this appendix apply to this section VI. In addition, when testing pumps using a calibrated motor, the conditions in Section C.4.3.1 of HI 40.6–2021 shall be met.

D. *Testing BEP for the Pump.* Determine the best efficiency point (BEP) of the pump as follows:

D.1. Adjust the flow by throttling the pump without changing the speed of rotation of the pump and conduct the test at a minimum of the following seven flow points: 40, 60, 75, 90, 100, 110, and 120 percent of the expected BEP flow rate of the pump at the nominal speed of rotation, as specified in Section 40.6.5.5.1 of HI 40.6–2021.

D.2. Determine the BEP flow rate as the flow rate at the operating point of maximum pump efficiency on the pump efficiency curve, as determined in accordance with Section 40.6.6.3 of HI 40.6–2021, where the pump efficiency is the ratio of the pump power output divided by the pump power input, as specified in Table 40.6.2 of HI 40.6–2021, disregarding the calculations provided in Section 40.6.6.2.

* * * * *

VII. Calculation-Based Approach for Pumps Sold With Motors and Controls

A. *Scope.* This section VII can only be used in lieu of the test method in section VI of this appendix to calculate the index for pumps listed in sections VII.A.1, VII.A.2, VII.A.3, and VII.A.4 of this appendix.

A.1. Pumps sold with motors regulated by DOE's energy conservation standards for polyphase NEMA Design B electric motors at § 431.25(g) and continuous controls,

A.2 Pumps sold with inverter-only synchronous electric motors regulated by DOE's energy conservation standards in subpart B of this part,

A.3 SVIL pumps sold with small electric motors regulated by DOE's energy conservation standards at § 431.446 or with SNEMs regulated by DOE's energy conservation standards in subpart B of this part (but including motors of such varieties that are less than 0.25 hp) and continuous controls,

A.4. Pumps sold with submersible motors and continuous controls, and

A.5. Pumps sold with motors not listed in sections VII.A.1, VII.A.2, VII.A.3, and VII.A.4 of this appendix and pumps sold without continuous controls, including pumps sold with non-continuous controls, cannot use this section and must apply the test method in section VI of this appendix.

B. *Measurement Equipment.* The requirements regarding measurement equipment presented in section I.B of this appendix apply to this section VII. In addition, when testing pumps using a calibrated motor, electrical measurement equipment shall meet the requirements of Section C.4.3 of HI 40.6–2021 and motor power input shall be determined according to Section 40.6.3.2.3 of HI 40.6–2021 and meet the requirements in Table 40.6.3.2.3 of HI 40.6–2021.

C. *Test Conditions.* The requirements regarding test conditions presented in section I.C of this appendix apply to this section VII. In addition, when testing pumps using a calibrated motor, the conditions in Section C.4.3.1 of HI 40.6–2021 shall be met.

D. *Testing BEP for the Pump.* Determine the best efficiency point (BEP) of the pump as follows:

D.1. Adjust the flow by throttling the pump without changing the speed of rotation of the pump and conduct the test at a minimum of the following seven flow points: 40, 60, 75, 90, 100, 110, and 120 percent of the expected BEP flow rate of the pump at the nominal speed of rotation, as specified in HI 40.6–2021, except Section 40.6.5.3, and appendix B.

D.2. Determine the BEP flow rate as the flow rate at the operating point of maximum pump efficiency on the pump efficiency curve, as determined in accordance with Section 40.6.6.3 of HI 40.6–2021, where the pump efficiency is the ratio of the pump power output divided by the pump power input, as specified in Table 40.6.2 of HI 40.6–2021, disregarding the calculations provided in Section 40.6.6.2.

* * * * *

E.1.2 * * *

* * * * *

L_{full} = motor losses at full load or, for inverter-only synchronous electric motors, motor + inverter losses at full load, as determined in accordance with section VII.E.1.2.1 of this appendix (hp),

* * * * *

E.1.2.1 Determine the full load motor losses using the appropriate motor efficiency value and horsepower as shown in the following equation:

$$L_{full} = \frac{MotorHP}{\left[\eta_{motor,full}/100\right]} - MotorHP$$

Where:

L_{full} = motor losses at full load (hp), or for inverter-only synchronous electric motors, motor + inverter losses at full load,

MotorHP = the horsepower of the motor with which the pump model is being tested (hp), and

$\eta_{motor,full}$ = the represented nominal full load motor efficiency (*i.e.,* nameplate/DOE-certified value) or the represented nominal full load motor + inverter efficiency or the default nominal full load submersible motor efficiency as determined in accordance with section VII.E.1.2.1.1 of this appendix (%).

E.1.2.1.1 For pumps sold with motors other than inverter-only synchronous electric motors or submersible motors, determine the represented nominal full load motor efficiency as described in section VII.E.1.2.1.1.1 of this appendix. For pumps sold with inverter-only synchronous electric motors, determine the represented nominal full load motor + inverter efficiency as described in section VII.E.1.2.1.1.2 of this appendix. For pumps sold with submersible motors, determine the default nominal full load submersible motor efficiency as described in section VII.E.1.2.1.1.3 of this appendix.

E.1.2.1.1.1 For pumps sold with motors other than inverter-only synchronous electric motors or submersible motors, the represented nominal full load motor efficiency is that of the motor with which the given pump model is being tested, as determined in accordance with the DOE test procedure for electric motors at § 431.16 or, for SVIL, the DOE test procedure for small electric motors at § 431.444 or the DOE test procedure for SNEMs in subpart B of this part, as applicable (including for motors less than 0.25 hp), and, if available, applicable representation procedures in 10 CFR part 429 and this part.

E.1.2.1.1.2 For pumps sold with inverter-only synchronous electric motors, the represented nominal full load motor + inverter efficiency is that of the motor with which the given pump model is being tested, as determined in accordance with any DOE test procedure for inverter-only synchronous electric motors in subpart B of this part, and, if available, applicable representation procedures in 10 CFR part 429 and this part.

E.1.2.1.1.3 For pumps sold with submersible motors, prior to the compliance date of any energy conservation standards for submersible motors in subpart B of this part, the default nominal full load submersible motor efficiency is that listed in table 2 of this appendix, with the number of poles relevant to the speed at which the pump is being tested (see section I.C.1 of this appendix) and the motor horsepower of the pump being tested, or if a test procedure for submersible motors is provided in subpart B of this part, the represented nominal full load motor efficiency of the motor with which the given pump model is being tested, as determined in accordance with the applicable test procedure in subpart B of this part and applicable representation procedures in 10 CFR part 429 and this part, may be used instead. Starting on the compliance date of any energy conservation standards for submersible motors in subpart B of this part, the default nominal full load submersible motor efficiency may no longer be used and instead the represented nominal full load motor efficiency of the motor with which the given pump model is being tested, as determined in accordance with the applicable test procedure in subpart B of this part and applicable representation procedures in 10 CFR part 429 and this part, must be used instead.

E.1.2.2 For load points corresponding to 25, 50, 75, and 100 percent of the BEP flow rate, determine the part load loss factor at each load point as follows:

$$z_i = a \times \left(\frac{P_i}{MotorHP}\right)^2 + b \times \left(\frac{P_i}{MotorHP}\right) + c$$

Where:

z_i = the motor and control part load loss factor at load point i,

a,b,c = coefficients listed in either Table 4 of this appendix for induction motors or Table 5 of this appendix for inverter-only synchronous electric motors, based on the horsepower of the motor with which the pump is being tested,

P_i = the pump power input to the bare pump at load point i, as determined in accordance with section VII.E.1.1 of this appendix (hp),

MotorHP = the horsepower of the motor with which the pump is being tested (hp),

i = load point corresponding to 25, 50, 75, or 100 percent of BEP flow rate, and

$\frac{P_i}{MotorHP} \leq 1.000$. If $\frac{P_i}{MotorHP} > 1.000$, then set $\frac{P_i}{MotorHP} = 1.000$ in the equation in section VII.E.1.2.2 of this appendix to calculate the part load loss factor at load point i.

TABLE 2—DEFAULT NOMINAL FULL LOAD SUBMERSIBLE MOTOR EFFICIENCY BY MOTOR HORSEPOWER AND POLE

Motor horsepower (hp)	Default nominal full load submersible motor efficiency		
	2 poles	4 poles	6 poles
1	55	68	64
1.5	66	70	72
2	68	70	74
3	70	75.5	75.5
5	74	75.5	75.5
7.5	68	74	72
10	70	74	72
15	72	75.5	74
20	72	77	74
25	74	78.5	77
30	77	80	78.5
40	78.5	81.5	81.5
50	80	82.5	81.5
60	81.5	84	82.5
75	81.5	85.5	82.5
100	81.5	84	82.5
125	84	84	82.5
150	84	85.5	85.5
200	85.5	86.5	85.5
250	86.5	86.5	85.5

* * * * *

TABLE 4—INDUCTION MOTOR AND CONTROL PART LOAD LOSS FACTOR EQUATION COEFFICIENTS FOR SECTION VII.E.1.2.2 OF THIS APPENDIX A

Motor horsepower (hp)	Coefficients for induction motor and control part load loss factor (z_i)		
	a	b	c
≤5	−0.4658	1.4965	0.5303
>5 and ≤20	−1.3198	2.9551	0.1052
>20 and ≤50	−1.5122	3.0777	0.1847
>50 and ≤100	−0.6629	2.1452	0.1952
>100	−0.7583	2.4538	0.2233

TABLE 5—INVERTER-ONLY SYNCHRONOUS ELECTRIC MOTOR AND CONTROL PART LOAD LOSS FACTOR EQUATION COEFFICIENTS FOR SECTION VII.E.1.2.2 OF THIS APPENDIX A

Motor horsepower (hp)	Coefficients for induction motor and control part load loss factor ($z_{i)}$		
	a	b	c
≤5	−0.0898	1.0251	0.0667
>5 and ≤20	−0.1591	1.1683	−0.0085
>20 and ≤50	−0.4071	1.4028	0.0055
>50 and ≤100	−0.3341	1.3377	−0.0023
>100	−0.0749	1.0864	−0.0096

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Part III

Securities and Exchange Commission

17 CFR Part 210, 229, 232, et al.
The Enhancement and Standardization of Climate-Related Disclosures for Investors; Proposed Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 210, 229, 232, 239, and 249

[Release Nos. 33–11042; 34–94478; File No. S7–10–22]

RIN 3235–AM87

The Enhancement and Standardization of Climate-Related Disclosures for Investors

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rule.

SUMMARY: The Securities and Exchange Commission (''Commission'') is proposing for public comment amendments to its rules under the Securities Act of 1933 (''Securities Act'') and Securities Exchange Act of 1934 (''Exchange Act'') that would require registrants to provide certain climate-related information in their registration statements and annual reports. The proposed rules would require information about a registrant's climate-related risks that are reasonably likely to have a material impact on its business, results of operations, or financial condition. The required information about climate-related risks would also include disclosure of a registrant's greenhouse gas emissions, which have become a commonly used metric to assess a registrant's exposure to such risks. In addition, under the proposed rules, certain climate-related financial metrics would be required in a registrant's audited financial statements.

DATES: Comments should be received on or before May 20, 2022.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/submitcomments.htm*).
- Send an email to *rule-comments@sec.gov.* Please include File Number S7–xx–xx on the subject line.

Paper Comments

- Send paper comments to Vanessa A. Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number S7–10–22. 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 of submission. The Commission will post all comments on the Commission's website (*https://www.sec.gov/rules/proposed.shtml*). Comments are also 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. Operating conditions may limit access to the Commission's Public Reference Room. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

Studies, memoranda, or other substantive items may be added by the Commission or staff to the comment file during this rulemaking. A notification of the inclusion in the comment file of any such materials will be made available on our website. To ensure direct electronic receipt of such notifications, sign up through the ''Stay Connected'' option at *www.sec.gov* to receive notifications by email.

FOR FURTHER INFORMATION CONTACT: Elliot Staffin, Special Counsel, Office of Rulemaking, at (202) 551–3430, in the Division of Corporation Finance; or Anita H. Chan, Professional Accounting Fellow or Shehzad K. Niazi, Acting Deputy Chief Counsel, in the Office of the Chief Accountant, at (202) 551–5300, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SUPPLEMENTARY INFORMATION: We are proposing to add 17 CFR 210.14–01 and 14–02 (Article 14 of Regulation S–X) and 17 CFR 17 CFR 229.1500 through 1506 (subpart 1500 of Regulation S–K) under the Securities Act [1] and the Exchange Act,[2] and amend 17 CFR 239.11 (Form S–1), 17 CFR 239.18 (Form S–11), 17 CFR 239.25 (Form S–4), and 17 CFR 239.34 (Form F–4) under the Securities Act, and 17 CFR 249.210 (Form 10), 17 CFR 249.220f (Form 20–F), 17 CFR 249.306 (Form 6–K), 17 CFR 249.308a (Form 10–Q), and 17 CFR 249.310 (Form 10–K) under the Exchange Act.

Table of Contents

[1] 15 U.S.C. 77a *et seq.*

[2] 15 U.S.C. 78a *et seq.*

I. Introduction

We are proposing to require registrants to provide certain climate-related information in their registration statements and annual reports, including certain information about climate-related financial risks and climate-related financial metrics in their financial statements. The disclosure of this information would provide consistent, comparable, and reliable—and therefore decision-useful—information to investors to enable them to make informed judgments about the impact of climate-related risks on current and potential investments.

The Commission has broad authority to promulgate disclosure requirements that are ''necessary or appropriate in the public interest or for the protection of investors.'' [3] We have considered this statutory standard and determined that disclosure of information about climate-related risks and metrics would be in the public interest and would protect investors. In making this determination, we have also considered whether the proposed disclosures ''will promote efficiency, competition, and capital formation.'' [4]

We are proposing to require disclosures about climate-related risks and metrics reflecting those risks because this information can have an impact on public companies' financial performance or position and may be material to investors in making investment or voting decisions. For this reason, many investors—including shareholders, investment advisers, and investment management companies—currently seek information about climate-related risks from companies to inform their investment decision-making. Furthermore, many companies have begun to provide some of this information in response to investor demand and in recognition of the potential financial effects of climate-related risks on their businesses.

We are concerned that the existing disclosures of climate-related risks do not adequately protect investors. For this reason, we believe that additional disclosure requirements may be necessary or appropriate to elicit climate-related disclosures and to improve the consistency, comparability, and reliability of climate-related disclosures. With respect to their existing climate-related disclosures (to the extent registrants are already disclosing such information), registrants often provide information outside of Commission filings and provide different information, in varying degrees of completeness, and in different documents and formats—meaning that the same information may not be available to investors across different companies. This could result in increased costs to investors in obtaining useful climate-related information and impair the ability to make investment or voting decisions in line with investors' risk preferences. Also, companies may not disclose certain information needed to understand their existing climate-related disclosures, such as the methodologies, data sources, assumptions, and other key parameters used to assess climate-related risks. To the extent companies primarily provide this information separate from their financial reporting, it may be difficult for investors to determine whether a company's financial disclosures are consistent with its climate-related disclosures.[5] In addition, the information provided outside of Commission filings is not subject to the full range of liability and other investor protections that help elicit complete and accurate disclosure by public companies.

Investors need information about climate-related risks—and it is squarely within the Commission's authority to require such disclosure in the public interest and for the protection of investors—because climate-related risks have present financial consequences that investors in public

[3] *See, e.g.,* Section 7 of the Securities Act [15 U.S.C. 77g] and Sections 12, 13, and 15 of the Exchange Act [15 U.S.C. 78*l,* 78m, and 78o].

[4] *See, e.g.,* Section 2(b) of the Securities Act [15 U.S.C. 77b(b)] and Section 3(f) of the Exchange Act [15 U.S.C. 78c(f)].

[5] S&P Global, *Seven ESG Trends to Watch in 2021* (Feb. 7, 2021), available at *https://www.spglobal.com/en/research-insights/featured/seven-esg-trends-to-watch-in-2021.* This study found that approximately 90% of S&P 500 companies publish sustainability reports but only 16% include any reference to ESG factors in their Commission filings.

companies consider in making investment and voting decisions.[6] Investors have noted that climate-related inputs have many uses in the capital allocation decision-making process including, but not limited to, insight into governance and risks management practices,[7] integration into various valuation models, and credit research and assessments.[8] Further, we understand investors often employ diversified strategies, and therefore do not necessarily consider risk and return of a particular security in isolation but also in terms of the security's effect on the portfolio as a whole, which requires comparable data across registrants.[9]

While climate-related risks implicate broader concerns—and are subject to various other regulatory schemes—our objective is to advance the Commission's mission to protect investors, maintain fair, orderly and efficient markets, and promote capital formation, not to address climate-related issues more generally. In particular, the impact of climate-related risks on both individual businesses and the financial system as a whole are well documented.[10] For example, the Financial Stability Oversight Council's (''FSOC's'') Report on Climate-Related Financial Risk 2021 found that businesses, financial institutions, investors, and households may experience direct financial effects from climate-related risks, and observed that the costs would likely be broadly felt as they are passed through supply chains and to customers and as they reduce firms' ability to service debt or produce returns for investors.[11] As a result, these climate-related risks and their financial impact could negatively affect the economy as a whole and create systemic risk for the financial system.[12] SEC-reporting companies and their investors are an essential component of this system.[13]

Climate-related risks can affect a company's business and its financial performance and position in a number of ways. Severe and frequent natural disasters can damage assets, disrupt operations, and increase costs.[14] Transitions to lower carbon products, practices, and services, triggered by changes in regulations, consumer preferences,[15] availability of financing, technology and other market forces,[16]

[6] *See* Financial Stability Oversight Council (''FSOC''), Report on Climate-Related Financial Risk 2021 (Oct. 2021) (''2021 FSOC Report''), available at *https://home.treasury.gov/system/files/261/FSOC-Climate-Report.pdf* (detailing the myriad ways that climate-related risks pose financial threats both at the firm level and financial system level). *See also Managing Climate Risk in the U.S. Financial System,* Report of the Climate-Related Market Risk Subcommittee, Market Risk Advisory Committee of the U.S. Commodity Futures Trading Commission (2020), available at *https://www.cftc.gov/sites/default/files/2020-09/9-9-20%20Report%20of%20the%20Subcommittee%20on%20Climate-Related%20Market%20Risk%20-%20Managing%20Climate%20Risk%20in%20the%20U.S.%20Financial%20System%20for%20posting.pdf* (''CFTC Advisory Subcommittee Report'') (stating that climate-related risks pose a major risk to the stability of the U.S. financial system and to its ability to sustain the American economy).

[7] *See, e.g.,* letters from Amalgamated Bank (June 14, 2021); and Norges Bank Investment Management (June 13, 2021).

[8] *See, e.g.,* letter from Principles for Responsible Investment (PRI) (Consultation Response) (June 11, 2021).

[9] *See, e.g., id.* (stating that broadly diversified investors evaluating any individual asset for addition to a portfolio need to consider its risk and return characteristics not in isolation, but in terms of the asset's effect on the portfolio as a whole, and providing CalPERS as an example of an asset owner holding a diversified growth-oriented portfolio that has integrated climate risk assessment into its investment process); *see also* letter from Amalgamated Bank (stating that the principal mitigant of investment risk is diversity of exposure and indicating that comprehensive climate disclosures help investors assess systemic risk); and Norges Bank Investment Management (stating that for sustainability information to support investment decisions, risk management processes, and ownership activities across a diversified portfolio, it must be consistent and comparable across companies and over time).

[10] In 2020 alone, a record 22 separate climate-related disasters with at least $1 billion in damages struck across the United States, surpassing the previous annual highs of 16 such events set in 2011 and 2017. *See* NOAA, National Center for Environmental Information, *Billion Dollar Weather and Climate Disasters: Summary Stats* (3rd Quarter release 2021), available at *https://www.ncdc.noaa.gov/billions/summary-stats/US/2020.* In 2021, the United States experienced 20 separate billion-dollar climate-related disasters. *See* NOAA, *U.S. saw its 4th-warmest year on record, fueled by a record-warm December* (Jan. 10, 2022), available at *https://www.noaa.gov/news/us-saw-its-4th-warmest-year-on-record-fueled-by-record-warm-december.*

[11] *See* 2021 FSOC Report, Chapter 1: *From Climate-Related Physical Risks to Financial Risks; From Climate-related Transition Risks to Financial Risks.* We discuss climate-related physical risks and climate-related transition risks in greater detail in Section II.B.1.

[12] *See* 2021 FSOC Report, Chapter 1: An Emerging Consensus Framework for Climate-related Financial Risks (stating that these effects would likely propagate through the financial sector, which may experience credit and market risks associated with loss of income, defaults and changes in the values of assets, liquidity risks associated with changing demand for liquidity, and operational risks associated with disruptions to infrastructure). *See also* Financial Stability Board (''FSB''), The Implications of Climate Change for Financial Stability (Nov. 2020) (stating that climate-related effects may be far-reaching in their breadth and magnitude, and could affect a wide variety of firms, sectors and geographies in a highly correlated manner, indicating that the value of financial assets/liabilities could be affected either by the actual or expected economic effects of a continuation of climate-related physical risks, which could lead to a sharp fall in asset prices and increase in uncertainty, or by risks associated with a transition towards a low-carbon economy, particularly if the transition is disorderly, which could have a destabilizing effect on the global financial system). *See also* Basel Committee on Banking Supervision, *Climate-related Risk Drivers and Their Transmission Channels* (Apr. 2021), at *https://www.bis.org/bcbs/publ/d517.pdf.*

[13] *See, e.g.,* The Editors, *Don't Drag Banks Into the Culture Wars,* The Washington Post (Mar. 7, 2022) (''No doubt, all companies—including those in the financial sector—must do more to manage social and environmental risks, in particular those related to climate change. To that end, the Securities and Exchange Commission is rightly working on climate-risk disclosure rules, so investors will have the information they need to make the best possible decisions and to hold public companies accountable.'').

[14] *See, e.g.,* 2021 FSOC Report, Chapter 1: From Climate-related Physical Risks to Financial Risks.

[15] *See, e.g., Why the automotive future is electric,* McKinsey & Company (Sept. 7, 2021), at *https://www.mckinsey.com/industries/automotive-and-assembly/our-insights/why-the-automotive-future-is-electric* (attributing the shift toward lower emissions forms of transportation, such as electric vehicles, to a combination of regulation, consumer behavior and technology); *A Fifth Of World's Largest Companies Committed To Net Zero Target,* Forbes (Mar. 24, 2021), at *https://www.forbes.com/sites/dishashetty/2021/03/24/a-fifth-of-worlds-largest-companies-committed-to-net-zero-target/?sh=2a72640f662f*; *See also, More than 1,000 companies commit to science-based emissions reductions in line with 1.5 °C climate ambition,* Joint Press Release by the United Nations Global Compact and the Science Based Targets Initiative (Nov. 9, 2021), at *https://finance.yahoo.com/news/more-1-000-companies-commit-000800027.html* (1,045 companies with more than $23 trillion in market capitalization are setting 1.5 °C aligned science based targets). *See also, Why Engage Suppliers on GHG Emissions?,* EPA Center for Corporate Climate Leadership, at *https://www.epa.gov/climateleadership/why-engage-suppliers-ghg-emissions* (''As organizations commit to reduce the carbon footprints of the products and services they provide, they look to their suppliers to align their efforts with the organization's sustainability goals'').

[16] *See, e.g.,* World Economic Forum, *First Movers Coalition is tackling the climate crisis,* at *https://www.weforum.org/our-impact/first-movers-coalition-is-tackling-the-climate-crisis/#:~:text=The%20First%20Movers%20Coalition%2C%20which%20was%20launched%20at,companies%20that%20use%20steel%20to%20build%20wind%20turbines* (''The World Economic Forum is partnering with the US Special Presidential Envoy for Climate John Kerry and over 30 global businesses to invest in innovative green technologies so they are available for massive scale-up by 2030 to enable net-zero emissions by 2050 at the latest.''); *COP26 made net zero a core principle for business. Here's how leaders can act,* McKinsey & Company (Nov. 12, 2021), at What COP26 means for business | McKinsey, at *https://www.mckinsey.com/business-functions/sustainability/our-insights/cop26-made-net-zero-a-core-principle-for-business-heres-how-leaders-can-act* (''The net-zero imperative is no longer in question—it has become an organizing principle for business . . . leaders who put convincing net-zero plans in place can distinguish their companies from peers. To put that another way: the basis of competition has changed, and there is now a premium on sound net-zero planning and execution.''); see also *S&P Dow Jones Indices Launches Net Zero 2050 Climate Transition and Paris-Aligned Select Indices* (Nov. 22, 2021), at *https://finance.yahoo.com/news/p-dow-jones-indices-launches-090000812.html* (The index is designed to ''bring greater transparency in measuring climate-related risks'' and help market participants ''achieve their goals in the path to net zero by 2050'').

can lead to changes in a company's business model.[17] Governments around the world have made public commitments to transition to a lower carbon economy, and efforts towards meeting those greenhouse gas (''GHG'') reduction goals have financial effects that may materially impact registrants.[18] In addition, banking regulators have recently launched initiatives to incorporate climate risk in their supervision of financial institutions.[19] How a company assesses and plans for climate-related risks may have a significant impact on its future financial performance and investors' return on their investment in the company.

Consistent, comparable, and reliable disclosures on the material climate-related risks public companies face would serve both investors and capital markets. Investors would be able to use this information to make investment or voting decisions in line with their risk preferences. Capital allocation would become more efficient as investors are better able to price climate-related risks. In addition, more transparency and comparability in climate-related disclosures would foster competition. Many other jurisdictions and financial regulators around the globe have taken action or reached similar conclusions regarding the importance of climate-related disclosures and are also moving towards the adoption of climate-related disclosure standards.[20]

This proposal builds on the Commission's previous rules and guidance on climate-related disclosures, which date back to the 1970s. In 2010, in response to increasing calls by the public and shareholders for public companies to disclose information regarding how climate change may affect their business and operations, the Commission published guidance (''2010 Guidance'') for registrants on how the Commission's existing disclosure rules may require disclosure of the impacts of climate change on a registrant's business or financial condition.[21] Since that time, as climate-related impacts have increasingly been well-documented and awareness of climate-related risks to businesses and the economy has grown,[22] investors have increased their demand for more detailed information about the effects of the climate on a registrant's business and for more information about how a registrant has addressed climate-related risks and opportunities when conducting its operations and developing its business strategy and financial plans.[23] It is appropriate for us to consider such investor demand in exercising our authority and responsibility to design an effective and efficient disclosure regime under the federal securities laws.

In developing these proposals, we have considered the feedback we have received to date from a wide range of commenters, including comments from investors as to the information they need to make informed investment or voting decisions, as well as concerns expressed by registrants with regard to compliance burdens and liability risk.[24] While our proposals include disclosure requirements designed to foster greater consistency, comparability, and reliability of available information, they also include a number of features designed to mitigate the burdens on registrants, such as phase-in periods for the proposed climate-related disclosure requirements,[25] a safe harbor for certain emissions disclosures,[26] and an exemption from certain emissions reporting requirements for smaller reporting companies.[27] In addition, the existing safe harbors for forward-looking statements under the Securities Act and Exchange Act would be available for aspects of the proposed disclosures.[28]

Although the various requirements we are proposing are supported by overlapping rationales, we emphasize that the different aspects of the proposal serve independent, albeit complementary, objectives. In addition, we have carefully considered how to craft this proposal to best advance investor protection and the public interest, consistent with the Commission's disclosure authority and regulatory mission, and we welcome comments on how we can further achieve that goal.

A. Background

The Commission first addressed the disclosure of material environmental issues in the early 1970s when it issued an interpretive release stating that registrants should consider disclosing in their SEC filings the financial impact of

[17] *See, e.g.,* Juan C.Reboredo and Luis A. Otero, *Are investors aware of climate-related transition risks? Evidence from mutual fund flows,* 189 Ecological Economics (Nov. 2021), available at *https://www.sciencedirect.com/science/article/abs/pii/S0921800921002068#!*; and BlackRock, *Climate risk and the transition to a low-carbon economy,* available at *https://www.blackrock.com/corporate/literature/publication/blk-commentary-climate-risk-and-energy-transition.pdf.*

[18] *See* Antony J. Blinken, Secretary of State, *The United States Officially Rejoins the Paris Agreement,* Press Statement, (Feb. 19, 2021). 191 countries plus the European Union have now signed the Paris Climate Agreement. The central aim of the Paris Climate Agreement is to strengthen the global response to the threat of climate change by keeping a global temperature rise this century to well below 2 °Celsius above pre-industrial levels and to pursue efforts to limit the temperature increase even further to 1.5 ° degrees Celsius. *See* Paris Agreement (Paris, Dec. 12, 2015) (entered into force Nov. 4, 2016). Moreover, at the UN Climate Change Conference (COP 26), the United States committed to become net zero by 2050, China by 2060, and India by 2070. Further, over 100 countries formed a coalition to reduce methane emissions by 30 percent by 2030. *See* Environment+Energy Leader, *COP26 Net Zero Commitments will Speed Energy Transition, Increase Pressure on Industries, According to Moody's Report* (Nov. 17, 2021).

[19] *See, e.g.,* OCC announcement: Risk Management: Principles for Climate-Related Financial Risk Management for Large Banks; Request for Feedback | OCC (treas.gov), available at *https://www.occ.treas.gov/news-issuances/bulletins/2021/bulletin-2021-62.html;* and Principles for Climate-Related Financial Risk Management for Large Banks (treas.gov) (Dec. 16, 2021), available at *https://www.occ.treas.gov/news-issuances/bulletins/2021/bulletin-2021-62a.pdf.*

[20] *See infra* Section I.C.2.

[21] *See* Commission Guidance Regarding Disclosure Related to Climate Change, Release No. 33–9106 (Feb. 2, 2010) [75 FR 6290 (Feb. 8, 2010)]. We discuss the 2010 Guidance in greater detail in Section I.A. below.

[22] *See, e.g., supra* notes 6, 10, and 12.

[23] *See, e.g.,* Larry Fink, *A Fundamental Reshaping of Finance,* 2020 Letter to CEOs, at *https://www.blackrock.com/corporate/investor-relations/2020-larry-fink-ceo-letter*, available at *https://www.blackrock.com/corporate/investor-relations/2020-larry-fink-ceo-letter* (stating that climate risk is investment risk and asking the companies that BlackRock invests in to, among other matters, disclose climate-related risks in line with the recommendations of the Task Force on Climate-related Financial Disclosures); *see also* Climate Action 100+, at *https://www.climateaction100.org/.* Climate Action 100+ is an investor-led initiative composed of 615 investors who manage $60 trillion in assets (as of Nov. 2021), who aim ''to mitigate investment exposure to climate risk and secure ongoing sustainable returns for their beneficiaries.'' *See also* Glasgow Financial Alliance for Net Zero (GFANZ), at *https://www.gfanzero.com/,* a global coalition of leading financial institutions focused on promoting the transition to a net zero global economy. Formed in Apr. 2021, its membership as of Nov. 2021 included over 450 financial firms controlling assets of over $130 trillion. Further, more than 500 investor signatories with assets under management of nearly $100 trillion are signatories to the CDP climate risk disclosure program, *https://cdn.cdp.net/cdp-production/comfy/cms/files/files/000/004/697/original/2021_CDP_Capital_Markets_Brochure_General.pdf.* We discuss the growing investor demand for climate-related information in greater detail in Section I.C below.

[24] *See* Acting Chair Allison Herren Lee Public Statement, *Public Input Welcomed on Climate Change Disclosures* (Mar. 15, 2021), available at *https://www.sec.gov/news/public-statement/lee-climate-change-disclosures. See also, e.g., Concept Release: Business and Financial Disclosure Required by Regulation S–K,* Release No. 33–10064 (Apr. 16, 2016), [83 FR 23915 (Apr. 22, 2016)] and related comments, available at *https://www.sec.gov/rules/concept/conceptarchive/conceptarch2016.shtml.*

[25] *See infra* Section II.M.

[26] *See* Section II.G.3.

[27] *See id.*

[28] *See* Securities Act Section 27A [15 U.S.C. 77z–2] and Exchange Act Section 21E [15 U.S.C. 78u–5]. We discuss the application of the existing forward-looking statement safe harbors to the proposed climate-related disclosures primarily in Sections II.C.3–4, II.E, II.G.1, and II.I.

compliance with environmental laws.[29] Throughout the 1970s, the Commission continued to explore the need for specific rules mandating disclosure of information relating to litigation and other business costs arising out of compliance with federal, state, and local laws that regulate the discharge of materials into the environment or otherwise relate to the protection of the environment. These topics were the subject of several rulemaking efforts, extensive litigation, and public hearings, all of which resulted in the rules that now specifically address disclosure of environmental issues.[30]

After almost a decade of consideration, the Commission adopted rules in 1982 mandating disclosure of information relating to litigation and other business costs arising out of compliance with federal, state, and local laws that regulate the discharge of materials into the environment or otherwise relate to the protection of the environment.[31] In addition to these specific disclosure requirements, the Commission's other disclosure rules requiring, for example, information about material risks and a description of the registrant's business, could give rise to an obligation to provide disclosure related to the effects of climate change.[32]

In its 2010 Guidance, the Commission observed that, in response to investor demand for climate-related information, many companies were voluntarily reporting climate-related information outside their filings with the Commission. The Commission emphasized that ''registrants should be aware that some of the information they may be reporting pursuant to these mechanisms also may be required to be disclosed in filings made with the Commission pursuant to existing disclosure requirements.'' [33] Specifically, the 2010 Guidance emphasized that climate change disclosure might, depending on the circumstances, be required in a company's Description of Business, Risk Factors, Legal Proceedings, and Management's Discussion and Analysis of Financial Condition and Results of Operations (''MD&A'').[34] The 2010 Guidance further identified certain climate-related issues that companies may need to consider in making their disclosures, including the direct and indirect impact of climate-related legislation or regulations, international agreements, indirect consequences of business trends including changing demand for goods, and the physical impacts of climate change.

The proposals set forth in this release would augment and supplement the disclosures already required in SEC filings. Accordingly, registrants should continue to evaluate the climate-related risks they face and assess whether disclosures related to those climate-related risks must be disclosed in their Description of Business, Risk Factors, Legal Proceedings, and MD&A as described in the 2010 Guidance. These disclosures should be based on the registrant's specific facts and circumstances. While climate risks impact many issuers across industries, the impacts of those risks on a particular registrant and how the registrant addresses those risks are fact-specific and may vary significantly by registrant.[35] The disclosures required by our existing rules should reflect these company-specific risks.

B. The March 2021 Request for Public Input

On March 15, 2021, Acting Chair Allison Herren Lee requested public input on climate disclosure from investors, registrants, and other market participants.[36] The Acting Chair solicited input on several issues, including how the Commission could best regulate disclosure concerning climate change in order to provide more consistent, comparable, and reliable information for investors, whether the Commission should require the disclosure of certain metrics and other climate-related information, the role that existing third-party climate-related disclosure frameworks should play in the Commission's regulation of such disclosure, and whether and how such disclosure should be subject to assurance.

The Commission received approximately 600 unique letters and over 5800 form letters in response to the Acting Chair's request for public input.[37] We received letters from academics, accounting and audit firms, individuals, industry groups, investor groups, registrants, non-governmental organizations, professional climate advisors, law firms, professional investment advisors and investment management companies, standard-setters, state government officials, and US Senators and Members of the House of Representatives.

Many of these commenters, including investors with trillions of dollars of assets under management collectively,[38]

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[29] *See* Release No. 33–5170 (July 19, 1971) [36 FR 13989]. The Commission codified this interpretive position in its disclosure forms two years later. See Release 33–5386 (Apr. 20, 1973) [38 FR 12100] (''1972 Amendments'').

[30] *See* Interpretive Release No. 33–6130 (Sept. 27, 1979) [44 FR 56924], which includes a brief summary of the National Environmental Policy Act of 1969 and the legal and administrative actions taken with regard to the Commission's environmental disclosure during the 1970s. *See also NRDC* v. *SEC,* 606 F.2d 1031, 1036–42 (DC Cir. 1979) (discussing this history). More information relating to the Commission's efforts in this area is chronicled in Release No. 33–6315 (May 4, 1981) [46 FR 25638].

[31] *See* Release No. 33–6383 (Mar. 3, 1982) [47 FR 11380] (''1982 Release'') (adopting 17 CFR 229.103, which requires a registrant to describe its material pending legal proceedings, other than ordinary routine litigation incidental to the business, and indicating that administrative or judicial proceedings arising under federal, state, or local law regulating the discharge of materials into the environment or primarily for the purpose of protecting the environment, shall not be deemed ''ordinary routine litigation incidental to the business'' and must be described if meeting certain conditions). The 1982 Release also moved the information called for by the 1973 Amendments to 17 CFR 229.101(c)(1)(xii), which, as part of a registrant's business description, required the disclosure of the material effects that compliance with Federal, State and local provisions regulating the discharge of materials into the environment, or otherwise relating to the protection of the environment, have had upon the registrant's capital expenditures, earnings and competitive position, as well as the disclosure of its material estimated capital expenditures for environmental control facilities. In 2020, the Commission amended 17 CFR 229.101(c)(1) to require, to the extent material to an understanding of the business taken as a whole, disclosure of the material effects that compliance with government regulations, including environmental regulations, may have upon the capital expenditures, earnings, and competitive position of the registrant and its subsidiaries. *See Modernization of Regulation S–K Items 101, 103, and 105,* Release No. 33–10825 (Aug. 26, 2020) [85 FR 63726 (Oct. 8, 2020)] (''2020 Release'').

[32] *See* Release No. 33–9106, Section III.

[33] *See* Release No. 33–9106, Section I.

[34] The 2010 Guidance also applies to corresponding disclosure requirements in Form 20–F by foreign private issuers.

[35] Our recent amendments to Item 105 of Regulation S–K discourage the presentation of generic risks that could apply generally to any registrant or offering. The fact that climate risks are broad-based does not, in our view, cause them to be generic. For example, thousands of companies in Houston were impacted by Hurricane Harvey. However, (1) their flood risk varied and some companies may have been far more impacted than others (and would be more vulnerable to future catastrophic storms); (2) their operations were different and some may have been more disrupted as a result than others—*e.g.,* a services business on the 10th floor of a building may have experienced just a few days of disruption while an oil refinery may have been shut down for weeks; and (3) their risk management processes may have been different—two similarly situated companies may have different continuity of operations plans or may have taken steps to mitigate those types of risks. In sum, while the source of the risk may be common to many companies, the impact is not.

[36] *See* Acting Chair Allison Herren Lee Public Statement, Public Input Welcomed on Climate Change Disclosures.

[37] The comment letters are available at *https://www.sec.gov/comments/climate-disclosure/cll12.htm*. Except as otherwise noted, references to comments in this release pertain to these comments.

[38] *See, e.g.,* letters from BlackRock (June 11, 2021) ($9T); Ceres (June 10, 2021) (representing Investor Network on Climate Risk and Sustainability) ($37T); Council of Institutional Investors (June 11,

supported implementation of climate-related disclosure rules. A number of commenters [39] stated that mandated disclosures are necessary because climate change poses significant financial risks to registrants and their investors.[40] According to one of the commenters, 68 out of 77 industries are likely to be significantly affected by climate risk.[41] Many commenters criticized the current disclosure practice, in which some issuers voluntarily provide climate disclosures based on a variety of different third-party frameworks, because it has not produced consistent, comparable, reliable information for investors and their advisors, who otherwise have difficulty obtaining that information.[42]

Other commenters, however, questioned whether climate change posed a risk to companies or their investors. These commenters stated their belief that the assumptions underlying the assessment of the impact of climate change were too uncertain to permit companies to ascertain the real risks to their operations and financial condition caused by climate change.[43] These commenters stated that they opposed implementation of climate-related disclosure rules, and argued that such rules would exceed the Commission's statutory authority. Some of these commenters also argued that such rules are not necessary because registrants are already required to disclose material climate risks, or that such rules would be more costly than the current ''private ordering'' of climate disclosures.[44] Some commenters also argued that mandated climate disclosure rules could violate First Amendment rights.[45]

As noted above, we have considered these comments and other feedback received from the public in formulating the current proposal. As part of its filing review process, the Commission staff also assessed the extent to which registrants currently disclose climate-related risks in their Commission filings. Since 2010, disclosures related to climate change have generally increased, but there is considerable variation in the content, detail, and location (*i.e.,* in reports filed with the Commission, in sustainability reports posted on registrant websites, or elsewhere) of climate-related disclosures. The staff has observed significant inconsistency in the depth and specificity of disclosures by registrants across industries and within the same industry. The staff has found significantly more extensive information in registrants' sustainability reports and other locations such as their websites as compared with their reports filed with the Commission. In addition, the disclosures in registrants' Forms 10–K frequently contain general, boilerplate discussions that provide limited information as to the registrants' assessment of their climate-related risks or their impact on the companies' business.[46]

We are also mindful of the benefits to investors of requiring climate-related information in SEC filings. Providing more extensive climate-related disclosure in sustainability reports, while excluding such relevant information from Forms 10–K, may make it difficult for investors to analyze and compare how climate-related risks and impacts affect registrants' businesses and consolidated financial statements. The inclusion of climate-related disclosures in SEC filings should increase the consistency, comparability, and reliability of climate-related information for investors. The placement of climate-related information in different locations can make it difficult for investors to find comparable climate-related disclosures, whereas inclusion in a registrant's Form 10–K or registration statement should make it easier for investors to find and compare this information.[47] Further, information that is filed with the Commission in Exchange Act periodic reports is subject to disclosure controls and procedures (''DCP''), which help to ensure that a registrant maintains appropriate processes for collecting and communicating the necessary information by which to formulate the climate-related disclosures.[48] Moreover, information filed as part of a registrant's Form 10–K carries certain additional potential liability, which itself can cause registrants to prepare and review information filed in the Form 10–K more carefully than information presented outside SEC filings.[49]

2021) ($4T); Investment Adviser Association (June 11, 2021) ($25T); Investment Company Institute (June 4, 2021) ($30.8T); PIMCO (June 9, 2021) ($2T); SIFMA (June 10, 2021) ($45T); State Street Global Advisors (June 14, 2021) (3.9T); and Vanguard Group, Inc. (June 11, 2021) ($7T).

[39] *See, e.g.,* letters from AllianceBernstein; Amalgamated Bank; Boston Common Asset Management (June 14, 2021); Calvert Research and Management (June 1, 2021); Ceres; the Committee on Mission Responsibility through Investment by Presbyterian Church (June 10, 2021); Katherine DiMatteo (June 1, 2021); Domini Impact Investments (June 14, 2021); Felician Sisters of North America (June 8, 2021); Friends Fiduciary (June 11, 2021); Melanie Bender (May 26, 2021); Miller/Howard Investments (June 11, 2021); Mercy Investment Services, Inc. (June 4, 2021); Parametric Portfolio Associates, LLC (June 4, 2021); San Francisco City and County Employees' Retirement System (June 12, 2021); Seventh Generation Interfaith, Inc. (May 20, 2021); State Street Global Advisors; Sustainability Accounting Standards Board (SASB) (May 19, 2021); the Sustainability Group (June 4, 2021); and Trillium Asset Management (June 9, 2021).

[40] Several commenters referred to various reports by the Intergovernmental Panel on Climate Change (''IPCC'') to demonstrate that there is scientific consensus that climate change is the result of global warming caused by human-induced emissions of greenhouse gases and poses significant global risks. *See, e.g.,* letters from Better Markets (June 14, 2021); Center for Human Rights and Environment (June 9, 2021); Commonwealth Climate and Law Initiative (June 13, 2021); Charles E. Frye (Apr. 3, 2021); Interfaith Center on Corporate Responsibility (June 14, 2021); and Mike Levin and 23 other Members of Congress (June 15, 2021). IPCC's latest report is IPCC, AR6 Climate Change 2021: The Physical Science Basis (Aug. 7, 2021), available at *https://www.ipcc.ch/report/ar6/wg1/.*

[41] *See* letter from SASB.

[42] *See, e.g.,* letters from Amalgamated Bank; Bank of Finland (June 1, 2021); Blueprint Financial (June 11, 2021); Canadian Coalition of Good Governance (June 9, 2021); Center for Climate and Energy Solutions (June 12, 2021); Clean Yield Asset Management (June 11, 2021); Coalition for Inclusive Capitalism (June 14, 2021); Felician Sisters of North America; First Affirmative Financial Network (June 2, 2021); William and Flora Hewitt Foundation (June 9, 2021); Impact Investors, Inc. (June 2, 2021); Impax Asset Management (June 9, 2021); Institute of International Bankers (June 8, 2021); Investment Company Institute; Investment Consultants Sustainability Working Group (June 11, 2021); Miller/Howard Investments; Norge Bank Investment Management (June 13, 2021); Parametric Portfolio Associates; Praxis Mutual Funds and Everence Financial (June 10, 2021); PRI (Consultation Response); Salesforce.com Inc. (June 11, 2021); San Francisco City and County Employees' Retirement System; SASB; Seventh Generation Interfaith, Inc.; S&P Global (June 11, 2021); Trillium Asset Management; World Business Council for Development (WBCSD) (June 11, 2021); Vanguard Group, Inc.; and US Impact Investing Alliance (June 14, 2021).

[43] *See, e.g.,* letters from American Enterprise Institute (June 10, 2021); CO_2 Coalition (June 1, 2021); the Heritage Foundation (June 13, 2021); Steve Milloy (June 1, 2021); Berkeley T. Rulon-Miller (Apr. 9, 2021); and the Texas Public Policy Foundation (June 11, 2021).

[44] *See, e.g.,* letters from American Enterprise Institute; the Cato Institute; the Heritage Foundation; and Texas Public Policy Foundation.

[45] *See, e.g.,* letters from the Institute for Free Speech (June 10, 2021); Patrick Morrisey, West Virginia Attorney General (Mar. 25, 2021); and Texas Public Policy Foundation.

[46] The staff of the Division of Corporation Finance has developed a sample comment letter for registrants to elicit improved disclosure on some of the deficient areas noted in their review of filings. *See* Climate Change Disclosure-Sample Letter, *available at https://www.sec.gov/corpfin/sample-letter-climate-change-disclosures.*

[47] *See, e.g.,* letter from Pricewaterhouse Coopers.

[48] *See* 17 CFR 240.13a–15 and 17 CFR 240.15d–15.

[49] We note that the liability provisions of Section 10(b) and Rule 10b–5 of the Exchange Act can apply to statements made in filings with the SEC or elsewhere, such as in sustainability reports or on company websites. *See, e.g.,* SEC v. *Stinson,* No. 10–3130, 2011 U.S. Dist. LEXIS 65723, 2011 WL 2462038, at 12 (E.D. Pa. June 20, 2011) (finding defendants liable under Section 10(b) when they communicated material misstatements and omissions in direct solicitations via email, a webinar, and various websites). As such, registrants should scrutinize and ensure the accuracy of such statements whether or not filed with the

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Having considered the public feedback and the staff's experience with climate-related disclosures, we believe that the current disclosure system is not eliciting consistent, comparable, and reliable information that enables investors both to assess accurately the potential impacts of climate-related risks on the nature of a registrant's business and to gauge how a registrant's board and management are assessing and addressing those impacts.[50] The Commission has broad authority to promulgate disclosure rules that are in the public interest or for the protection of investors and that promote efficiency, competition, and capital formation.[51] In light of the present and growing significance of climate-related risks to registrants and the inadequacies of current climate disclosures, we are proposing to revise our rules to include climate-related disclosure items and metrics to elicit investment decision-useful information that is necessary or appropriate to protect investors.

We also believe that enhanced climate disclosure requirements could increase confidence in the capital markets and help promote efficient valuation of securities and capital formation by requiring more consistent, comparable, and reliable disclosure about climate-related risks, including how those risks are likely to impact a registrant's business operations and financial performance.[52] The proposed requirements may also result in benefits to registrants, given existing costs to registrants that have resulted from the inconsistent market response to investor demand for climate-related information.[53] In this regard our proposal would provide registrants with a more standardized framework to communicate their assessments of climate-related risks as well as the measures they are taking to address those risks.[54] At the same time, we are open to exploring ways in which registrants could be afforded flexibility in making the necessary disclosures while still providing appropriate consistency and comparability, and are seeking comment in that regard.

C. The Growing Investor Demand for Climate-Related Risk Disclosure and Related Information

1. Major Investor Climate-Related Initiatives

As the Commission recognized in 2010 and earlier, there has been significant investor demand for information about how climate conditions may impact their investments. That demand has been increasing in recent years. Several major institutional investors, which collectively have trillions of dollars in investments under management, have demanded climate-related information from the companies in which they invest because of their assessment of climate change as a risk to their portfolios, and to investments generally, and also to satisfy investor interest in investments that are considered ''sustainable.'' As a result, these investors have sought to include and consider climate risk as part of their investment selection process.[55] These institutional investors have formed investor initiatives to collectively urge companies to provide better information about the impact that climate change has had or is likely to have on their businesses, and to urge governments and companies to take steps to reduce investors' exposure to climate risks. Among these initiatives:[56]

- In 2019, more than 630 investors collectively managing more than $37 trillion signed the Global Investor Statement to Governments on Climate Change urging governments to require climate-related financial reporting; [57]
- This investor initiative continued as the Investor Agenda's 2021 Global Investor Statement to Governments on the Climate Crisis, which was signed by 733 global institutional investors, including some of the largest investors, with more than US $52 trillion in assets under management in the aggregate. This Statement called for governments to implement a number of measures, including mandating climate risk disclosure.[58]
- The UN Principles for Responsible Investment (''PRI'') [59] has acquired over 4,000 signatories who, as of July 13, 2021, have, in the aggregate, assets under management exceeding $120 trillion as of July 13, 2021; [60]
- The Net Zero Asset Managers Initiative, which was formed by an international group of asset managers, has 128 signatories that collectively

Commission. In addition, information filed in a Form 10–K is subject to Section 18 of the Exchange Act. Further, information filed in an annual report on Form 10–K (and other current and periodic reports) can be incorporated by reference in certain Securities Act registration statements, such as those filed on Form S–3, and thereby become subject to the liability provisions of the Securities Act. See Securities Act Section 11 (15 U.S.C. 77k) and Section 12 (15 U.S.C. 77l). *See infra* Section II.C.3–4, II.E, II.G.1, and II.I regarding the application to forward-looking climate disclosures of the safe harbor for forward-looking statements that was added to the Securities Act and Exchange Act pursuant to the Private Securities Litigation Reform Act of 1995.

[50] *See supra* note 42 and accompanying text.

[51] *See* letters from Jill E. Fisch and 18 other law professor signatories (June 11, 2021) (referencing Sections 7, 10, and 19(a) of the Securities Act; and Sections 3(b), 12, 13, 14, 15(d), and 23(a) of the Exchange Act); and Natural Resources Defense Council (June 11, 2021).

[52] *See* letters from Eni SpA (June 12, 2021); Jill. E. Fisch *et al;* Natural Resources Defense Council; SASB; and Value Balancing Alliance (June 28, 2021); *see also infra* Section IV.

[53] *See, e.g.,* letter from SASB (stating that through the ''multiple voluntary disclosure frameworks (*i.e.,* the ''alphabet soup'' decried by companies) . . . and numerous direct requests to companies for information through surveys, the current private ordering-led system has increased the burden on companies—and investors—while still leaving many companies uncertain as to whether they are, in practice, providing the decision-useful information required by investors.''); *see also* letters from Americans for Financial Reform Education Fund and Public Citizen (June 14, 2021) (stating that ''the proliferation of differing frameworks has increased compliance complexities and costs for companies''); Eni SpA (stating that the fragmentation of data fostered by the proliferation of reporting frameworks has multiplied the efforts of companies in satisfying all their requirements); and BSR (June 11, 2021) (providing that ''a fragmented environment is limiting the impact of reporting and creating undue confusion and cost on the part of reporters.'').

[54] Providing a more standardized framework for climate-related disclosures would be consistent with the Recommendation from the Investor-as-Owner Subcommittee of the SEC Investor Advisory Committee Relating to ESG Disclosure (May 14, 2020) (''IAC Recommendation''), available at *https://www.sec.gov/spotlight/investor-advisory-committee-2012/recommendation-of-the-investor-as-owner-subcommittee-on-esg-disclosure.pdf.* The term ''ESG'' refers to environmental, social, and governance matters, of which climate-related disclosures is a part. The IAC Recommendation focused on the inadequacies of ESG disclosures broadly, and not just on those involving climate. The IAC Recommendation stated that, to the extent that SEC reporting obligations would require a single standard of material, decision-useful ESG information, as relevant to each issuer, and based upon data that issuers already use to make their business decisions, such an approach would level the playing field between well-financed large issuers and capital constrained small issuers.

[55] *See supra* note 23.

[56] There is some overlap in the signatories to the listed initiatives.

[57] *See* United Nations Climate Change, *631 Institutional Investors Managing More than USD 37 Trillion in Assets Urge Governments to Step up Climate Ambition* (Dec. 9, 2019), available at *https://unfccc.int/news/631-institutional-investors-managing-more-than-usd-37-trillion-in-assets-urge-governments-to-step-up.*

[58] *See* The Investor Agenda, 2021 Global Investor Statement to Governments on the Climate Crisis (Oct. 27, 2021), available at *https://theinvestoragenda.org/wp-content/uploads/2021/09/2021-Global-Investor-Statement-to-Governments-on-the-Climate-Crisis.pdf.*

[59] PRI was created by a UN-sponsored small group of large global investors in 2006. A stated core goal of the PRI is to help investors protect their portfolios from climate-related risks and to take advantage of climate-related opportunities associated with a shift to a low-carbon global economy. *See* PRI, *Climate Change,* available at *https://www.unpri.org/climate-change.*

[60] *See* PRI, *CEO quarterly update: Celebrating 4000 signatories and supporting the evolution of PRI* (July 13, 2021), available at *https://www.unpri.org/pri-blog/ceo-quarterly-update-celebrating-4000-signatories-and-supporting-the-evolution-of-ri/8033.article.*

manage $43 trillion in assets as of July 2021;[61]

- The Climate Action 100+, an investor-led initiative, now comprises 617 global investors that together have more than $60 trillion in assets under management;[62] and
- The Glasgow Financial Alliance for Net Zero (''GFANZ''), a coalition of over 450 financial firms from 45 countries, responsible for assets of over $130 trillion, that are committed to achieving net-zero emissions by 2050, reaching 2030 interim targets, covering all emission scopes and providing transparent climate-related reporting.[63]

Each of these investor initiatives has emphasized the need for improved disclosure by companies regarding climate-related impacts. Each of these initiatives has advocated for mandatory climate risk disclosure requirements aligned with the recommendations of the Task Force on Climate-Related Financial Disclosures (''TCFD'')[64] so that disclosures are consistent, comparable, and reliable. The investor signatories of Climate Action 100+ emphasized that obtaining better disclosure of climate-related risks and companies' strategies to address their exposure to those risks is consistent with the exercise of their fiduciary duties to their respective clients.[65]

At the same time, many companies have made commitments with respect to climate change, such as commitments to reduce greenhouse gas emissions or become ''net zero'' by a particular date.[66] Companies may make these commitments to attract investors, to appeal to customers that prioritize sustainability, or to reduce their exposure to risks posed by an expected transition to a lower carbon economy.[67] In response to these commitments, investors have demanded more detailed information about climate-related targets and companies' plans to achieve them in order to assess the credibility of those commitments and compare companies based on those commitments.[68]

These initiatives demonstrate that investors are using information about climate risks now as part of their investment selection process and are seeking more informative disclosures about those risks. As an increasing number of investors incorporate this information, in particular GHG emissions, into their investment selection or voting decisions, this may in turn create transition risks for companies that are seeking to raise capital.

2. Third-Party Data, Voluntary Disclosure Frameworks, and International Disclosure Initiatives

Despite increasing investor demand for information about climate-related risks and strategies, many investors maintain that they cannot obtain the consistent, comparable, and material information that they need to properly inform their investment or voting decisions.[69] In 2020, the Commission's Investor Advisory Committee (''IAC'') noted the fragmentation of information that has resulted from a rise in third-party data providers that have emerged to try to meet the informational demands of investors.[70] The IAC recommended that the Commission take action to ensure investors have the material, comparable, consistent information about climate and other ESG matters that they need to make investment and voting decisions.

In addition, a diverse group of third parties has developed climate-related reporting frameworks seeking to meet investors' informational demands. These include the Global Reporting Initiative (''GRI''),[71] CDP (formerly the Carbon Disclosure Project),[72] Climate Disclosure Standards Board (''CDSB''),[73] Value Reporting Foundation (formed through a merger of the Sustainability Accounting Standards Board (''SASB'') and the International Integrated Reporting Council (''IIRC'')),[74] and the TCFD.[75]

To some extent, the development of these disparate frameworks has led to an increase in the number of companies that are providing some climate-related disclosures.[76] However, because they

[61] *See* Net Zero Asset Managers Initiative, *Net Zero Asset Managers initiative announces 41 new signatories, with sector seeing 'net zero tipping point'* (July 6, 2021), available at *https://www.netzeroassetmanagers.org/net-zero-asset-managers-initiative-announces-41-new-signatories-with-sector-seeing-net-zero-tipping-point.*

[62] *See* Climate Action 100+, *About Climate Action 100+*, available at *https://www.climateaction100.org/about/* (indicating that the initiative is engaging companies on strengthening climate-related financial disclosures).

[63] *See* GFANZ, *About Us,* available at *https://www.gfanzero.com/about/.* Another organization, the CDP, provides a means for investors to request that companies provide climate-related disclosures through the CDP. In 2021, over 590 investors with $110 trillion in assets under management requested that thousands of companies disclose climate related information to them through the CDP. *See* CDP, *Request Environmental Information,* available at *https://www.cdp.net/en/investor/request-environmental-information#d52d69887a88f63e15931b5db2cbe80d.*

[64] We discuss the TCFD in greater detail in Section I.D.1 below.

[65] *See* Climate Action 100+, *About Climate Action 100+*. Further, commenters noted their fiduciary obligations to consider climate-related risks. *See, e.g.,* letters from PRI (Consultation Response); and California Public Employee Retirement System (CalPERS) (June 12, 2021).

[66] According to one publication, two-thirds of S&P 500 companies had set a carbon reduction target by the end of 2020. *See* Jean Eaglesham, *Climate Promises by Businesses Face New Scrutiny,* The Wall Street Journal (Nov. 5, 2021).

[67] *See* Global Survey Shows Race to Decarbonization is on: Johnson Controls finds Delivering Growth and Competitive Advantage are Main Drivers for Companies to Commit to Net Zero (Dec. 1, 2021), available at *https://ih.advfn.com/stock-market/NYSE/johnson-controls-JCI/stock-news/86696470/global-survey-shows-race-to-decarbonization-is-on#:~:text=Global%20Survey%20Shows%20Race%20to%20Decarbonization%20is%20on%3A,December%2001%202021%20-%2007%3A01AM%20PR%20Newswire%20%28US%29;* and COP26 made net zero a core principle for business. Here's how leaders can act, McKinsey (Nov. 12, 2021), available at *https://www.mckinsey.com/business-functions/sustainability/our-insights/cop26-made-net-zero-a-core-principle-for-business-heres-how-leaders-can-act.*

[68] *See, e.g.,* letters from Ceres; Investor Adviser Association (June 11, 2021); SIFMA Asset Management Group (June 10, 2021); Trillium Asset Management; and T. Rowe Price (June 11, 2021); *see also* letters from Boston University Impact Measurement and Allocation Program (June 7, 2021); CDP (June 11, 2021); Christopher Lish (June 12, 2021); and Pricewaterhouse Coopers (June 10, 2021).

[69] *See supra* note 42.

[70] *See* IAC Recommendation. The IAC Recommendation noted that more than 125 third-party ESG data providers, including ESG ratings firms, have emerged to try to meet the informational demands of investors. According to the IAC Recommendation, these data providers are limited in their ability collectively to provide investors with comparable and consistent information as they use different information sources and different—frequently opaque—methodologies to conduct their analyses, which compromises the usefulness and reliability of the information. This current heterogeneity in practices and disparate demands from investors and ratings firms places a significant burden on companies asked to provide this information in a variety of formats. The IAC Recommendation further observed that many companies feel compelled to respond to the multiple surveys of ESG rating firms because ignoring them or refusing to respond can lead to a low rating, which can adversely affect stock price and access to capital. While the proposed rules would not necessarily eliminate third-party questionnaires, they would help to provide standardized information to all investors and might reduce the need to obtain the information obtained through questionnaires.

[71] *See* GRI, *About GRI,* available at *https://www.globalreporting.org/about-gri/.*

[72] *See* CDP, *About Us,* available at *https://www.cdp.net/en/info/about-us.* In 2018, CDP revised its questionnaire to companies so that it aligns with the TCFD recommended framework. *See* letter from CDP.

[73] *See* CDSB, *About the Climate Disclosure Standards Board,* available at *https://www.cdsb.net/our-story.*

[74] *See* Value Reporting Foundation, *Understanding the Value Reporting Foundation,* available at *https://www.valuereportingfoundation.org/.*

[75] *See* TCFD, *About,* available at *https://www.fsb-tcfd.org/about/.*

[76] For example, according to the CDP, over 3,000 companies have provided climate-related disclosures through the CDP's platform by responding to the CDP's questionnaires that are aligned with the TCFD's disclosure recommendations. *See* letter from CDP. The TCFD

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are voluntary, companies that choose to disclose under these frameworks may provide partial disclosures or they may choose not to participate every year. In addition, the form and content of the disclosures may vary significantly from company to company, or from period to period for the same company. The situation resulting from these multiple voluntary frameworks has failed to produce the consistent, comparable, and reliable information that investors need.[77] Instead, the proliferation of third-party reporting frameworks has contributed to reporting fragmentation, which can hinder investors' ability to understand and compare registrants' climate-related disclosures. An analysis conducted by the World Business Council for Sustainable Development found that investors had difficulty using existing sustainability disclosures because they lack consistency and comparability.[78] In addition, a 2020 study by the Yale Initiative on Sustainable Finance found that the proliferation of reporting frameworks may have made reporting more difficult for issuers.[79] Moreover, given the voluntary nature of these third-party frameworks, there may not be sufficient incentives or external disciplines to ensure that companies are providing complete and robust disclosure under those frameworks.[80]

The staff has reviewed more than a dozen studies of climate-related disclosures conducted by third parties, such as the CDP,[81] KPMG,[82] TCFD[83], and Ernst & Young,[84] which assessed the adherence of the climate-related disclosures to various third-party frameworks, such as the TCFD. These studies have reinforced the staff's observations from their review of filings that there is significant variation across companies and industries with regard to the content of current climate disclosures.[85] Further, much of this climate-related information, particularly GHG emissions and targets, appears outside of Commission filings, in sustainability reports, and on corporate websites. Other analyses of current climate reporting have found a lack of transparency and standardization with regard to the methodologies companies apply in disclosing climate-related information.[86]

The increased fragmentation of climate reporting resulting from the proliferation of third-party reporting frameworks has motivated a number of recent international efforts to obtain more consistent, comparable, and reliable climate-related information for investors. For example:

- A consultation paper published by the IFRS Foundation[87] Trustees in 2020 noted the broad range of voluntary sustainability reporting frameworks that have increased complexity and cost to preparers without improving the quality of the information available to investors;[88]
- Based on the response to the IFRS Foundation consultation paper, the IFRS Foundation took steps toward the establishment of an International Sustainability Standards Board (''ISSB'') operating within the existing governance structure of the IFRS Foundation;
- In 2021, following two roundtables hosted by its Sustainable Finance Task Force, IOSCO[89] issued a report that concluded that companies' current sustainability disclosures do not meet investors' needs, and the proliferation of voluntary disclosure frameworks has led to inconsistency in application of the frameworks and, in some cases ''cherry picking'' of information that might not present an accurate picture of companies' risks.[90]
- A Technical Experts' Group of IOSCO worked with a Technical Readiness Working Group of the IFRS Foundation to assess and fine-tune a prototype climate-related financial disclosure standard (''Prototype'') drafted by an alliance of prominent sustainability reporting organizations and designed as a potential model for

has similarly reported growth in the number of companies and countries supporting its climate-related disclosure recommendations. *See* TCFD, *2021 Status Report* (Oct. 2021), available at *https://assets.bbhub.io/company/sites/60/2021/07/2021-TCFD-Status-Report.pdf* (stating that, as of Oct. 6, 2021, the TCFD had over 2,600 supporters globally, including 1,069 financial institutions responsible for assets of US $194 trillion).

[77] *See supra* note 42.

[78] Dr. Rodney Irwin, Alan McGill, *Enhancing the Credibility of Non-Financial Information,* the Investor Perspective, WBCSD and PwC (Oct. 2018).

[79] Yale Initiative on Sustainable Finance, *Toward Enhanced Sustainability Disclosure: Identifying Obstacles to Broader and More Actionable ESG Reporting* (Sept. 2020), available at *https://pages.fiscalnote.com/rs/109-ILL-989/images/YISF%20ESG%20Reporting%20White%20Paper.pdf.*

[80] *See, e.g.,* TCFD, *2021 Status Report (indicating that there is* a need to improve companies' climate-related disclosures, particularly regarding governance and risk management, to better align with the TCFD's recommendations).

[81] *See* CDP, ANALYSIS OF CA100+ COMPANY DATA (2020), available at *https://cdn.cdp.net/cdp-production/cms/reports/documents/000/005/312/original/Analysis_of_CA100__Data_for_CDP_Investor_Signatories_v5.pdf?1596046258.*

[82] *See* KPMG, *The Time Has Come-The KPMG Survey of Sustainability Reporting 2020* (Dec. 2020), available at https://assets.kpmg/content/dam/kpmg/xx/pdf/2020/11/the-time-has-come.pdf.

[83] *See* TCFD 2020 Status Report (Sept. 2020), available at *https://assets.bbhub.io/company/sites/60/2020/09/2020-TCFD_Status-Report.pdf.*

[84] *See* Ernst & Young, *How can climate change disclosures protect reputation and value?-The 2019 EY Global Climate Risk Disclosure Barometer* (Apr. 2020), available at *https://www.ey.com/en_us/climate-change-sustainability-services/how-can-climate-change-disclosures-protect-reputation-and-value.*

[85] For example, the TCFD report found that the average level of disclosure across the TCFD's 11 disclosure categories was 40% for the energy sector, 30% for the materials and building sector, 18% for the consumer goods sector and 13% for the technology sector. The level of disclosure varied among categories with only 4% or reporting companies disclosing the resilience of their strategies in North America and 50% reporting their risks and opportunities (the category with the highest level of disclosure). The Ernst & Young report found many companies in industries considered to have high exposure to climate-related risks lack high quality climate disclosures. The Ernst & Young report graded the average quality of the disclosures at 27 out of 100.

[86] *See, e.g., The SEC's Time to Act,* Center for American Progress (Feb. 19, 2021) (''[T]here is a lack of standardization of the data, assumptions, and methodologies companies use to meet the standards, with much of this information being opaque. Clearly, the current path of climate disclosure will not provide the transparency that an increasing number of investors are seeking and, indeed, a properly functioning market requires—consistency of disclosures across time, comparability of disclosures across companies, and reliability of the information that is disclosed.'') See, also, Andy Green and Andrew Schwartz, *Corporate Long-Termism, Transparency, and the Public Interest* (Oct. 2, 2018) (''[C]orporate disclosure available today is insufficient, not comparable, and unreliable''); and *Managing Climate Risk in the U.S. Financial System,* Report of the Climate-Related Market Risk Subcommittee, Market Risk Advisory Committee of the U.S. Commodity Futures Trading Commission (2020) (''Large companies are increasingly disclosing some climate-related information, but significant variations remain in the information disclosed by each company, making it difficult for investors and others to understand exposure and manage climate risks.'').

[87] The *IFRS* Foundation refers to the International Financial Reporting Standards Foundation, which was established to develop a single set of ''high-quality,'' enforceable, and globally accepted accounting standards. *See IFRS—Who we are,* available at *https://www.ifrs.org/about-us/who-we-are/.* The IFRS Foundation was formed in 2010 and succeeded the International Accounting Standards Foundation, which was formed in 2001.

[88] IFRS Foundation, *IFRS Foundation Trustees' Feedback Statement on the Consultation Paper on Sustainability Reporting* (Apr. 2021), available at *https://www.ifrs.org/content/dam/ifrs/project/sustainability-reporting/sustainability-consultation-paper-feedback-statement.pdf.*

[89] IOSCO refers to the International Organization of Securities Commissions, of which the Commission is a member.

[90] IOSCO, *Report on Sustainability-related Issuer Disclosures,* Final Report (June 2021) available at *https://www.iosco.org/library/pubdocs/pdf/IOSCOPD678.pdf.*

standards that an ISSB might eventually develop; [91]

- In November 2021, the IFRS Foundation announced the formation of the ISSB.[92] The ISSB is expected to engage in standard setting to build on the Prototype, including developing climate-specific disclosure standards based on the recommendations of the TCFD.[93]
- Several jurisdictions, including the European Union,[94] are developing or revising their mandatory climate-related disclosure regimes to provide investors with more consistent, useful climate-related financial information, including associated assurance requirements and data tagging to facilitate the use of the information.[95]

These international developments show an increasing global recognition of the need to improve companies' climate-related disclosures, which the proposed rules would help address, as well as the convergence of investors and issuers around the TCFD as a useful framework for communicating information about climate-related risks that companies may face.

D. Development of a Climate-Related Reporting Framework

In recent years, two significant developments have occurred that support and inform the Commission's proposed climate-related reporting rules. The first involves the TCFD, which has developed a climate-related reporting framework that has become widely accepted by both registrants and investors.[96] The second involves the Greenhouse Gas Protocol (''GHG Protocol''), which has become a leading accounting and reporting standard for greenhouse gas emissions.[97] Both the TCFD and the GHG Protocol have developed concepts and a vocabulary that are commonly used by companies when providing climate-related disclosures in their sustainability or related reports. As discussed in greater detail below, the Commission's proposed rules incorporate some of these concepts and vocabulary, which by now are familiar to many registrants and investors.

1. The Task Force on Climate-Related Financial Disclosure

Our proposed climate-related disclosure framework is modeled in part on the TCFD's recommendations. A goal of the proposed rules is to elicit climate-related disclosures that are consistent, comparable, and reliable while also attempting to limit the compliance burden associated with these disclosures. The TCFD framework has been widely accepted by issuers, investors, and other market participants, and, accordingly, we believe that proposing rules based on the TCFD framework may facilitate achieving this balance between eliciting better disclosure and limiting compliance costs.[98]

In April 2015, the Group of 20 Finance Ministers directed the Financial Stability Board (''FSB'') to evaluate ways in which the financial sector could address climate-related concerns.[99] The FSB concluded that better information was needed to facilitate informed investment decisions and to help investors and other market participants to better understand and take into account climate-related risks. The FSB established the TCFD, an industry-led task force charged with promoting better-informed investment, credit, and insurance underwriting decisions.[100] Since then, the framework for climate-related disclosures developed by the TCFD has been refined and garnered global support as a reliable framework for climate-related financial reporting.[101]

In 2017, the TCFD published disclosure recommendations that provide a framework by which to evaluate material climate-related risks and opportunities through an assessment of their projected short-, medium-, and long-term financial impacts on a registrant. The TCFD framework establishes eleven disclosure topics related to four core themes that provide a structure for the assessment, management, and disclosure of climate-related financial risks: Governance, strategy, risk management, and metrics and targets.[102]

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[91] *See* CDP, CDSB, GRI, IIRC and SASB, *Reporting on enterprise value Illustrated with a prototype climate-related financial disclosure standard* (Dec. 2020), available at *https://29kjwb3armds2g3gi4lq2sx1-wpengine.netdna-ssl.com/wp-content/uploads/Reporting-on-enterprise-value_climate-prototype_Dec20.pdf;* and IFRS Foundation, *IFRS Foundation announces International Sustainability Standards Board, consolidation with CDSB and VRF, and publication of prototype disclosure requirements,* available at *https://www.ifrs.org/news-and-events/news/2021/11/ifrs-foundation-announces-issb-consolidation-with-cdsb-vrf-publication-of-prototypes/.*

[92] *See* IFRS Foundation, *IFRS Foundation announces International Sustainability Standards Board, consolidation with CDSB and VRF, and publication of prototype disclosure requirements* (Nov. 3, 2021), available at *https://www.ifrs.org/news-and-events/news/2021/11/ifrs-foundation-announces-issb-consolidation-with-cdsb-vrf-publication-of-prototypes/.* At the same time, the IFRS Foundation announced the planned consolidation of the Climate Disclosure Standards Board and the Value Reporting Foundation into the ISSB during 2022. The ISSB is expected to develop reporting standards using the Prototype as a starting point and engaging in rigorous due process under the oversight of the IFRS Foundation Trustees' Due Process Oversight Committee.

[93] *Id.*

[94] *Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2013/34/EU, Directive 2004/109/EC, Directive 2006/43/EC and Regulation (EU) No 537/2014, as regards corporate sustainability reporting* (Apr. 2021), available at *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0189.* In proposing revised corporate sustainability reporting requirements, the EU explained that there exists a widening gap between the sustainability information, including climate-related data, companies report and the needs of the intended users of that information, which may mean that investors are unable to take sufficient account of climate-related risks in their investment decisions.

[95] *See* IOSCO, *Report on Sustainability-related Issuer Disclosures,* Final Report (June 2021) (noting progress in several jurisdictions, including Hong Kong, India, Japan, New Zealand and the United Kingdom, to incorporate TCFD's disclosure recommendations into their legal and regulatory frameworks).

[96] A number of registrants recommended basing the Commission's climate-related disclosure rules on the TCFD framework. *See, e.g.,* letters from Adobe; Alphabet Inc. *et al.;* BNP Paribas (June 11, 2021); bp; Chevron (June 11, 2021; ConocoPhilips; and Walmart. Similarly, numerous investors and investor groups recommended the TCFD framework. *See* letters from Alberta Investment Management Corporation; BlackRock; CalPERS; CALSTRS (June 4, 2021); Impact Investors, Inc.; and San Francisco Employees Retirement System. *See also infra* Section II.A.1 for further discussion of the many commenters that recommended basing the Commission's climate-related disclosure rules on the TCFD framework.

[97] *See, e.g.,* letter from Natural Resources Defense Council (stating that most companies providing climate-related information do so using the three-part (scope) framework developed by the GHG Protocol and noting other organizations, such as the CDP, that use the GHG Protocol's framework and methodology); *see also* GHG Protocol, Companies and Organizations, available at *https://ghgprotocol.org/companies-and-organizations* (stating that 92% of companies responding to the CDP in 2016 used the GHG Protocol's standards and guidance).

[98] *See infra* Section II.A.1 and notes 145 through 149.

[99] *See* TCFD, 2020 Status Report (Oct. 2020). The Group of 20 (''G20'') is a group of finance ministers and central bank governors from 19 countries, including the United States, plus the European Union, which was formed in 1999 to promote global economic growth, international trade, and regulation of financial markets. According to the G20, its members represent more than 80% of world GDP, 75% of international trade, and 60% of the world population. *See* G20, About the G20, available at *https://g20.org/about-the-g20/.*

[100] See TCFD, *Recommendations of the Task Force on Climate-related Financial Disclosures* (June 2017), available at *https://assets.bbhub.io/company/sites/60/2020/10/FINAL-2017-TCFD-Report-11052018.pdf.*

[101] *See, e.g.,* Climate Action 100+, *The Three Asks,* available at *https://www.climateaction100.org/approach/the-three-asks/* (requiring participating investors to ask the companies with which they engage to provide enhanced corporate disclosure in line with the TCFD's recommendations; and CDP, *How CDP is aligned to the TCFD,* available at *https://www.cdp.net/en/guidance/how-cdp-is-aligned-to-the-tcfd* (explaining how the CDP has aligned its questionnaires to elicit disclosures aligned with the TCFD's recommendations).

[102] *See* TCFD, *TCFD_Booklet_FNL_Digital_March-2020.pdf* (*bbhub.io*) (Mar. 2021), available at

Continued

Support for the TCFD's recommendations by companies and other reporting frameworks has grown steadily since the TCFD's formation.[103] As of October 2021 more than 2,600 organizations globally, with a total market capitalization of $25 trillion have expressed support for the TCFD.[104] Further, 1,069 financial institutions, managing assets of $194 trillion, also support the TCFD.[105] In recognition of the widespread adoption by companies of TCFD reporting, a number of countries, including the United Kingdom, New Zealand, and Switzerland, and the European Union that have proposed mandatory climate-risk disclosure requirements have indicated an intention to base disclosure requirements on the TCFD framework.[106] Further, the TCFD's recommendations have been adopted by, and incorporated into, other voluntary climate disclosure frameworks such as the CDP, GRI, CDSB, and SASB frameworks. The TCFD also forms the framework for the Prototype that the IFRS Foundation provided to the ISSB as a potential starting point for its standard setting initiative.[107] The G7 Finance Ministers and Central Bank Governors have also endorsed the TCFD.[108] As a result, although the reporting landscape is crowded with voluntary standards that seek different information in different formats, the TCFD framework has been widely endorsed by U.S. companies and regulators and standard-setters around the world.

2. The Greenhouse Gas Protocol

Quantitative greenhouse gas (''GHG'') emissions data can enable investors to assess a registrant's exposure to climate-related risks, including regulatory, technological, and market risks driven by a transition to a lower-GHG intensive economy.[109] This data also could help investors to assess the progress of registrants with public commitments to reduce GHG emissions, which would be important in assessing potential future capital outlays that might be required to meet such commitments. For these reasons, many investors and other commenters recommended that we require disclosure of a registrant's GHG emissions.[110] Many commenters also recommended that we base any GHG emissions disclosure requirement on the GHG Protocol.[111] These commenters indicated that the GHG Protocol has become the most widely-used global greenhouse gas accounting standard.[112] For example, the Environmental Protection Agency (''EPA'') Center for Corporate Climate Leadership references the GHG Protocol's standards and guidance as resources for companies that seek to calculate their GHG emissions.[113]

The GHG Protocol was created through a partnership between the World Resources Institute and the World Business Council for Sustainable Development, which agreed in 1997 to collaborate with businesses and NGOs to create a standardized GHG accounting methodology.[114] The GHG Protocol has been updated periodically since its original publication and has been broadly incorporated into sustainability reporting frameworks, including the TCFD, Value Reporting Foundation, GRI, CDP, CDSB, and the IFRS Foundation's Prototype.

The GHG Protocol's Corporate Accounting and Reporting Standard provides uniform methods to measure and report the seven greenhouse gasses covered by the Kyoto Protocol—carbon dioxide, methane, nitrous oxide, hydrofluorocarbons, perfluorocarbons, sulfur hexafluoride, and nitrogen trifluoride.[115] The GHG Protocol introduced the concept of ''scopes'' of emissions to help delineate those emissions that are directly attributable to the reporting entity and those that are indirectly attributable to the company's activities.[116] Under the GHG Protocol, Scope 1 emissions are direct GHG emissions that occur from sources owned or controlled by the company. These might include emissions from company-owned or controlled machinery or vehicles, or methane emissions from petroleum operations. Scope 2 emissions are those emissions primarily resulting from the generation of electricity purchased and consumed by the company.[117] Because these emissions derive from the activities of another party (the power provider), they are considered indirect emissions. Scope 3 emissions are all other indirect emissions not accounted for in Scope 2 emissions. These emissions are a consequence of the company's activities but are generated from sources that are neither owned nor controlled by the

https://assets.bbhub.io/company/sites/60/2020/10/TCFD_Booklet_FNL_Digital_March-2020.pdf.

[103] According to the TCFD, ''[for] companies, support is a commitment to work toward their own implementation of the TCFD recommendations.'' *https://www.fsb-tcfd.org/support-tcfd/*

[104] *See* TCFD, 2021 Status Report. A recent survey by Moody's of over 3,800 companies worldwide indicated that the global average disclosure rate of companies that reported across all 11 TCFD's recommendations increased to 22% in 2021 from 16% in 2020. *See* Moody's *State of TCFD Disclosures 2021*, available at *https://assets.website-files.com/5df9172583d7eec04960799a/616d36184f3e6431a424b9df_BX9303_MESG_State%20of%20TCFD%20Disclosures%202021.pdf.* In addition, according to a recent report by the Governance & Accountability Institute, Inc., 70% of companies in the Russell 1000 Index published sustainability reports in 2020, and of those reporters, 30% mentioned or aligned their disclosures with the TCFD framework, and 40% responded to the CDP questionnaires, which are aligned with the TCFD. *See* Governance & Accountability Institute, *Sustainability Reporting in Focus, 2021*, available at *https://www.ga-institute.com/fileadmin/ga_institute/images/FlashReports/2021/Russell-1000/G_A-Russell-Report-2021-Final.pdf?vgo_ee=NK5m02JiOOHgDiUUST7fBRwUnRnlmwiuCIJkd9A7F3A%3D.* We discuss the findings of this report, and other similar findings, in greater detail in Section IV.A.5.c below.

[105] *See* TCFD, *2021 Status Report.*

[106] *See id.*

[107] *See* Climate-related Disclosures Prototype, Developed by the Technical Readiness Working Group, chaired by the IFRS Foundation, to provide recommendations to the International Sustainability Standards Board for consideration (Nov. 2021).

[108] HM Treasury, *G7 Finance Ministers and Central Bank Governors Communique—Policy Paper* (June 2021), available at *https://www.gov.uk/government/publications/g7-finance-ministers-meeting-june-2021-communique/g7-finance-ministers-and-central-bank-governors-communique* (stating their support of mandatory climate-related financial disclosures based on the TCFD framework because of investors' need for high quality, reliable, comparable climate-risk data).

[109] *See, e.g.,* letters from Calvert Research and Management (June 1, 2021); Ceres *et al* (June 10, 2021); NY State Comptroller (June 8, 2021); and SASB (May 19, 2021).

[110] *See infra* Section II.G.1 and note 412.

[111] *See, e.g.,* letters from Apple, Inc. (June 11, 2021); bp (June 11, 2021); Carbon Tracker Initiative (June 14, 2021); Consumer Federation of America (June 14, 2021); ERM CVS (June 11, 2021); Ethic Inc. (June 11, 2021); First Affirmative Financial Network; Regenerative Crisis Response Committee; MSCI, Inc. (June 12, 2021); Natural Resources Defense Council; New York State Society of Certified Public Accountants(June 11, 2021); Paradice Investment Management (June 11, 2021); Stray Dog Capital (June 15, 2021); and Huw Thomas (June 16, 2021).

[112] *See, e.g.,* letters from ERM CVS; and Natural Resources Defense Council; *see also* Greenhouse Gas Protocol, *About Us | Greenhouse Gas Protocol,* available at *https://ghgprotocol.org/about-us.*

[113] *See, e.g.,* EPA Center for Corporate Climate Leadership, *Scope 1 and Scope 2 Inventory Guidance,* at *https://www.epa.gov/climateleadership/scope-1-and-scope-2-inventory-guidance.*

[114] *See* Greenhouse Gas Protocol, *About Us | Greenhouse Gas Protocol* (*ghgprotocol.org*), available at *https://ghgprotocol.org/about-us.*

[115] *See id.* The Kyoto Protocol, adopted in 1997, implemented the United Nations Framework Convention on Climate Change by obtaining commitments from industrialized countries to reduce emissions of the seven identified gasses according to agreed targets. *See* United Nations Climate Change, What is the Kyoto Protocol?, *available at https://unfccc.int/kyoto_protocol.* The EPA includes these seven greenhouse gases in its greenhouse gas reporting program. *See, e.g.,* EPA, *GHGRP Emissions by GHG,* available at *https://www.epa.gov/ghgreporting/ghgrp-emissions-ghg.*

[116] *See* World Business Council for Sustainable Development and World Resources Institute, *The Greenhouse Gas Protocol, A Corporate Accounting and Reporting Standard* REVISED EDITION, available at *https://ghgprotocol.org/corporate-standard.*

[117] *Id.*

company.[118] These might include emissions associated with the production and transportation of goods a registrant purchases from third parties, employee commuting or business travel, and the processing or use of the registrant's products by third parties.[119]

We have based our proposed GHG emissions disclosure requirement primarily on the GHG Protocol's concept of scopes and related methodology.[120] By basing this requirement on an established GHG emissions reporting framework, we believe the compliance burden would be mitigated, especially for those registrants that are already disclosing or estimating their GHG emissions pursuant to the GHG Protocol.

E. Summary of the Proposed Rules

We are proposing to add a new subpart to Regulation S–K, 17 CFR 229.1500–1507 (''Subpart 1500 of Regulation S–K'') that would require a registrant to disclose certain climate-related information, including information about its climate-related risks that are reasonably likely to have material impacts on its business or consolidated financial statements, and GHG emissions metrics that could help investors assess those risks.[121] A registrant may also include disclosure about its climate-related opportunities. The proposed new subpart to Regulation S–K would include an attestation requirement for accelerated filers[122] and large accelerated filers[123] regarding certain proposed GHG emissions metrics disclosures.[124]

We are also proposing to add a new article to Regulation S–X, 17 CFR 210.14–01 and 02 (''Article 14 of Regulation S–X'') that would require certain climate-related financial statement metrics and related disclosure to be included in a note to a registrant's audited financial statements.[125] The proposed financial statement metrics would consist of disaggregated climate-related impacts on existing financial statement line items. As part of the registrant's financial statements, the financial statement metrics would be subject to audit by an independent registered public accounting firm, and come within the scope of the registrant's internal control over financial reporting (''ICFR'').[126]

1. Content of the Proposed Disclosures

The proposed climate-related disclosure framework is modeled in part on the TCFD's recommendations, and also draws upon the GHG Protocol. In particular, the proposed rules would require a registrant to disclose information about:

- The oversight and governance of climate-related risks by the registrant's board and management;[127]
- How any climate-related risks identified by the registrant have had or are likely to have a material impact on its business and consolidated financial statements, which may manifest over the short-, medium-, or long-term;[128]
- How any identified climate-related risks have affected or are likely to affect the registrant's strategy, business model, and outlook;[129]
- The registrant's processes for identifying, assessing, and managing climate-related risks and whether any such processes are integrated into the registrant's overall risk management system or processes;[130]
- The impact of climate-related events (severe weather events and other natural conditions as well as physical risks identified by the registrant) and transition activities (including transition risks identified by the registrant) on the line items of a registrant's consolidated financial statements and related expenditures,[131] and disclosure of financial estimates and assumptions impacted by such climate-related events and transition activities.[132]
- Scopes 1 and 2 GHG emissions metrics, separately disclosed, expressed:
  - Both by disaggregated constituent greenhouse gases and in the aggregate, and
  - In absolute and intensity terms;[133]
- Scope 3 GHG emissions and intensity, if material, or if the registrant has set a GHG emissions reduction target or goal that includes its Scope 3 emissions; and
- The registrant's climate-related targets or goals, and transition plan, if any.[134]

When responding to any of the proposed rules' provisions concerning governance, strategy, and risk management, a registrant may also disclose information concerning any identified climate-related opportunities.

2. Presentation of the Proposed Disclosures

The proposed rules would require a registrant (both domestic and foreign private issuers):[135]

- To provide the climate-related disclosure in its registration statements and Exchange Act annual reports;[136]

[118] The Scope 3 emissions standard was developed over a three-year period with participation by businesses, government agencies, academics, and NGOs to help companies understand and manage their climate-related risks and opportunities in their upstream and downstream value chains. *See* Greenhouse Gas Protocol, *Corporate Value Chain (Scope 3) Accounting and Reporting Standard, Supplement to the GHG Protocol Corporate Accounting and Reporting Standard* (Sept. 2011), available at *https://ghgprotocol.org/sites/default/files/standards/Corporate-Value-Chain-Accounting-Reporing-Standard_041613_2.pdf.* This standard identified eight upstream and seven downstream emission categories that can give rise to Scope 3 emissions. The GHG Protocol is developing additional guidance that may impact Scope 3 emissions related to land use and land sector activities. *See* Greenhouse Gas Protocol, *Update on Greenhouse Gas Protocol Carbon Removals and Land Sector Initiative* (July 8, 2021), available at *https://ghgprotocol.org/blog/update-greenhouse-gas-protocol-carbon-removals-and-land-sector-initiative.*

[119] *See* Section II.G.1, below, for a more extensive discussion of Scope 3 categories and emissions.

[120] *See id.*

[121] *See infra* Sections II.B through E and II.G through I.

[122] *See* 17 CFR 240.12b–2 (defining ''accelerated filer'' as an issuer after it first meets the following conditions as of the end of its fiscal year: (i) The issuer had an aggregate worldwide market value of the voting and non-voting common equity held by its non-affiliates of $75 million or more, but less than $700 million, as of the last business day of the issuer's most recently completed second fiscal quarter; (ii) the issuer has been subject to the requirements of Section 13(a) or 15(d) of the Exchange Act for a period of at least twelve calendar months; (iii) the issuer has filed at least one annual report pursuant to Section 13(a) or 15(d) of the Exchange Act; and (iv) the issuer is not eligible to use the requirements for SRCs under the SRC revenue test).

[123] *See* 17 CFR 240.12b–2 (defining ''large accelerated filer'' as an issuer after it first meets the following conditions as of the end of its fiscal year: (i) The issuer had an aggregate worldwide market value of the voting and non-voting common equity held by its non-affiliates of $700 million or more, as of the last business day of the issuer's most recently completed second fiscal quarter; (ii) the issuer has been subject to the requirements of Section 13(a) or 15(d) of the Exchange Act for a period of at least twelve calendar months; (iii) the issuer has filed at least one annual report pursuant to Section 13(a) or 15(d) of the Exchange Act; and (iv) the issuer is not eligible to use the requirements for SRCs under the SRC revenue test).

[124] *See infra* Section II.H.

[125] *See infra* Section II.F.

[126] *See infra* Sections II.F.2 and 3.

[127] *See infra* Section II.D.

[128] *See infra* Sections II.B and C.

[129] *See infra* Section II.C.

[130] *See infra* Section II.E.

[131] *See infra* Sections II.F.2 and 3.

[132] *See infra* Sections II.F.4.

[133] *See infra* Section II.G.1.

[134] *See infra* Section II.I.

[135] As defined by Commission rules, a foreign private issuer is any foreign issuer other than a foreign government except an issuer meeting the following conditions as of the last business day of its most recently completed second fiscal quarter: More than 50% of the outstanding voting securities of such issuer are directly or indirectly owned of record by residents of the United States; and either the majority of its executive officers or directors are United States citizens or residents, more than 50% of the assets of the issuer are located in the United States, or the business of the issuer is administered principally in the United States. *See* 17 CFR 230.405 and 17 CFR 240.3b–4.

[136] *See infra* Section II.A.2.

• To provide the Regulation S–K mandated climate-related disclosure in a separate, appropriately captioned section of its registration statement or annual report, or alternatively to incorporate that information in the separate, appropriately captioned section by reference from another section, such as Risk Factors, Description of Business, or Management's Discussion and Analysis (''MD&A''); [137]

• To provide the Regulation S–X mandated climate-related financial statement metrics and related disclosure in a note to the registrant's audited financial statements; [138]

• To electronically tag both narrative and quantitative climate-related disclosures in Inline XBRL; [139] and

• To file rather than furnish the climate-related disclosure.[140]

3. Attestation for Scope 1 and Scope 2 Emissions Disclosure

The proposed rules would require an accelerated filer or a large accelerated filer to include, in the relevant filing, an attestation report covering, at a minimum, the disclosure of its Scope 1 and Scope 2 emissions and to provide certain related disclosures about the service provider.[141] As proposed, both accelerated filers and large accelerated filers would have time to transition to the minimum attestation requirements. The proposed transition periods would provide existing accelerated filers and large accelerated filers one fiscal year to transition to providing limited assurance and two additional fiscal years to transition to providing reasonable assurance, starting with the respective compliance dates for Scopes 1 and 2 disclosure described below.[142] The proposed rules would provide minimum attestation report requirements, minimum standards for acceptable attestation frameworks, and would require an attestation service provider to meet certain minimum qualifications. The proposed rules would not require an attestation service provider to be a registered public accounting firm.

4. Phase-In Periods and Accommodations for the Proposed Disclosures

The proposed rules would include:

• A phase-in for all registrants, with the compliance date dependent on the registrant's filer status;

• An additional phase-in period for Scope 3 emissions disclosure;

• A safe harbor for Scope 3 emissions disclosure;

• An exemption from the Scope 3 emissions disclosure requirement for a registrant meeting the definition of a smaller reporting company (''SRC''); [143] and

• A provision permitting a registrant, if actual reported data is not reasonably available, to use a reasonable estimate of its GHG emissions for its fourth fiscal quarter, together with actual, determined GHG emissions data for the first three fiscal quarters, as long as the registrant promptly discloses in a subsequent filing any material difference between the estimate used and the actual, determined GHG emissions data for the fourth fiscal quarter.

The proposed rules would be phased in for all registrants, with the compliance date dependent upon the status of the registrant as a large accelerated filer, accelerated or non-accelerated filer, or SRC, and the content of the item of disclosure. For example, assuming that the effective date of the proposed rules occurs in December 2022 and that the registrant has a December 31st fiscal year-end, the compliance date for the proposed disclosures in annual reports, other than the Scope 3 disclosure, would be:

• For large accelerated filers, fiscal year 2023 (filed in 2024);

• For accelerated and non-accelerated filers, fiscal year 2024 (filed in 2025); and

• For SRCs, fiscal year 2025 (filed in 2026).[144]

Registrants subject to the proposed Scope 3 disclosure requirements would have one additional year to comply with those disclosure requirements.

We welcome feedback and encourage interested parties to submit comments on any or all aspects of the proposed rules. When commenting, it would be most helpful if you include the reasoning behind your position or recommendation.

II. Discussion

A. Overview of the Climate-Related Disclosure Framework

1. Proposed TCFD-Based Disclosure Framework

We have modeled the proposed disclosure rules in part on the TCFD disclosure framework. Building on the TCFD framework should enable companies to leverage the framework with which many investors and issuers are already familiar, which should help to mitigate both the compliance burden for issuers and any burdens faced by investors in analyzing and comparing the new proposed disclosures.

Many commenters that supported climate disclosure rules recommended that we consider the TCFD framework in developing those rules. Numerous commenters stated that the Commission should base its climate-related disclosure rules on the TCFD framework either as a standalone framework,[145] or in conjunction with industry-specific metrics drawn from the SASB [146] or

[137] *See id.*

[138] *See infra* Section II.F.

[139] *See infra* Section II.K.

[140] *See infra* Section II.L.

[141] *See infra* Section II.H.

[142] *See infra* Section II.H.1 (providing further details on the proposed timing of the minimum attestation requirements).

[143] *See infra* Section II.G.3. The Commission's rules define a smaller reporting company to mean an issuer that is not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent that is not a smaller reporting company and that: (1) Had a public float of less than $250 million; or (2) had annual revenues of less than $100 million and either: (i) No public float; or (ii) a public float of less than $700 million. *See* 17 CFR 229.10(f)(1), 230.405, and 17 CFR 240.12b–2.

[144] *See infra* Section II.M.

[145] *See, e.g.,* letters from Alphabet Inc., Amazon.com Inc., Autodesk, Inc., eBay Inc., Facebook, Inc., Intel Corporation, and Salesforce.com, Inc. (June 11, 2021) (''Alphabet Inc. *et al.*); the Aluminum Association (June 11, 2021); Amalgamated Bank; Apple, Inc.; Bank of Finland; BNP Paribas; Boston Common Asset Management; Ceres and other signatories representing NGOs, academics, and investors (Ceres *et al.*) (June 11, 2021); Certified B Corporations (June 11, 2021); Chevron; Clean Yield Asset Management; Climate Advisers (June 13, 2021); Climate Governance Initiative (June 12, 2021); Committee on Financial and Capital Markets (Keidenren) (June 13, 2021); Commonwealth Climate and Law Initiative; Crowe LLP (June 11, 2021); E2 (June 14, 2021); ERM CVS; Eumedion (June 11, 2021); Fossil Fuel Divest Harvard (June 14, 2021); Impact Investors, Inc.; Impax Asset Management; Information Technology Industry Council (June 11, 2021); Institutional Limited Partners Association (June 11, 2021); Japanese Bankers Association (June 11, 2021); Keramida (June 11, 2021); Carolyn Kohoot (June 11, 2021); Legal and General Investment Management America (June 11, 2021); Christopher Lish (June 12, 2021); Manifest Climate (June 13, 2021); Mercy Investment Services, Inc.; Miller/Howard Investments; Mirova US LLC (June 14, 2021); M.J. Bradley & Associates, on behalf of Energy Strategy Coalition (June 13, 2021); Morningstar, Inc. (June 9, 2021); MSCI, Inc.; Natural Resources Defense Council (June 11, 2021); Persefoni (June 14, 2021); PRI; S&P Global; Maria Stoica (June 11, 2021); Trillium Asset Management; United Nations Environment Programme (UNEP) (June 9, 2021); Walmart, Inc. (June 11, 2021); and World Business Council for Development (June 11, 2021) (WBCSD).

[146] *See, e.g.,* letters from Adobe Inc. (June 11, 2021); Alberta Investment Management Corporation (June 11, 2021); AllianceBernstein; American Chemistry Council (June 11, 2021); American Society of Adaptation Professionals (June 11, 2021); Baillie Gifford (June 11, 2021); Bank Policy Institute (June 9, 2021); BlackRock; Bloomberg, LP (June 3, 2021); bp; BSR (June 11, 2021); Canadian Bankers Association (June 11, 2021); Canadian Coalition of Good Governance; Capital Group (June 11, 2021); Catavento Consultancy (Apr. 30, 2021); Center for Climate and Energy Solutions; Confluence Philanthropy (June 14, 2021); ConocoPhilips, Inc.

other third-party frameworks.[147] A broad range of commenters, including both issuers [148] and investors,[149] supported basing new climate-related disclosure rules on the TCFD framework.

Commenters provided several reasons for their support of the TCFD framework. First, commenters indicated that, because of the widespread adoption of the framework, issuers and investors have experience making and using TCFD disclosures. As a result, according to commenters, aligning SEC rules with the TCFD could reduce the burden on issuers and increase the consistency and comparability of climate disclosures.[150] Second, commenters stated that the information that the TCFD disclosures elicit is useful for investors to understand companies' exposure to and management of climate-related risks.[151] Third, various jurisdictions around the world have announced their intention to align their domestic disclosure rules with the TCFD.[152] Commenters stated that by aligning with the TCFD framework, the Commission could potentially facilitate higher levels of consistency and comparability of disclosures globally.[153]

The consistency and breadth of these comments comport with our understanding that the TCFD framework has been widely accepted by issuers, investors, and other market participants and reinforce our view that the framework would provide an appropriate foundation for the proposed amendments.[154] Basing the Commission's climate-related disclosure rules on a globally recognized framework should help elicit climate-related disclosures that are consistent, comparable, and reliable while also limiting the compliance burden for registrants that are already providing climate-related disclosures based on this framework.

Similar to the TCFD framework, the proposed climate-related provisions under Regulation S–K would require disclosure of a registrant's: Governance of climate-related risks; [155] any material climate-related impacts on its strategy, business model, and outlook; [156] climate-related risk management; [157] GHG emissions metrics; [158] and climate-related targets and goals, if any.[159]

The proposed climate-related provisions under Regulation S–X would require a registrant to disclose in a note to its financial statements certain disaggregated climate-related financial statement metrics that are mainly derived from existing financial statement line items.[160] The proposed rules would require disclosure falling under the following three categories of information: Financial impact metrics; [161] expenditure metrics; [162] and financial estimates and assumptions.[163] Similar to the TCFD's recommendation regarding financial impacts, the proposed financial statement metrics have the objective of increasing transparency about how climate-related risks impact a registrant's financial statements.[164] The TCFD framework identifies two broad categories of actual and potential financial impacts driven by climate-related risks and opportunities: Financial performance (income statement focused) and financial position (balance sheet focused), and includes suggested metrics such as the amount of capital expenditure deployed toward climate-related risks and opportunities, which is similar to our proposed financial statement metrics.[165]

2. Location of the Climate-Related Disclosure

Many commenters stated that the Commission should amend Regulation S–K or Regulation S–X to include climate-related disclosure requirements.[166] Other commenters

(June 11, 2021); CPP Investments (June 11, 2021); Enbridge, Inc. (June 11, 2021); Energy Workforce and Technology Council (June 11, 2021); Entelligent, Inc. (June 14, 2021); Ethic Inc.; Emmanuelle Haack (Apr. 27, 2021); Harvard Management Company (June 11, 2021); Hermes Equity Ownership Services Limited (June 14, 2021); Douglas Hileman Consulting (June 7, 2021); HP, Inc. (June 14, 2021); Virginia Harper Ho (June 12, 2021); IHS Markit (June 13, 2021); Institute of International Bankers; Institute of International Finance (June 13, 2021); Institute of Management Accountants (June 12, 2021); Invesco (June 10, 2021); Investment Company Institute; Investment Consultants Sustainability Working Group (June 11, 2021); Richard Love (May 20, 2021); Manulife Investment Management (June 11, 2021); NEI Investments (June 11, 2021); Neuberger Berman (June 11, 2021); New York State Society of Certified Public Accountants; Nordea Asset Management (June 11, 2021); Norges Bank Investment Management (June 13, 2021); NY State Comptroller; Paradice Investment Management (June 11, 2021); Parametric Portfolio Associates; PayPal Holdings, Inc. (June 12, 2021); PGIM (June 13, 2021); Reinsurance Association of America (June 9, 2021); Salesforce.com (June 11, 2021); San Francisco Employees Retirement System (June 12, 2021); State Street Global Advisors; Summit Strategy Group (June 11, 2021); Teachers Insurance and Annuity Association of America (June 11, 2021); T Rowe Price (June 11, 2021); Value Reporting Foundation (June 11, 2021); Wellington Management Co. (June 11, 2021); and Westpath Benefits and Assessments (June 11, 2021).

[147] *See, e.g.,* letters from Gabrielle F. Preiser (Mar. 31, 2021) and Worldbenchmarking Alliance (June 11, 2021) (recommending the Global Reporting Initiative (GRI) standards); letter from Mathew Roling and Samantha Tirakian (June 11, 2021) (recommending the CDSB standards); and Pricewaterhouse Coopers and Grant Thornton (June 11, 2021) (recommending the Sustainability Standards Board (SSB) standards once the SSB is established by the IFRS Foundation and others as a global standard-setter and once it promulgates standards).

[148] *See, e.g.,* letters from Adobe; Alphabet Inc. *et al.;* BNP Paribas; bp; Chevron; ConocoPhilips; and Walmart.

[149] *See, e.g.,* letters from Alberta Investment Management Corporation; BlackRock; CalPERS; CALSTRS; Impact Investors, Inc.; and San Francisco Employees Retirement System.

[150] *See, e.g.,* letters from BNP Paribas; Deutsche Bank (June 11, 2021); and Institute of International Bankers.

[151] *See, e.g.,* letters from AllianceBernstein; CALSTRS; Investment Company Institute; and NY State Comptroller.

[152] *See supra* note 95 and accompanying text.

[153] *See, e.g.,* letters from BNP Paribas; bp; and Chevron.

[154] Proponents of the TCFD framework include academics (*see, e.g.,* letters from Jill Fisch *et al.,* J. Robert Gibson (May 26, 2021), and Gina-Gail S Fletcher (June 14, 2021)); accounting and audit firms (*see, e.g.,* letters from AICPA (June 11, 2021), Center for Audit Quality (''CAQ'') (June 11, 2021), and KPMG LLP (June 12, 2021)); foreign firms (*see, e.g.,* letters from Bank of Finland, BNP Paribas, bp, and Deutsche Bank); industry groups (*see, e.g.,* letters from American Chemistry Council, Association of American Railroads (June 11, 2021), and Information Technology Industry Council (June 11, 2021)); investor groups (*see, e.g.,* letters from CalPERS; CALSTRS; and San Francisco Employees Retirement System); individuals (*see, e.g.,* letters from Emmanuelle Haack, Christopher Lish, and Maria Stoica); issuers (*see, e.g.,* letters from Adobe, Alphabet Inc. *et al.,* Apple, and Chevron); NGOs (*see, e.g.,* letters from Ceres *et al.,* Climate Governance Initiative, Natural Resources Defense Council, and UNEP); professional climate advisors (*see, e.g.,* letters from Catavento Consultancy, Douglas Hileman Consulting, ERM CVS, and Ethic Inc.); and professional investment advisors/investment management companies (*see, e.g.,* letters from AllianceBernstein, Impact Investors, Miller/Howard Investments, and Neuberger Berman).

[155] *See* proposed 17 CFR 229.1501.

[156] *See* proposed 17 CFR 229.1502.

[157] *See* proposed 17 CFR 229.1503.

[158] *See* proposed 17 CFR 229.1504.

[159] *See* proposed 17 CFR 229.1506.

[160] *See* proposed 17 CFR 210.14–01 and 14–02.

[161] *See* proposed 17 CFR 210.14–02(c) and (d).

[162] *See* proposed 17 CFR 210.14–02(e) and (f).

[163] *See* proposed 17 CFR 210.14–02(g) and (h).

[164] *See* TCFD, *Recommendations of the Task Force on Climate-related Financial Disclosures* (June 2017), Section B.3 (Financial Impacts).

[165] *See* TCFD, Guidance on Metrics, Targets, and Transition Plans (Oct. 2021), Section F (Financial Impacts), *available at https://assets.bbhub.io/company/sites/60/2021/07/2021-Metrics_Targets_Guidance-1.pdf.* For avoidance of doubt, disclosure of climate-related opportunities is optional, not required, under our proposal.

[166] *See, e.g.,* letters from AllianceBernstein; American Society of Adaptation Professionals; Seema Arora (June 22, 2021); Associated General Contractors of America (June 11, 2021); Baillie Gifford; CalPERS; Cardano Risk Management Ltd. (Apr. 19, 2021); Center for American Progress; Ceres *et al.;* Eni SpA; Jill Fisch (June 3, 2021); George S. Georgiev (June 22, 2021); Hannon Armstrong (June 15, 2021); Henry Schein, Inc.; Hermes Equity Ownership Services Limited; Virginia Harper Ho; Institute for Governance and Sustainable Development (June 9, 2021); Institute for Market Transformation (June 12, 2021); Interfaith Center on Corporate Responsibility; International Corporate Governance Network (June 11, 2021); Japanese Bankers Association; Morrison & Foerster LLP; National Investor Relations Institute (June 11, 2021); Natural Resources Defense Council; Newmont Corporation (June 13, 2021); New York

Continued

recommended that the Commission adopt a new stand-alone regulation for climate-related disclosure.[167] We are proposing to include the climate-related disclosure rules in Regulation S–K and Regulation S–X because the required disclosure is fundamental to investors' understanding the nature of a registrant's business and its operating prospects and financial performance, and therefore, should be presented together with other disclosure about the registrant's business and its financial condition.

Specifically, we are proposing to require a registrant to include climate-related disclosure in Securities Act or Exchange Act registration statements and Exchange Act annual reports in a separately captioned ''Climate-Related Disclosure'' section and in the financial statements.[168] Requiring climate-related disclosure to be presented in this manner would facilitate review of the climate-related disclosure by investors alongside other relevant company financial and non-financial information.

A registrant would be able to incorporate by reference disclosure from other parts of the registration statement or annual report (*e.g.,* Risk Factors, MD&A, or the financial statements) or, in most cases, from other filed or submitted reports into the Climate-Related Disclosure item if it is responsive to the topics specified in Items 1500–1506 of Regulation S–K and if the registrant satisfies the incorporation by reference requirements under the Commission's rules and forms.[169] Allowing incorporation by reference for the Regulation S–K climate-related disclosure would be consistent with the treatment of other types of business disclosure under our rules and would provide some flexibility for registrants while reducing redundancy in disclosure.[170]

Many commenters stated that the Commission should require registrants to discuss and analyze their quantitative climate data in a manner similar to that required for MD&A.[171] These commenters stressed the importance of placing climate-related metrics in the context of other company financial and non-financial information to enable investors to see how those metrics intersect with business operations and industrial processes.[172] Other commenters supported a requirement to discuss and analyze the climate-related metrics, but stated that such discussion should be part of the existing MD&A disclosures.[173] We agree with the commenters supporting a narrative discussion and analysis of the climate-related metrics as means to present these disclosures in context and explain how they relate to the registrant's strategy and management of its climate-related risks. In this way, such a discussion will serve a similar function to the MD&A but will focus on climate-related risk specifically. Our proposed approach, which requires the climate-related disclosure to be included in a specific section but allows registrants to incorporate from disclosure elsewhere (consistent with applicable incorporation by reference requirements), provides some flexibility to the proposed climate-related disclosure scheme while ensuring the disclosure is consistent and comparable across registrants.

Request for Comment

1. Should we add a new subpart to Regulation S–K and a new article to Regulation S–X that would require a registrant to disclose certain climate-related information, as proposed? Would including the climate-related disclosure in Regulation S–K and Regulation S–X facilitate the presentation of climate information as part of a registrant's regular business reporting? Should we instead place the climate-related disclosure requirements in a new regulation or report? Are there certain proposed provisions, such as GHG emissions disclosure requirements, that would be more appropriate under Regulation S–X than Regulation S–K?

2. If adopted, how will investors utilize the disclosures contemplated in this release to assess climate-related risks? How will investors use the information to assess the physical effects and related financial impacts from climate-related events? How will investors use the information to assess risks associated with a transition to a lower carbon economy?

3. Should we model the Commission's climate-related disclosure framework in part on the framework recommended by the TCFD, as proposed? Would alignment with the TCFD help elicit climate-related disclosures that are consistent, comparable, and reliable for investors? Would alignment with the TCFD framework help mitigate the reporting burden for issuers and facilitate understanding of climate-related information by investors because the framework is widely used by companies in the United States and around the world? Are there aspects of the TCFD framework that we should not adopt? Should we instead adopt rules that are based on a different third-party framework? If so, which framework? Should we base the rules on something other than an existing third-party framework?

4. Do our current reporting requirements yield adequate and sufficient information regarding climate-related risks to allow investors to make informed decisions? In lieu of, or in addition to the proposed amendments, should we provide updated guidance on how our existing rules may elicit better disclosure about climate-related risks?

5. Should we require a registrant to present the climate-related disclosure in an appropriately captioned, separate part of the registration statement or annual report, as proposed? Should this disclosure instead be presented as part of the registrant's MD&A?

6. Should we permit a registrant to incorporate by reference some of the

State Society of Certified Public Accountants; NY State Comptroller; PayPal Holdings, Inc.; PRI (Consultation Response); PricewaterhouseCoopers LLP; Maria Stoica; Sunrise Bay Area (June 14, 2021); Teachers Insurance and Annuity Association of America; Vert Asset Management LLC (June 14, 2021); WBCSD; and Wespath Benefits and Investments (June 11, 2021).

[167] *See* letters from Bank Policy Institute; Andrew Behar (As You Sow) (June 14, 2021); Entelligent Inc. (June 14, 2021); Impax Asset Management; Information Technology Industry Council; Majedie Asset Management (May 25, 2021); David Marriage (June 15, 2021); and XBRL US (June 15, 2021).

[168] *See infra* Section II.J for a discussion of the registrants and forms to which the proposed rules would apply.

[169] *See* 17 CFR 230.411; 17 CFR 240.12b–23; and the applicable forms.

[170] A registrant that elects to incorporate by reference any of the metrics or narrative disclosure that is subject to XBRL tagging must comply with the electronic tagging requirement in the section of the registration statement or report where the metrics or narrative disclosure appears in full. We discuss the XBRL tagging requirement in Section II.K.

[171] *See, e.g.,* letters from Acadian Asset Management LLC (June 14, 2021); Actual Systems, Inc. (June 11, 2021); Baillie Gifford; Biotechnology Innovation Organization; CDP; ClientEarth US (June 14, 2021); FAIRR Initiative (June 15, 2021); Jill Fisch (June 3, 2021); Hermes Equity Ownership Services Limited; International Corporate Governance Network; Japanese Bankers Association; Majedie Asset Management; Morningstar, Inc.; NEI Investments; NY State Comptroller; Paradice Investment Management; Pre-Distribution Initiative (June 14, 2021); PricewaterhouseCoopers LLP; Matthew Roling and Samantha Tirakian (June 11, 2021); Terra Alpha Investments; Vert Asset Management; and WBCSD.

[172] *See, e.g.,* letters from Pricewaterhouse Coopers Ltd.; Vert Asset Management; and WBCSD.

[173] *See, e.g.,* letters from Canadian Coalition for Good Governance; Clean Production Action and Environmental Health Network (June 11, 2021); Decatur Capital Management; Dimensional Fund Advisors (June 11, 2021); Environmental Industry Group (June 9, 2021); Institute for Governance and Sustainable Development; PRI (Consultation Response); Kenya Rothstein (May 3, 2021); and Maria Stoica. *But see* letter from Sarah Ladin (June 14, 2021) (doubting that a ''sustainability discussion and analysis'' requirement would achieve the desired results and stating that it would be difficult to enforce); and David Marriage (indicating that a discussion and analysis requirement for climate-related data would make the data difficult for the market to absorb).

climate-related disclosure from other parts of the registration statement or annual report, as proposed? Should we permit a registrant to incorporate by reference climate-related disclosure that appears in a sustainability report if the registrant includes the incorporated by referenced disclosure as an exhibit to the registration statement or annual report? Are there some climate-related disclosure items, such as GHG emissions data, that we should not permit a registrant to incorporate by reference? Would requiring a registrant to include all of the proposed climate-related disclosures in a separate, appropriately captioned section, while precluding a registrant from incorporating by reference some or all of the climate-related disclosures, promote comparability and ease of use of the climate-related information for investors?

7. Should we permit a registrant to provide certain of the proposed climate-related disclosures in Commission filings other than the annual report or registration statement? For example, should we permit a registrant to provide information about board and management oversight of climate-related risks in its proxy statement?

B. Disclosure of Climate-Related Risks

As many commenters have noted when seeking more detailed climate-related disclosures,[174] climate events and contingencies can pose financial risks to issuers across industrial sectors.[175] Physical risks may include harm to businesses and their assets arising from acute climate-related disasters such as wildfires, hurricanes, tornadoes, floods, and heatwaves. Companies and their investors may also face chronic risks and more gradual impacts from long-term temperature increases, drought, and sea level rise.

In addition to the physical risks associated with the climate, issuers and investors may also face risks associated with a potential transition to a less carbon intensive economy. These risks may arise from potential adoption of climate-related regulatory policies including those that may be necessary to achieve the national climate goals that may be or have been adopted in the United States and other countries; [176] climate-related litigation; changing consumer, investor, and employee behavior and choices; changing demands of business partners; long-term shifts in market prices; technological challenges and opportunities, and other transitional impacts. Disclosure about a registrant's exposure to transition risks, as well as how the registrant is assessing and managing those risks, would help investors assess and plan for how the registrant would be financially impacted by a transition to a lower-carbon economy.

1. Definitions of Climate-Related Risks and Climate-Related Opportunities

A central focus of the Commission's proposed rules is the identification and disclosure of a registrant's material climate-related risks. The proposed rules would require a registrant to disclose any climate-related risks reasonably likely to have a material impact on the registrant's business or consolidated financial statements.[177] A registrant may also disclose, as applicable, the actual and potential impacts of any climate-related opportunities it is pursuing.[178] The proposed definitions are substantially similar to the TCFD's definitions of climate-related risks and climate-related opportunities.[179] We have based our definitions on the TCFD's definitions because they provide a common terminology that allows registrants to disclose climate-related risks and opportunities in a consistent and comparable way. Grounding our definitions in a framework that is already widely accepted also could help limit the burden on issuers to identify and describe climate-related risks and improve the comparability and usefulness of the disclosures for investors.

As proposed, ''climate-related risks'' means the actual or potential negative impacts of climate-related conditions and events on a registrant's consolidated financial statements, business operations, or value chains, as a whole.[180] ''Value chain'' would mean the upstream and downstream activities related to a registrant's operations.[181] Under the proposed definition, upstream activities include activities by a party other than the registrant that relate to the initial stages of a registrant's production of a good or service (*e.g.,* materials sourcing, materials processing, and supplier activities). Downstream activities would be defined to include activities by a party other than the registrant that relate to processing materials into a finished product and delivering it or providing a service to the end user (*e.g.,* transportation and distribution, processing of sold products, use of sold products, end of life treatment of sold products, and investments).[182] We have proposed including a registrant's value chain within the definition of climate-related risks to capture the full extent of a registrant's potential exposure to climate-related risks, which can extend beyond its own operations to those of its suppliers, distributors, and others engaged in upstream or downstream activities.[183]

Climate-related conditions and events can present risks related to the physical impacts of the climate (''physical risks'') and risks related to a potential transition to a lower carbon economy (''transition risks''). As proposed, ''physical risks'' is defined to include both acute and chronic risks to a registrant's business operations or the operations of those with whom it does business.[184] ''Acute risks'' is defined as event-driven risks related to shorter-term extreme weather events, such as hurricanes, floods, and tornadoes.[185] ''Chronic risks'' is defined as those risks that the business may face as a result of longer term weather

[174] *See supra* note 40.

[175] The 2020 CFTC Advisory Subcommittee Report found that climate change currently impacts or is expected to affect every part of the U.S. economy, including agriculture, real estate, infrastructure, and the financial sectors. *See infra* note 361.

[176] A National Climate Taskforce created by the president established commitments to reduce economy-wide net greenhouse gas emissions by 50–52% by 2030 as compared to 2005 levels, and to reach net zero emissions by 2050. *See* The White House, FACT SHEET: *President Biden Sets 2030 Greenhouse Gas Pollution Reduction Target Aimed at Creating Good-Paying Union Jobs and Securing U.S. Leadership on Clean Energy Technologies* (Apr. 22, 2021). An Executive Order also directs the Federal government to achieve net-zero emissions from overall Federal operations by 2050, and a 65% emissions reduction by 2030. *See* The White House, FACT SHEET: *President Biden Signs Executive Order Catalyzing America's Clean Energy Economy Through Federal Sustainability* (Dec. 8, 2021), at *https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/08/fact-sheet-president-biden-signs-executive-order-catalyzing-americas-clean-energy-economy-through-federal-sustainability/*. A growing number of governments and companies have made net zero commitments or announced similar carbon-reduction goals or targets. *See* United Nations Climate Change, *Commitments to Net Zero Double in Less Than a Year* (Sept. 21, 2020), available at *https://unfccc.int/news/commitments-to-net-zero-double-in-less-than-a-year*.

[177] *See* proposed 17 CFR 229.1502(a).

[178] *See id.*

[179] *See* TCFD, *Recommendations of the Task Force on Climate-related Financial Disclosures,* Appendix 5.

[180] *See* proposed 17 CFR 229.1500(c). The reference to 'negative' impact is intended to refer to the actual or potential impact on the registrant's consolidated financial statements, business operations, or value chains as a whole, rather than the mathematical impacts on a specific financial statement line item. *See infra* Section II.F.2 (discussing the proposed financial impact metrics, which focus on the line items in a registrant's consolidated financial statements).

[181] *See* proposed 17 CFR 229.1500(t).

[182] *See id.*

[183] *See, e.g., infra* Section II.G.1.

[184] *See* proposed 17 CFR 229.1500(c)(1).

[185] *See* proposed 17 CFR 229.1500(c)(2).

patterns and related effects, such as sustained higher temperatures, sea level rise, drought, and increased wildfires, as well as related effects such as decreased arability of farmland, decreased habitability of land, and decreased availability of fresh water.[186] Many of these physical risks have already impacted and may continue to impact registrants across a wide range of economic sectors.[187] The proposed rules would define transition risks to mean the actual or potential negative impacts on a registrant's consolidated financial statements, business operations, or value chains attributable to regulatory, technological, and market changes to address the mitigation of, or adaptation to, climate-related risks.[188] Transition risks would include, but are not limited to, increased costs attributable to climate-related changes in law or policy, reduced market demand for carbon-intensive products leading to decreased sales, prices, or profits for such products, the devaluation or abandonment of assets, risk of legal liability and litigation defense costs, competitive pressures associated with the adoption of new technologies, reputational impacts (including those stemming from a registrant's customers or business counterparties) that might trigger changes to market behavior, changes in consumer preferences or behavior, or changes in a registrant's behavior. A registrant that has significant operations in a jurisdiction that has made a GHG emissions reduction commitment would likely be exposed to transition risks related to the implementation of the commitment.[189]

The proposed rules would require a registrant to specify whether an identified climate-related risk is a physical or transition risk so that investors can better understand the nature of the risk [190] and the registrant's actions or plan to mitigate or adapt to the risk.[191] If a physical risk, the proposed rules would require a registrant to describe the nature of the risk, including whether it may be categorized as an acute or chronic risk.[192]

The proposed rules would require a registrant to include in its description of an identified physical risk the location of the properties, processes, or operations subject to the physical risk.[193] The proposed location disclosure would only be required for a physical risk that a registrant has determined has had or is likely to have a material impact on its business or consolidated financial statements. In such instances, a registrant would be required to provide the ZIP code for the location or, if the location is in a jurisdiction that does not use ZIP codes, a similar subnational postal zone or geographic location.[194] Because physical risks can be concentrated in particular geographic areas, the proposed disclosure would allow investors to better assess the risk exposure of one or more registrants with properties or operations in a particular area. One commenter cited location information as a key component of how it, as an investor, assesses the climate risk facing a company, particularly for companies with fixed assets that may be disproportionately exposed to climate-related physical risks.[195] Several other commenters recommended that we require the disclosure of certain climate data to be disaggregated by location using a point source's zip code for risk assessment.[196] Disclosing the zip codes of its identified material climate-related risks, rather than a broader location designation, could help investors more accurately assess a registrant's specific risk exposure.

Some registrants might be exposed to water-related acute physical risks, such as flooding, which could impair a registrant's operations or devalue its property. If flooding presents a material physical risk, the proposed rules would require a registrant to disclose the percentage of buildings, plants, or properties (square meters or acres) that are located in flood hazard areas in addition to their location.[197] This information could help investors evaluate the magnitude of a registrant's exposure to flooding, which, for example, could cause a registrant in the real estate sector to lose revenues from the rental or sale of coastal property or incur higher costs or a diminished ability to obtain property insurance, or a manufacturing registrant to incur increased expenses due to the need to replace water-damaged equipment or move an entire plant.

Additional disclosure would be required if a material risk concerns the location of assets in regions of high or extremely high water stress.[198] For example, some registrants might be impacted by water-related chronic physical risks, such as increased temperatures and changes in weather patterns that result in water scarcity. Registrants that are heavily reliant on water for their operations, such as registrants in the energy sector, materials and buildings sector, or agriculture sector,[199] could face regulatory restrictions on water use, increased expenses related to the acquisition and purchase of alternative sources of water, or curtailment of its operations due to a reduced water supply that diminishes its earning capacity. If the location of assets in regions of high or extremely high water stress presents a material risk, the proposed rules would require a registrant to disclose the amount of assets (*e.g.,* book value and as a percentage of total assets) located in such regions in addition to their location. The registrant would also be required to disclose the percentage of its total water usage from water withdrawn in those regions.[200] These disclosures could help investors understand the magnitude of a registrant's material water-stress risks with a degree of specificity that might not be elicited under our current risk factor disclosure standards.

Any increased temperatures could also materially impact a registrant in other ways. For example, a registrant in the construction industry might be required to disclose the physical risk of increased heat waves that affect the

[186] *See* proposed 17 CFR 229.1500(c)(3). The physical risks described are examples, but registrants may be exposed to many other types of physical risks from climate change depending on their specific facts and circumstances. As such, any reference to certain types of risks should be considered as non-exhaustive examples.

[187] The IPCC's Sixth Assessment Report noted drought, heatwaves, hurricanes, and heavy precipitation. *See* IPCC, *Climate Change 2021, The Physical Science Basis Summary for Policymakers.*

[188] *See* proposed 17 CFR 229.1500(c)(4).

[189] *See* proposed 17 CFR 229.1502(a)(1)(ii).

[190] *See* proposed 17 CFR 229.1502(a)(1).

[191] *See, e.g.,* proposed 17 CFR 229.1502(b)(1) and 229.1503(c)(1) and (2).

[192] *See* proposed 17 CFR 229.1502(a)(1)(i). In some instances, chronic risks might give rise to acute risks. For example, drought (a chronic risk) that increases acute risks, such as wildfires, or increased temperatures (a chronic risk) that increases acute risks, such as severe storms. In such instances, a registrant should provide a clear and consistent description of the nature of the risk and how it may affect a related risk.

[193] *See id.*

[194] *See* proposed 17 CFR 229.1500(k).

[195] *See* letter from Wellington Management Co.

[196] *See* letters from Action Center on Race and Economy (June 14, 2021); Americans for Financial Reform Education Fund; Confluence Philanthropy; Domini Impact Investments; William and Flora Hewlett Foundation; Public Citizen; and Revolving Door Project.

[197] *See* proposed 17 CFR 229.1502(a)(1)(i)(A).

[198] *See* proposed 1502(a)(1)(i)(B).

[199] Registrants in these industry sectors could be particularly susceptible to water-stress risks because operations in these sectors require large amounts of water. *See* TCFD, *Implementing the Recommendations of the Task Force on Climate-Related Financial Disclosures,* Section E (Oct. 2021), available at *https://assets.bbhub.io/company/sites/60/2021/07/2021/TCFD/Implementing_Guidance.pdf* (discussing the listed events and other risks).

[200] *See* proposed 17 CFR 229.1502(a)(1)(i)(B).

ability of its personnel to safely work outdoors, which could result in a cessation or delay of operations, and a reduction in its current or future earnings.[201] A registrant operating in wildfire-prone areas could be exposed to potential disruption of operations, destruction of property, and relocation of personnel in the event of heat-induced wildfires.[202] A registrant in the real estate sector might similarly be required to disclose the likelihood that sea levels could rise faster than expected and reduce the value of its coastal properties.[203]

The proposed rules would require a registrant to describe the nature of transition risks, including whether they relate to regulatory, technological, market (including changing consumer, business counterparty, and investor preferences), liability, reputational, or other transition-related factors, and how those factors impact the registrant.[204] For example, an automobile manufacturer might describe how market factors, such as changing consumer and investor preferences for low-emission vehicles, have impacted or will likely impact its production choices, operational capabilities, and future expenditures. An energy producer might describe how regulatory and reputational factors have impacted or are likely to impact its operational activities, reserve valuations, and investments in renewable energy. An industrial manufacturer might describe how investments in innovative technologies, such as carbon capture and storage, have impacted or are likely to impact its consolidated financial statements, such as by increasing its capital expenditures.

Climate related conditions and any transition to a lower carbon economy may also present opportunities for companies and investors. The proposed rules would define ''climate-related opportunities'' to mean the actual or potential positive impacts of climate-related conditions and events on a registrant's consolidated financial statements, business operations, or value chains, as a whole.[205] Efforts to mitigate or adapt to the effects of climate-related conditions and events can produce opportunities, such as cost savings associated with the increased use of renewable energy, increased resource efficiency, the development of new products, services, and methods, access to new markets caused by the transition to a lower carbon economy, and increased resilience along a registrant's supply or distribution network related to potential climate-related regulatory or market constraints. A registrant, at its option, may disclose information about any climate-related opportunities it may be pursuing when responding to the proposed disclosure requirements concerning governance, strategy, and risk management in connection with climate-related risks. We are proposing to treat this disclosure as optional to allay any anti-competitive concerns that might arise from a requirement to disclose a particular business opportunity.[206] By defining ''climate-related opportunities,'' the proposed rules would promote consistency when such opportunities are disclosed, even if such disclosure is not required.

2. Proposed Time Horizons and the Materiality Determination

The proposed rules would require a registrant to disclose whether any climate-related risk is reasonably likely to have a material impact on a registrant, including its business or consolidated financial statements, which may manifest over the short, medium, and long term.[207] Several commenters made a similar recommendation, stating that disclosure of climate-related risks and impacts across short, medium, and long-term time horizons is necessary to fully understand a registrant's susceptibility to material climate-related risks.[208]

As proposed, a registrant would be required to describe how it defines short-, medium-, and long-term time horizons, including how it takes into account or reassesses the expected useful life of the registrant's assets and the time horizons for the registrant's planning processes and goals. We have not proposed a specific range of years to define short-, medium-, and long-term time horizons in order to allow flexibility for a registrant to select the time horizons that are most appropriate to its particular circumstances.

As defined by the Commission and consistent with Supreme Court precedent, a matter is material if there is a substantial likelihood that a reasonable investor would consider it important when determining whether to buy or sell securities or how to vote.[209] As the Commission has previously indicated, the materiality determination is largely fact specific and one that requires both quantitative and qualitative considerations.[210] Moreover, as the Supreme Court has articulated, the materiality determination with regard to potential future events requires an assessment of both the probability of the event occurring and its potential magnitude, or significance to the registrant.[211]

[201] *See, e.g., How Seasonal Temperature Changes Affect the Construction Industry (constructconnect.com)* (Aug. 15, 2018), available at *https://www.constructconnect.com/blog/seasonal-temperature-changes-affect-construction-industry.*

[202] *See, e.g., The Impact of Wildfires on Business is Enormous| Are You Ready? (alertmedia.com)* (Aug. 27, 2020), available at *https://www.alertmedia.com/blog/the-impact-of-wildfires-on-business/.*

[203] *See, e.g., Climate change and the coming coastal real estate crash—Curbed* (Oct. 16, 2018), available at *https://archive.curbed.com/2018/10/16/17981244/real-estate-climate-change-infrastructure.*

[204] *See* proposed 17 CFR 229.1502(a)(1)(ii).

[205] *See* proposed 17 CFR 229.1500(b). The reference to 'positive' impact is intended to refer to the actual or potential impact on the registrant's consolidated financial statements, business operations, or value chains as a whole, rather than the mathematical impacts on a specific financial statement line item. *See infra* Section II.F.2 (discussing the proposed financial impact metrics, which focus on the line items in a registrant's consolidated financial statements).

[206] Some commenters expressed concern about potential anti-competitive effects of the Commission's possible climate disclosure rules. *See, e.g.,* letters from Association of General Contractors of America (June 11, 2021); and Healthy Markets Association (June 14, 2021).

[207] *See* proposed Item 1502(a) of Regulation S–K.

[208] *See, e.g.,* letters from Boston Common Asset Management; Christian Brothers Investment Services (June 11, 2021); Clean Yield Asset Management; and Miller/Howard Investments; *see also* American Institute of CPAs (AICPA) (June 11, 2021).

[209] *See* 17 CFR 240.12b–2 (definition of ''material''). *See also Basic Inc.* v. *Levinson,* 485 U.S. 224, 231, 232, and 240 (1988) (holding that information is material if there is a substantial likelihood that a reasonable investor would consider the information important in deciding how to vote or make an investment decision; and quoting *TSC Industries, Inc.* v. *Northway, Inc.,* 426 U. S. 438, 449 (1977) to further explain that an omitted fact is material if there is ''a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available.'').

[210] *See* Release No. 33–10064, *Business and Financial Disclosure Required by Regulation S–K* (Apr. 13, 2016), [81 FR 23915 (Apr. 22, 2016)] (discussing materiality in the context of, among other matters, restating financial statements). See also Staff Accounting Bulletin No. 99 (Aug. 12, 1999), available at *https://www.sec.gov/interps/account/sab99.htm* (emphasizing that a registrant or an auditor may not substitute a percentage threshold for a materiality determination that is required by applicable accounting principles). Staff accounting bulletins are not rules or interpretations of the Commission, nor are they published as bearing the Commission's official approval. They represent interpretations and practices followed by the Division of Corporation Finance and the Office of the Chief Accountant in administering the disclosure requirements of the Federal securities laws.

[211] *See Basic, Inc.* v. *Levinson,* 485 U.S. 224, 238 (1988). When considering the materiality of different climate-related risks, a registrant might, for example, determine that certain transition risks and chronic physical risks are material when balancing their likelihood and impact. It also might determine that certain acute physical risks are material even if they are less likely to occur if the magnitude of their impact would be high.

The materiality determination that a registrant would be required to make regarding climate-related risks under the proposed rules is similar to what is required when preparing the MD&A section in a registration statement or annual report. The Commission's rules require a registrant to disclose material events and uncertainties known to management that are reasonably likely to cause reported financial information not to be necessarily indicative of future operating results or of future financial condition.[212] As the Commission has stated, MD&A should include descriptions and amounts of matters that have had a material impact on reported operations as well as matters that are reasonably likely to have a material impact on future operations.[213]

The proposed rule serves to emphasize that, when assessing the materiality of a particular risk, management should consider its magnitude and probability over the short, medium, and long term. In the context of climate, the magnitude and probability of such risks vary and can be significant over such time periods. For example, wildfires in California, which recently have become more frequent and more intense, may be a material risk for wineries, farmers, and other property owners.[214] Some insurance companies have withdrawn from certain wildfire prone areas after concluding the risk is no longer insurable.[215] For many investors, the availability of insurance and the potential exposure to damage, loss, and legal liability from wildfires may be a determining factor in their investment decision-making. Moreover, registrants must bear in mind that the materiality determination is made with regard to the information that a reasonable investor considers important to an investment or voting decision.

To help ensure that management considers the dynamic nature of climate-related risks, we are proposing to require a registrant to discuss its assessment of the materiality of climate-related risks over the short, medium, and long term. We recognize that determining the likely future impacts on a registrant's business may be difficult for some registrants. Commenters have noted that the science of climate modelling has progressed in recent years and enabled the development of various software tools and that climate consulting firms are available to assist registrants in making this determination.[216] We also note that, under our existing rules, registrants long have had to disclose forward-looking information, including pursuant to MD&A requirements. To the extent that the proposed climate-related disclosures constitute forward-looking statements, as discussed below,[217] the forward-looking statement safe harbors pursuant to the Private Securities Litigation Reform Act (''PSLRA'')[218] would apply, assuming the conditions specified in those safe harbor provisions are met.[219] We note, however, that there are important limitations to the PSLRA safe harbor. For example, we are proposing that climate-related disclosures would be required in registration statements, including those for initial public offerings, and forward-looking statements made in connection with an initial public offering are excluded from the protections afforded by the PSLRA. In addition, the PSLRA does not limit the Commission's ability to bring enforcement actions.

Request for Comment

8. Should we require a registrant to disclose any climate-related risks that are reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements, which may manifest over the short, medium, and long term, as proposed? If so, should we specify a particular time period, or minimum or maximum range of years, for ''short,'' ''medium,'' and ''long term?'' For example, should we define short term as 1 year, 1–3 years, or 1–5 years? Should we define medium term as 5–10 years, 5–15 years, or 5–20 years? Should we define long-term as 10–20 years, 20–30 years, or 30–50 years? Are there other possible years or ranges of years that we should consider as the definitions of short, medium, and long term? What, if any, are the benefits to leaving those terms undefined? What, if any, are the concerns to leaving those terms undefined? Would the proposed provision requiring a registrant to specify what it means by the short, medium, and long term mitigate any such concerns?

9. Should we define ''climate-related risks'' to mean the actual or potential negative impacts of climate-related conditions and events on a registrant's consolidated financial statements, business operations, or value chains, as proposed? Should we define climate-related risks to include both physical and transition risks, as proposed? Should we define physical risks to include both acute and chronic risks and define each of those risks, as proposed? Should we define transition risks, as proposed? Are there any aspects of the definitions of climate-related risks, physical risks, acute risks, chronic risks, and transition risks that we should revise? Are there other distinctions among types of climate-related risks that we should use in our definitions? Are there any risks that we should add to the definition of transition risk? How should we address risks that may involve both physical and transition risks?

10. We define transition risks to include legal liability, litigation, or reputational risks. Should we provide more examples about these types of risks? Should we require more specific disclosures about how a registrant assesses and manages material legal liability, litigation, or reputational risks that may arise from a registrant's business operations, climate mitigation efforts, or transition activities?

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[212] *See* 17 CFR 229.303(a).

[213] See Release No. 33–10890, *Management's Discussion and Analysis, Selected Financial Data, and Supplementary Financial Information* (Nov. 19, 2020), [86 FR 2080, 2089 (Jan. 11, 2021)].

[214] *See, e.g.,* Daoping Wang, Dabo Guan, Shupeng Zhu, *et al., Economic footprint of California wildfires in 2018,* Nature Sustainability (Dec. 2020) (stating that the frequency and size of wildfires in the western United States has been increasing for several decades, driven by decreases in precipitation and related changes in the moisture in vegetation, which, together with land use and fire management practices, has dramatically increased wildfire risks, culminating in a series of enormously damaging fires in California in 2017, 2018 and 2020); Andrew Freedman, *California wildfires prompt new warnings amid record heat, erratic winds,* the Washington Post (Oct. 1, 2020) (reporting that the ''Glass Fire'' forced about 80,000 to evacuate from Napa and Sonoma Counties and took a heavy toll on the wine industry).

[215] *See* Shelby Vittek, *California Farmers Struggle to Secure Wildfire Insurance Coverage,* Modern Farmer (Aug. 2, 2021), available at *https://modernfarmer.com/2021/08/california-farmers-struggle-to-secure-wildfire-insurance-coverage/*

[216] *See, e.g.,* letters from AIR Worldwide (June 11, 2021); Coastal Risk Consulting (May 3, 2021); CoreLogic (June 12, 2021); Datamaran (June 14, 2021); Dynamhex, Inc. (June 15, 2021); EC-Map (June 12, 2021); FutureProof Technologies, Inc. (June 7, 2021); and right.based on science GmbH (June 12, 2021).

[217] *See, e.g., infra* Sections II.C.4 and II.I.

[218] Pub. Law 104–67, 109 Stat. 737.

[219] *See* Securities Act Section 27A and Exchange Act Section 21E. The statutory safe harbors by their terms do not apply to forward-looking statements included in financial statements prepared in accordance with generally accepted accounting principles (''GAAP''). The statutory safe harbors also would not apply to forward-looking statements made: (i) In connection with an initial public offering; a tender offer; an offering by, or relating to the operations of, a partnership, limited liability company, or a direct participation investment program, an offering of securities by a blank check company; a roll-up transaction; or a going private transaction; or (ii) by an issuer of penny stock. *See* Section 27A(b) of the Securities Act and Section 21E(b) of the Exchange Act. Also, the statutory safe harbors do not, absent a rule, regulation, or Commission order, apply to forward-looking statements by certain ''bad actor'' issuers under Section 27A(b)(1)(A) of the Securities Act and Section 21E(b)(1)(A) of the Exchange Act.

11. Some chronic risks might give rise to acute risks, *e.g.,* drought (a chronic risk) that increases acute risks, such as wildfires, or increased temperatures (a chronic risk) that increases acute risks, such as severe storms. Should we require a registrant to discuss how the acute and chronic risks they face may affect one another?

12. For the location of its business operations, properties or processes subject to an identified material physical risk, should we require a registrant to provide the ZIP code of the location or, if located in a jurisdiction that does not use ZIP codes, a similar subnational postal zone or geographic location, as proposed? Is there another location identifier that we should use for all registrants, such as the county, province, municipality or other subnational jurisdiction? Would requiring granular location information, such as ZIP codes, present concerns about competitive harm or the physical security of assets? If so, how can we mitigate those concerns? Are there exceptions or exemptions to a granular location disclosure requirement that we should consider?

13. If a registrant determines that the flooding of its buildings, plants, or properties is a material risk, should we require it to disclose the percentage of those assets that are in flood hazard areas in addition to their location, as proposed? Would such disclosure help investors evaluate the registrant's exposure to physical risks related to floods? Should we require this disclosure from all registrants, including those that do not currently consider exposure to flooding to be a material physical risk? Should we require this disclosure from all registrants operating in certain industrial sectors and, if so, which sectors? Should we define ''flood hazard area'' or provide examples of such areas? If we should define the term, should we define it similar to a related definition by the Federal Emergency Management Agency (''FEMA'') as an area having flood, mudflow or flood-related erosion hazards, as depicted on a flood hazard boundary map or a flood insurance rate map? Should we require a registrant to disclose how it has defined ''flood hazard area'' or whether it has used particular maps or software tools when determining whether its buildings, plants, or properties are located in flood hazard areas? Should we recommend that certain maps be used to promote comparability? Should we require disclosure of whether a registrant's assets are located in zones that are subject to other physical risks, such as in locations subject to wildfire risk?

14. If a material risk concerns the location of assets in regions of high or extremely high water stress, should we require a registrant to quantify the assets (*e.g.,* book value and as a percentage of total assets) in those regions in addition to their location, as proposed? Should we also require such a registrant to disclose the percentage of its total water usage from water withdrawn in high or extremely high water stressed regions, as proposed? If so, should we include a definition of a ''high water stressed region'' similar to the definition provided by the World Resource Institute as a region where 40–80 percent of the water available to agricultural, domestic, and industrial users is withdrawn annually? Should we similarly define an ''extremely high water stressed area'' as a region where more than 80 percent of the water available to agricultural, domestic, and industrial users is withdrawn annually? Are there other definitions of high or extremely high water stressed areas we should use for purposes of this disclosure? Would these items of information help investors assess a registrant's exposure to climate-related risks impacting water availability? Should we require the disclosure of these items of information from all registrants, including those that do not currently consider having assets in high water-stressed areas a material physical risk? Should we require these disclosures from all registrants operating in certain industrial sectors and, if so, which sectors?

15. Are there other specific metrics that would provide investors with a better understanding of the physical and transition risks facing registrants? How would investors benefit from the disclosure of any additional metrics that would not necessarily be disclosed or disclosed in a consistent manner by the proposed climate risk disclosures? What, if any, additional burdens would registrants face if they were required to disclose additional climate risk metrics?

16. Are there other areas that should be included as examples in the definitions of acute or chronic risks? If so, for each example, please explain how the particular climate-related risk could materially impact a registrant's operations or financial condition.

17. Should we include the negative impacts on a registrant's value chain in the definition of climate-related risks, as proposed? Should we define ''value chain'' to mean the upstream and downstream activities related to a registrant's operations, as proposed? Are there any upstream or downstream activities included in the proposed definition of value chain that we should exclude or revise? Are there any upstream or downstream activities that we should add to the definition of value chain? Are there any upstream or downstream activities currently proposed that should not be included?

18. Should we define climate-related opportunities as proposed? Should we permit a registrant, at its option, to disclose information about any climate-related opportunities that it is pursuing, such as the actual or potential impacts of those opportunities on the registrant, including its business or consolidated financial statements, as proposed? Should we specifically require a registrant to provide disclosure about any climate-related opportunities that have materially impacted or are reasonably likely to impact materially the registrant, including its business or consolidated financial statements? Is there a risk that the disclosure of climate-related opportunities could be misleading and lead to ''greenwashing''? If so, how should this risk be addressed?

C. Disclosure Regarding Climate-Related Impacts on Strategy, Business Model, and Outlook

1. Disclosure of Material Impacts

Once a registrant has described the climate-related risks reasonably likely to have a material impact on the registrant's business or consolidated financial statements as manifested over the short, medium, and long term as required by proposed Item 1502(a), proposed Item 1502(b) would require the registrant to describe the actual and potential impacts of those risks on its strategy, business model, and outlook.[220] Several commenters stated that many registrants have included largely boilerplate discussions about climate-related risks and failed to provide a meaningful analysis of the impacts of those risks on their businesses.[221] The TCFD's most recent assessment of public companies' voluntary climate reports also noted that a minority of companies disclosed the impacts of climate-related risks and opportunities on their businesses in alignment with the TCFD framework.[222] Because information about how climate-related risks have impacted or are likely to impact a registrant's strategy,

[220] *See* proposed 17 CFR 229.1502(b).

[221] *See, e.g.,* letters from CALSTRS; Cardano Risk Management Ltd.; Climate Risk Disclosure Lab (June 14, 2021); and Colorado PERA (June 11, 2021).

[222] *See* TCFD, *2021 Status Report,* Section B (Oct. 2021) (stating that, based on a review of reports of 1,651 public companies from 2018–2020, while 38–52% of companies surveyed described climate-related risks and opportunities during 2018–2020, only 26–39% disclosed the impacts of those risks and opportunities during this period).

business model, and outlook can be important for purposes of making an investment or voting decision about the registrant, we are proposing the provisions below to elicit robust and company-specific disclosure on this topic.

As proposed, a registrant would be required to disclose impacts on its:

- Business operations, including the types and locations of its operations;
- Products or services;
- Suppliers and other parties in its value chain;
- Activities to mitigate or adapt to climate-related risks, including adoption of new technologies or processes;
- Expenditure for research and development; and
- Any other significant changes or impacts.[223]

A registrant would also be required to disclose the time horizon for each described impact (*i.e.,* as manifested in the short, medium, or long term, as defined by the registrant when determining its material climate-related risks).[224]

The proposed rules would require a registrant to discuss how it has considered the identified impacts as part of its business strategy, financial planning, and capital allocation.[225] A registrant would be required to provide both current and forward-looking disclosures [226] that facilitate an understanding of whether the implications of the identified climate-related risks have been integrated into the registrant's business model or strategy, including how resources are being used to mitigate climate-related risks.[227] The discussion must also include how any of the metrics referenced in proposed Rule 14–02 of Regulation S–X and Item 1504 of Regulation S–K or any of the targets referenced in proposed Item 1506 relate to the registrant's business model or business strategy.[228]

For example, a registrant that operates in a jurisdiction that has imposed or is likely to impose limits on GHG emissions in support of the Paris Agreement might set a long-term target of net zero GHG emissions from its operations in 2050, a medium-term target of reducing its emissions by 30 percent by 2030, and a short-term target of maintaining its emissions at its 2020 rate through 2023. This registrant could face material transition risks due to the estimated costs of the operational changes expected to be implemented to achieve these targets. The registrant would be required to disclose these transition risks and their impacts on its strategy, business model, and outlook.

Some of the described impacts would likely be common across industries and may involve reducing a registrant's Scopes 1 and 2 GHG emissions [229] and incurring increased expenses in the short term related to, for example, acquiring new technology to curb its operational emissions and increasing the amount of electricity purchased from renewable sources. Other described impacts of material transition risks, however, would likely vary by industry. For example, an oil company might determine that a likely change in demand for fossil fuel-based products would require it to modify its business model or alter its product mix to emphasize advanced diesel gas and biofuels in order to maintain or increase its earning capacity, thereby requiring disclosure under the proposed rules. An electric utilities company might disclose an increase in the amount of electricity generated from less carbon-intensive sources, such as wind turbines, nuclear, hydroelectric, or solar power to meet current or likely regulatory constraints.

A registrant would also be required to disclose the material impacts of physical risks on its strategy, business model, and outlook. For example, an agricultural producer or distributor might disclose the likely impacts of drought on its own product mix or that of its suppliers, including increased expenses for additional water or due to the procurement of alternative product sources. Similarly, a mining company that operates in areas susceptible to extreme rise in temperatures might disclose the likely impacts that this temperature rise has on its workforce and on its production schedule, including a reduction in output and future earning capacity. A real estate company that owns coastal property might disclose the likely impacts of rising sea levels on such property, including the potential diminution in value of, and a potential change in its strategy and outlook regarding, such properties.

The proposed rules would require a registrant to provide a narrative discussion of whether and how any of its identified climate-related risks described in response to proposed Item 1502(a) have affected or are reasonably likely to affect the registrant's consolidated financial statements.[230] The discussion should include any of the financial statement metrics disclosed pursuant to proposed Regulation S–X Rule 14–02.[231] As previously noted, many commenters recommended that we require registrants to discuss and analyze their quantitative climate data in a manner similar to that required for MD&A.[232] Proposed 17 CFR 229.1502(d) (Item 1502(d) of Regulation S–K) is intended to provide climate-related disclosure that is similar to MD&A, although, as previously noted, a registrant may provide such disclosure as part of its MD&A.

For example, an automobile manufacturer might discuss an increase in operating costs or capital expenditures due to the need to revamp its assembly lines to build lower emission vehicles to comply with new regulatory guidelines or to meet changing consumer demand. An oil company might discuss a change in the valuation of its proven reserves because of an anticipated reduced demand for fossil fuels. A freight company might discuss impairment charges or early write-offs for older equipment it might need to replace due to anticipated changes in regulation or policy favoring lower emissions equipment. While a registrant may currently have an obligation to make some of these disclosures pursuant to Regulation S–X, the disclosed impacts in the financial statements may not be in disaggregated form and may lack explanation. Proposed Item 1502(d) would require the disclosure in the form of a narrative analysis akin to MD&A that would be more easily accessible for investors.

Moreover, it is likely that any disclosed impacts in the financial statements would be assessed for the fiscal years presented in the financial statements with a focus on near short-term impacts. Because proposed Item 1502 would require a registrant to identify material climate-related impacts that may manifest in the short, medium, and long term, a registrant's narrative discussion of the likely climate-related impacts on its consolidated financial statements

[223] *See* proposed 17 CFR 229.1502(b)(1).

[224] *See* proposed 17 CFR 229.1502(b)(2).

[225] *See* proposed 17 CFR 229.1502(c).

[226] *See infra* Sections II.C.3 and 4, II.E, II.G.1, and II.I regarding the application to forward-looking climate disclosures of the PSLRA safe harbor for forward-looking statements.

[227] *See id.*

[228] *See infra* Sections II.F and II.G for a discussion of the proposed metrics and targets.

[229] *See supra* Section I.D.2 and *infra* Section II.G for a discussion of Scopes 1 and 2 emissions.

[230] *See* proposed 17 CFR 229.1502(d). To the extent that the proposed narrative discussion is provided in its MD&A, a registrant could incorporate by reference that part of the MD&A into the Climate-Related Disclosure section of the registration statement or report. *See supra* Section II.A.2.

[231] *See infra* Section II.F.

[232] *See supra* note 171.

should cover more than just short-term impacts. For example, if a registrant has a transition plan [233] that includes the development of lower carbon products and processes, that registrant might disclose that it expects to incur higher initial capital costs to implement its strategy, but anticipates increased revenues or reduced expenses over the longer term. An automobile manufacturer that transitions from the production of internal combustion engine vehicles to the production of electric vehicles might disclose that it expects to incur costs in the short term to change its manufacturing processes, but over the longer term, it expects to realize increased sales, protect its market share against transition risks, including reputational risks, and potentially avoid regulatory fines or other costs as consumer and regulatory demands change.

2. Disclosure of Carbon Offsets or Renewable Energy Credits if Used

If, as part of its net emissions reduction strategy, a registrant uses carbon offsets or renewable energy credits or certificates (''RECs''), the proposed rules would require it to disclose the role that carbon offsets or RECs play in the registrant's climate-related business strategy.[234] Under the proposed rules, carbon offsets represent an emissions reduction or removal of greenhouse gases in a manner calculated and traced for the purpose of offsetting an entity's GHG emissions.[235] We are proposing to define a REC, consistent with the EPA's commonly used definition, to mean a credit or certificate representing each purchased megawatt-hour (1 MWh or 1000 kilowatt-hours) of renewable electricity generated and delivered to a registrant's power grid.[236] While both carbon offsets and RECs represent commonly used GHG emissions mitigation options for companies, they are used for somewhat different purposes.[237]

Some registrants might plan to use carbon offsets or RECs as their primary means of meeting their GHG reduction goals, including those formulated in response to government law or policy or customer or investor demands. Other registrants, including those that set Science Based Targets pursuant to the Science Based Targets Initiative,[238] might develop strategies to reduce their emissions to the extent possible through operational changes—such as modifications to their product offerings or the development of solar or other renewable energy sources. They then might plan to use carbon offsets or RECs to offset the remainder of their emissions that they cannot reduce through operational changes or to meet their GHG reduction goals while they transition to lower carbon operations.

Understanding the role that carbon offsets or RECs play in a registrant's climate-related business strategy can help investors gain useful information about the registrant's strategy, including the potential risks and financial impacts. A registrant that relies on carbon offsets or RECs to meet its goals might incur lower expenses in the short term but could expect to continue to incur the expense of purchasing offsets or RECs over the long term. It also could bear the risk of increased costs of offsets or RECs if increased demand for offsets or RECs creates scarcity and higher costs to acquire them over time. Alternatively, the value of an offset may decrease substantially and suddenly if, for example, the offset represents protected forest land that burns in a wildfire and no longer represents a reduction in GHG emissions. In that case, the registrant may need to write off the offset and purchase a replacement. In other cases, increased demand for, or scarcity of, offsets and RECs may benefit a registrant that produces or generates offsets or RECs to the extent their prices increase. Accordingly, under the proposed rules, a registrant that purchases offsets or RECs to meet its goals as it makes the transition to lower carbon products would need to reflect this additional set of short and long-term costs and risks in its Item 1502 disclosure, including the risk that the availability or value of offsets or RECs might be curtailed by regulation or changes in the market.

3. Disclosure of a Maintained Internal Carbon Price

Some registrants may use an internal carbon price when assessing climate-related factors. Under the proposed definition, an internal carbon price is an estimated cost of carbon emissions used internally within an organization.[239] Internal carbon pricing may be used by a registrant, among other purposes, as a planning tool to help identify climate-related risks and opportunities, as an incentive to drive energy efficiencies to reduce costs, to quantify the potential costs the company would incur should a carbon price be put into effect, and to guide capital investment decisions. If a registrant uses an internal carbon price, the proposed rules would require it to disclose:

- The price in units of the registrant's reporting currency per metric ton of carbon dioxide equivalent (''CO_2e''); [240]
- The total price, including how the total price is estimated to change over time, if applicable;
- The boundaries for measurement of overall CO_2e on which the total price is based (if different from the GHG emission organizational boundary required pursuant to 17 CFR 229.1504(e)(2); [241] and
- The rationale for selecting the internal carbon price applied.[242]

These proposed items of disclosure would help investors understand the rationale and underlying assumptions for a registrant's internal carbon price and help them assess whether the registrant's use of an internal carbon price as a planning tool is reasonable and effective.

A registrant would also be required to describe how it uses its disclosed internal carbon price to evaluate and

[233] *See infra* Section II.E for proposed disclosure requirements regarding the use of a transition plan.

[234] *See* proposed 17 CFR 229.1502(c).

[235] *See* proposed 17 CFR 229.1500(a).

[236] *See* proposed 17 CFR 229.1500(n). *See, e.g.,* EPA, *Offsets and RECs: What's the Difference?,* available at *https://www.epa.gov/sites/default/files/2018-03/documents/gpp_guide_recs_offsets.pdf.*

[237] A company may purchase carbon offsets to address its direct and indirect GHG emissions (*i.e.,* its Scopes 1, 2, and 3 emissions) by verifying global emissions reductions at additional, external projects. The reduction in GHG emissions from one place (''offset project'') can be used to ''offset'' the emissions taking place somewhere else (at the company's operations). *See, e.g.,* EPA, *Offsets and RECs: What's the Difference?,* available at *https://www.epa.gov/sites/default/files/2018-03/documents/gpp_guide_recs_offsets.pdf.* In contrast, a company may purchase a REC in renewable electricity markets solely to address its indirect GHG emissions associated with purchased electricity (*i.e.,* Scope 2 emissions) by verifying the use of zero- or low-emissions renewable sources of electricity. Each REC provides its owner exclusive rights to the attributes of one megawatt-hour of renewable electricity whether that renewable electricity has been installed on the company's facilities or produced elsewhere. *See id.*

[238] Science Based Targets Initiative (''SBTi'') is a partnership between CDP, the United Nations Global Compact, World Resources Institute (WRI) and the World Wide Fund for Nature (WWF), which defines and promotes best practice in emissions reductions and net-zero targets in line with climate science. SBTi provides technical assistance and its expertise to companies who voluntarily set science-based targets in line with the latest climate science. *See* SBTi, *Who We Are/What We Do,* available at *https://sciencebasedtargets.org/about-us#who-we-are.* The SBTi does not permit offsets to be counted toward a company's emission reduction targets to meet its science-based targets but does permit offsets by companies that wish to finance additional emission reductions beyond their science-based targets. *See SBTi Criteria and Recommendations* (Apr. 2020), available at *https://sciencebasedtargets.org/resources/legacy/2019/03/SBTi-criteria.pdf.*

[239] *See* proposed 17 CFR 229.1500(j).

[240] *See infra* Section II.G for a discussion of our proposal to use CO_2e as a unit of measurement in the proposed requirements.

[241] *See infra* Section II.G.2 for a discussion of the proposed requirements for determining the GHG emission organizational boundary.

[242] *See* proposed 17 CFR 229.1502(e)(1).

manage climate-related risks.[243] If a registrant uses more than one internal carbon price, the proposed rules would require it to provide disclosures for each internal carbon price, and to disclose its reasons for using different prices.[244] For example, a registrant might disclose that it uses different internal carbon prices when considering different climate-related scenarios to help it develop an appropriate business strategy over the short-, medium-, and long-term.[245]

Commenters that addressed the topic of carbon price generally supported requiring its disclosure in some form, such as: (i) Establishing a broad-based carbon price; (ii) requiring companies to maintain and disclose an internal carbon price; (iii) requiring disclosure of any internal carbon price already used by a company; or (iv) requiring disclosure of carbon prices used in the context of scenario analysis.[246] One commenter referred to disclosure of a company's use of internal carbon pricing as one of several ''foundational climate disclosures'' that should be required in any Commission rule.[247] Another commenter also underscored the importance of this information, stating that ''the thorough quantification of climate risk has been hampered by the lack of carbon pricing.'' [248] We agree with commenters that supported the disclosure of carbon pricing as a key data point for evaluating how a registrant is planning for and managing climate-related risks. However, the proposed rules would not require registrants to maintain an internal carbon price or to mandate a particular carbon pricing methodology. We are aware that many registrants may not currently track this information and recognize that a robust carbon market on which to base such a price may not exist in many contexts.[249] Accordingly, the proposed disclosures would be required only if the registrant otherwise maintains an internal carbon price. For similar reasons, we have not proposed requiring a specific methodology for setting an internal carbon price.

Registrants may choose to use an internal carbon price when quantifying, analyzing, and assessing the financial impacts of climate-related risks and climate-related opportunities. For example, an internal carbon price helps monetize emissions by converting emissions data from CO_2e into a value in the registrant's reporting currency. A registrant may determine that monetization is useful when assessing the costs and benefits of its possible climate-related strategies, as it effectively puts a price on the emission impacts. Disclosure of an internal carbon price, when used by a registrant, would provide investors with material information regarding how the registrant developed a particular business strategy to mitigate or adapt to identified climate-related risks and would help quantify for investors at least part of the transition risks faced by a registrant. We believe that this proposed disclosure requirement would help investors assess whether a registrant's internal carbon pricing practice is reasonable and whether its overall evaluation and planning regarding climate-related factors is sound.[250]

A registrant's disclosure of any internal carbon price necessarily would include assumptions about future events. The carbon price applied should not be viewed as a promise or guarantee with regard to the future costs to the registrant of GHG emissions. Moreover, to the extent that certain information regarding a registrant's internal carbon pricing would constitute forward-looking statements, the PSLRA safe harbors would apply to such statements, assuming all other statutory requirements for those safe harbors are satisfied.

4. Disclosure of Scenario Analysis, if Used

We are proposing to require a registrant to describe the resilience of its business strategy in light of potential future changes in climate-related risks. A registrant also would be required to describe any analytical tools, such as scenario analysis, that the registrant uses to assess the impact of climate-related risks on its business and consolidated financial statements, or to support the resilience of its strategy and business model in light of foreseeable climate-related risks.[251] Scenario analysis is a process for identifying and assessing a potential range of outcomes of future events under conditions of uncertainty.[252] The proposed definition of scenario analysis both states that (i) when applied to climate-related assessments, scenario analysis is a tool used to consider how, under various possible future climate scenarios, climate-related risks may impact a registrant's operations, business strategy, and consolidated financial statements over time; and that (ii) registrants might use scenario analysis to test the resilience of their strategies under future climate scenarios, including scenarios that assume different global temperature increases, such as, for example, 3 °C, 2 °C, and 1.5 °C above pre-industrial levels.[253]

Many commenters recommended that we require a registrant to conduct scenario analysis and disclose the results of such analysis.[254] One commenter stated that scenario analysis was useful because it allows companies to test their business strategy against a spectrum of hypothetical future climate scenarios and develop a better informed view of implications for their enterprise value and value chains. The same commenter further indicated that disclosure of the scenarios used by a company was necessary to inform investors about the reliability, reasonableness, and resiliency of the company's plans to address climate-related risks and opportunities.[255]

Another commenter stated that the Commission should require disclosure of a registrant's climate scenario analysis by no later than 2025, and recommended that companies engage in scenario analysis involving a base case, worse case, better case, and ''Black

[243] *See* proposed 17 CFR 229.1502(e)(2).

[244] *See* proposed 17 CFR 229.1502(e)(3).

[245] *See infra* Section II.C.4 for the proposed disclosure required if a registrant uses scenario analysis.

[246] *See, e.g.,* letters from Rob Bonta, California Attorney General, on behalf of several state attorney generals (June 14, 2021); Catavento; Center for Climate and Energy Solutions; Ceres; Climate Risk Disclosure Lab; Hermes Equity Ownership Services Limited; Majedie Asset Management; Managed Funds Association; Norges Bank Investment Management; Open Source Climate; PRI (Consultation Response); Regenerative Crisis Response Committee; Total Energies (June 13, 2021); and Trillium Asset Management. *But see* Edison Electric Institute (stating that a '''robust carbon market' does not exist today'' and disclosures based on that market would be ''fraught with risk'').

[247] Letter from Ceres.

[248] Letter from PRI.

[249] *See* Edison Electric Institute.

[250] We also note, based on current voluntary reporting, an increasing trend among public companies to use internal carbon pricing. *See* CDP, *Putting a Price on Carbon* (2021), *available at https://cdn.cdp.net/cdp-production/cms/reports/documents/000/005/651/original/CDP_Global_Carbon_Price_report_2021.pdf?1618938446.*

[251] *See* proposed 17 CFR229.1502(f).

[252] *See, e.g.,* the definition of ''scenario analysis'' in TCFD, *Recommendations of the Task Force on Climate-related Financial Disclosures.*

[253] *See* proposed 17 CFR 229.1500(o).

[254] *See, e.g.,* letters from AllianceBernstein; Americans for Financial Reform Education Fund; R. Ted Atwood (June 23, 2021); BlackRock; Bloomberg, LP; Boston Common Asset Management; Cardano Risk Management Ltd.; Certified B Corporations; Climate Governance Initiative; Climate Risk Disclosure Law and Policy Lab (June 14, 2021); Consumer Federation of America; CPP Investments; E2; ERM CVS; FAIRR Initiative; Forum for Sustainable and Responsible Investment (June 11, 2021); Friends of the Earth *et al.*; George Georgiev; Global Equity Strategy (June 14, 2021); Impax Asset Management; Invesco; Christopher Lish; NY State Comptroller; PRI (Consultation Response); Revolving Door Project; RMI; Trillium Asset Management; UNEP; and Sens. Elizabeth Warren and Rep. Sean Casten (June 11, 2021).

[255] *See* letter from Bloomberg.

Swan'' scenarios related to possible climate transition pathways.[256] Alternatively, the commenter suggested that a company take into account three scenarios: A smooth economic transition to +1.5 °C, which would form the basis of the company's net-zero strategy; a disorderly and, therefore, more costly and disruptive transition to +1.5 °C; and a higher temperature scenario outcome of +3 °C of warming, which would be associated with extreme physical effects and unprecedented economic costs and disruption. This commenter further stated that robust disclosure of a company's scenario analysis was necessary so that investors can understand how longer-term ''climate drivers'' have been incorporated into its corporate strategy and financial disclosures.[257]

Another commenter expressed the view that, although many companies purport to use scenario analysis in the climate context, their reporting regarding such use has been generally deficient. That commenter stated that the assumptions underlying the selected scenarios often are undisclosed and that the analysis tends to be limited and not usefully comparable.[258] The TCFD's most recent assessment of public companies' voluntary climate reporting similarly found that only a small percentage of the surveyed companies disclosed the resilience of their strategies using scenario analysis as recommended by the TCFD.[259]

Some commenters recommended providing certain accommodations in connection with a scenario analysis requirement, such as creating a safe harbor for scenario analysis disclosure [260] or permitting scenario analysis to be furnished in a separate report that would not be subject to the same liability as Commission filings.[261] Other commenters stated that they opposed a scenario analysis requirement because of the lack of a common methodology for scenario analysis; [262] a belief that the underlying methodology would be too difficult for investors to understand; [263] the need for further development of scenario analysis as a discipline; [264] or a belief that the focus of climate-related disclosure should be on historical data, and not on forward-looking information.[265]

We agree with those commenters who stated that information concerning scenario analysis could help investors evaluate the resilience of the registrant's business strategy in the face of various climate scenarios that could impose potentially different climate-related risks. We are not, however, proposing to mandate that registrants conduct scenario analysis. We recognize that not every registrant conducts scenario analysis and that, in certain instances, it may be costly or difficult for some registrants to conduct such scenario analysis. Instead, the proposed rules would require that if a registrant uses scenario analysis or any analytical tools to assess the impact of climate-related risks on its business and consolidated financial statements, and to support the resilience of its strategy and business model, the registrant must disclose certain information about such analysis.[266] We believe this approach strikes an appropriate balance between the various positions expressed by commenters by requiring registrants to share any scenario analysis that they are otherwise conducting for their business operations while avoiding imposing a potentially difficult or burdensome requirement on those registrants that have not yet undertaken to conduct such analysis.

If a registrant uses scenario analysis, the proposed amendments would require disclosure of the scenarios considered (*e.g.,* an increase of no greater than 3°, 2°, or 1.5 °C above pre-industrial levels), including parameters, assumptions, and analytical choices, and the projected principal financial impacts on the registrant's business strategy under each scenario. The disclosure should include both quantitative and qualitative information. Disclosure of the parameters, assumptions, and analytical choices involved in the described scenarios would help investors better understand the various considered scenarios and help them evaluate whether the registrant has a plan to manage the climate-related risks posed by each scenario.

Because a registrant's scenario analysis disclosure would necessarily include predictions and other forward-looking statements based on assumptions concerning future events, we believe that the PSLRA forward-looking safe harbors would apply to much of the disclosure concerning scenario analysis provided the other statutory conditions for application of the safe harbor are met.

We note that there are a number of publicly-available climate-related scenarios that could form the basis of a registrant's scenario analysis. The TCFD has categorized these scenarios as transition scenarios and physical climate scenarios.[267] If a registrant uses scenario analysis to assess the resilience of its business strategy to climate-related risks, investors may benefit from the use of scientifically based, widely accepted scenarios, such as those developed by the IPCC, International Energy Agency (''IEA''),[268] or Network of Central Banks and Supervisors for Greening the Financial System (''NGFS'').[269] Investors may also benefit by the use of more than one climate scenario, including one that assumes a disorderly transition (*i.e.,* one that assumes that climate policies are delayed or divergent across countries and industrial sectors, resulting in higher transition risks to companies). These could enhance the reliability and usefulness of the scenario analysis for investors.

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19. Should we require a registrant to describe the actual and potential impacts of its material climate-related risks on its strategy, business model, and outlook, as proposed? Should we require a registrant to disclose impacts from climate-related risks on, or any resulting significant changes made to, its business operations, including the types and locations of its operations, as proposed?

20. Should we require a registrant to disclose climate-related impacts on, or

[256] *See* letter from Climate Governance Initiative.

[257] *See id.*

[258] *See* letter from Ceres. The CDP similarly reported that, although 54% of the 9,600+ companies that responded to their questionnaires in 2020 reported engaging in scenario analysis, 14% of the companies only considered one scenario with many others considering only slight variations of one scenario. *See* CDP, *3 common pitfalls of using scenario analysis—and how to avoid them* (Mar. 10, 2021), available at *https://www.cdp.net/en/articles/companies/3-common-pitfalls-companies-make-when-using-scenario-analysis-and-how-to-avoid-them.*

[259] *See* TCFD, 2021 Status Report, Section B (indicating that, during 2018–2020, only 5–13% of the surveyed companies disclosed the resilience of their strategies using scenario analysis).

[260] *See* letter from J. Robert Gibson.

[261] *See* letter from NEI Investments.

[262] *See* letter from Information Technology Industry Council.

[263] *See* letter from Dimensional Fund Advisors.

[264] *See* letter from bp.

[265] *See* letter from Nareit (June 11, 2021).

[266] *See* proposed 17 CFR 229.1502(f). One commenter recommended requiring the disclosure of the results of scenario analysis if a registrant has engaged in such analysis. *See* letter from E3G.

[267] *See* TCFD, Technical Supplement, *The Use of Scenario Analysis in Disclosure of Climate-Related Risks and Opportunities* (June 2017), available at *https://assets.bbhub.io/company/sites/60/2020/09/2020-TCFD_Guidance-Scenario-Analysis-Guidance.pdf.*

[268] The TCFD has summarized a number of publicly available scenario analysis models, with particular emphasis on the transition scenarios developed by the IEA and the physical risk scenarios developed by the IPCC. *See id.* at Appendix 1: IEA and IPCC Climate Scenarios.

[269] *See* NGFS, *Scenarios Portal,* available at *https://www.ngfs.net/ngfs-scenarios-portal/.*

any resulting significant changes made to, its products or services, supply chain or value chain, activities to mitigate or adapt to climate-related risks, including adoption of new technologies or processes, expenditure for research and development, and any other significant changes or impacts, as proposed? Are there any other aspects of a registrant's business operations, strategy, or business model that we should specify as being subject to this disclosure requirement to the extent they may be impacted by climate-related factors?

21. Should we require a registrant to specify the time horizon applied when assessing its climate-related impacts (*i.e.,* in the short, medium, or long term), as proposed?

22. Should we require a registrant to discuss whether and how it considers any of the described impacts as part of its business strategy, financial planning, and capital allocation, as proposed? Should we require a registrant to provide both current and forward-looking disclosures to facilitate an understanding of whether the implications of the identified climate-related risks have been integrated into the registrant's business model or strategy, as proposed? Would any of the proposed disclosures present competitive concerns for registrants? If so, how can we mitigate such concerns?

23. Should we require the disclosures to include how the registrant is using resources to mitigate climate-related risks, as proposed? Should the required discussion also include how any of the metrics or targets referenced in the proposed climate-related disclosure subpart of Regulation S–K or Article 14 of Regulation S–X relate to the registrant's business model or business strategy, as proposed? Should we require additional disclosures if a registrant leverages climate-related financing instruments, such as green bonds or other forms of ''sustainable finance'' such as ''sustainability-linked bonds,'' ''transition bonds,'' or other financial instruments linked to climate change as part of its strategy to address climate-related risks and opportunities? For example, should we require disclosure of the climate-related projects that the registrant plans to use the green bond proceeds to fund? Should we require disclosure of key performance metrics tied to such financing instruments?

24. If a registrant has used carbon offsets or RECs, should we require the registrant to disclose the role that the offsets or RECs play in its overall strategy to reduce its net carbon emissions, as proposed? Should the proposed definitions of carbon offsets and RECs be clarified or expanded in any way? Are there specific considerations about the use of carbon offsets or RECs that we should require to be disclosed in a registrant's discussion regarding how climate-related factors have impacted its strategy, business model, and outlook?

25. Should we require a registrant to provide a narrative discussion of whether and how any of its identified climate-related risks have affected or are reasonably likely to affect its consolidated financial statements, as proposed? Should the discussion include any of the financial statement metrics in proposed 17 CFR 210.14–02 (14–02 of Regulation S–X) that demonstrate that the identified climate-related risks have had a material impact on reported operations, as proposed? Should the discussion include a tabular representation of such metrics?

26. Should we require registrants to disclose information about an internal carbon price if they maintain one, as proposed? If so, should we require that the registrant disclose:

- The price in units of the registrant's reporting currency per metric ton of CO_2e;
- The total price;
- The boundaries for measurement of overall CO_2e on which the total price is based if different from the GHG emission organizational boundary required pursuant to 17 CFR 210.14–03(d)(4); and
- The rationale for selecting the internal or shadow carbon price applied, as proposed?

Should we also require registrants to describe the methodology used to calculate its internal carbon price?

27. Should we also require a registrant to disclose how it uses the described internal carbon price to evaluate and manage climate-related risks, as proposed? Should we further require a registrant that uses more than one internal carbon price to provide the above disclosures for each internal carbon price, and disclose its reasons for using different prices, as proposed? Are there other aspects regarding the use of an internal carbon price that we should require to be disclosed? Would disclosure regarding any internal carbon price maintained by a registrant elicit important or material information for investors? Would requiring the disclosure of the registrant's use of an internal carbon price raise competitive harm concerns that would act as a disincentive from the use of an internal carbon price? If so, should the Commission provide an accommodation that would mitigate those concerns? For example, are there exceptions or exemptions to an internal carbon price disclosure requirement that we should consider?

28. To the extent that disclosure that incorporates or is based on an internal carbon price constitutes forward-looking information, the PSLRA safe harbors would apply. Should we adopt a separate safe harbor for internal carbon price disclosure? If so, what disclosures should such a safe harbor cover and what should the conditions be for such a safe harbor?

29. Should we require all registrants to disclose an internal carbon price and prescribe a methodology for determining that price? If so, what corresponding disclosure requirements should we include in connection with such mandated carbon price? What methodology, if any, should we prescribe for calculating a mandatory internal or shadow carbon price? Would a different metric better elicit disclosure that would monetize emissions?

30. Should we require a registrant to disclose analytical tools, such as scenario analysis, that it uses to assess the impact of climate-related risks on its business and consolidated financial statements, and to support the resilience of its strategy and business model, as proposed? What other analytical tools do registrants use for these purposes, and should we require disclosure of these other tools? Are there other situations in which some registrants should be required to conduct and provide disclosure of scenario analysis? Alternatively, should we require all registrants to provide scenario analysis disclosure? If a registrant does provide scenario analysis disclosure, should we require it to follow certain publicly available scenario models, such as those published by the IPCC, the IEA, or NGFS and, if so, which scenarios? Should we require a registrant providing scenario analysis disclosure to include the scenarios considered (*e.g.,* an increase of global temperature of no greater than 3°, 2°, or 1.5 °C above pre-industrial levels), the parameters, assumptions, and analytical choices, and the projected principal financial impacts on the registrant's business strategy under each scenario, as proposed? Are there any other aspects of scenario analysis that we should require registrants to disclose? For example, should we require a registrant using scenario analysis to consider a scenario that assumes a disorderly transition? Is there a need for us to provide additional guidance regarding scenario analysis? Are there any aspects of scenario analysis in our proposed required disclosure that we should exclude? Should we also require a registrant that

does not use scenario analysis to disclose that it has not used this analytical tool? Should we also require a registrant to disclose its reasons for not using scenario analysis? Will requiring disclosure of scenario analysis if and when a registrant performs scenario analysis discourage registrants from conducting scenario analysis? If so, and to the extent scenario analysis is a useful tool for building strategic resilience, how could our regulations prevent such consequences?

31. Would the PSLRA forward-looking statement safe harbors provide adequate protection for the proposed scenario analysis disclosure? Should we instead adopt a separate safe harbor for scenario analysis disclosure? If so, what disclosures should such a safe harbor cover that would not be covered by the PSLRA safe harbors and what should the conditions be for such a safe harbor?

32. Should we adopt a provision similar to 17 CFR 229.305(d) that would apply the PSLRA forward-looking statement safe harbor to forward-looking statements made in response to specified climate-related disclosure items, such as proposed Item 1502 and Item 1505 (concerning targets and goals) of Regulation S–K? If so, which proposed items should we specifically include in the safe harbor?

33. As proposed, a registrant may provide disclosure regarding any climate-related opportunities when responding to any of the provisions under proposed 17 CFR 229.1502 (Item 1502). Should we require disclosure of climate-related opportunities under any or all of the proposed Item 1502 provisions?

D. Governance Disclosure

Similar to the TCFD framework, the proposed rules would require a registrant to disclose, as applicable, certain information concerning the board's oversight of climate-related risks, and management's role in assessing and managing those risks.[270] Many commenters asserted that climate-related issues should be subject to the same level of board oversight as other financially material matters.[271] Most of these commenters supported robust disclosure of a board's and management's governance of climate-related risks and opportunities, consistent with the TCFD framework.[272]

Our proposed disclosure requirements are based on specific recommendations of the TCFD. We agree with commenters that a comprehensive understanding of a board's oversight, and management's governance, of climate-related risks is necessary to aid investors in evaluating the extent to which a registrant is adequately addressing the material climate-related risks it faces, and whether those risks could reasonably affect the value of their investment.[273] We also note that, despite the importance of governance disclosure, according to the TCFD, only a small percentage of issuers that voluntarily provided climate-related information presented governance disclosure aligned with the TCFD's recommendations.[274] While the proposed rules are intended to provide investors with additional insight into a board's and management's governance of climate-related risks, they are similar to the Commission's existing rules under Regulation S–K that call for disclosure about corporate governance in that they are intended to provide investors with relevant information about a registrant's board, management, and principal committees.[275]

1. Board Oversight

The proposed rules would require a registrant to disclose a number of board governance items, as applicable. The first item would require a registrant to identify any board members or board committees responsible for the oversight of climate-related risks.[276] The responsible board committee might be an existing committee, such as the audit committee or risk committee, or a separate committee established to focus on climate-related risks. The next proposed item would require disclosure of whether any member of a registrant's board of directors has expertise in climate-related risks, with disclosure required in sufficient detail to fully describe the nature of the expertise.[277]

Another proposed item would require a description of the processes and frequency by which the board or board committee discusses climate-related risks.[278] The registrant would have to disclose how the board is informed about climate-related risks, and how frequently the board considers such risks. These proposed disclosure items could provide investors with insight into how a registrant's board considers climate-related risks and any relevant qualifications of board members.[279]

The proposed rule also would require disclosure about whether and how the board or board committee considers climate-related risks as part of its business strategy, risk management, and financial oversight.[280] This disclosure could enable an investor to understand whether and how the board or board committee considers climate-related risks when reviewing and guiding business strategy and major plans of action, when setting and monitoring implementation of risk management policies and performance objectives, when reviewing and approving annual budgets, and when overseeing major expenditures, acquisitions, and divestitures. In this way, the proposed disclosure requirement could help investors assess the degree to which a board's consideration of climate-related risks has been integrated into a registrant's strategic business and financial planning and its overall level of preparation to maintain its shareholder value.

Finally, the proposed rule would require disclosure about whether and how the board sets climate-related targets or goals and how it oversees

[270] *See* proposed 17 CFR 229.1501.

[271] *See, e.g.,* letters from Americans for Financial Reform Education Fund; Baillie Gifford; Andrew Behar; Bloomberg, LP; Canadian Coalition for Good Governance; Cardano Risk Management Ltd.; CDP NA (June 11, 2021); Center for American Progress; CAQ; Ceres *et al.*; Climate Disclosure Standards Board (June 14, 2021); Climate Governance Initiative; Climate Risk Disclosure Lab; Eni SpA; ERM CVS; Friends of the Earth, Amazon Watch, and Rainforest Action Network (June 11, 2021); Regenerative Crisis Response Committee; Hermes Equity Ownership Limited; William and Flora Hewlett Foundation (June 9, 2021); Impax Asset Management; Institute of Internal Auditors (May 23, 2021); Institutional Shareholder Services (June 14, 2021); Interfaith Center on Corporate Responsibility; International Corporate Governance Network; Morningstar, Inc.; International Organization for Standardization (June 11, 2021); Natural Resources Defense Council; NEI Investments; NY City Comptroller (June 14, 2021); NY State Comptroller; NY State Department of Financial Services (June 14, 2021); Oregon State Treasury (June 4, 2021); PRI (Consultation Response); Pricewaterhouse Coopers; Revolving Door Project (June 11, 2021); George Serafeim (June 9, 2021); Maria Stoica; TotalEnergies (June 13, 2021); Value Balancing Alliance; WBCSD; and World Benchmarking Alliance.

[272] *See, e.g.,* letters from Baillie Gifford; Bloomberg, LP; Ceres et al.; Climate Disclosure Standards Board; Climate Governance Initiative; Climate Risk Disclosure Lab; Eni SpA; William and Flora Hewlett Foundation; Impax Asset Management; Institute for Governance and Sustainable Development; International Corporate Governance Network; Richard Love; Morningstar, Inc.; Natural Resources Defense Council; NEI Investments; NY State Comptroller; Maria Stoica; TotalEnergies; and WBCSD. *But see* letter from Amanda Rose (stating that federalizing aspects of corporate governance could inhibit the ability of states to compete for corporate charters).

[273] *See, e.g.,* letters from Bloomberg, LP; and Natural Resources Defense Council.

[274] *See* TCFD, *2021 Status Report* (Oct. 2021) (finding that 9% of surveyed companies provided TCFD-recommended board disclosure in 2018, which increased to 25% in 2020; and 9% provided TCFD-recommended management disclosure in 2018, which increased to 18% in 2020).

[275] *See, e.g.,* 17 CFR 229.401 and 229.407.

[276] *See* proposed 17 CFR 229.1501(a)(1)(i).

[277] *See* proposed 17 CFR 229.1501(a)(1)(ii).

[278] *See* proposed 17 CFR 229.1501(a)(1)(iii).

[279] *See, e.g.,* letters from Bloomberg, LP; NY State Comptroller; and Vanguard Group, Inc.

[280] *See* proposed 17 CFR 229.1501(a)(1)(iv).

progress against those targets or goals, including the establishment of any interim targets or goals.[281] Such a target might be, for example, to achieve net-zero carbon emissions for all or a large percentage of its operations by 2050 or to reduce the carbon intensity of its products by a certain percentage by 2030 in order to mitigate transition risk. This proposed requirement would help investors evaluate whether and how a board is preparing to mitigate or adapt to any material transition risks, and whether it is providing oversight for the registrant's potential transition to a lower carbon economy. If applicable, a registrant can elect also to discuss the board's oversight of climate-related opportunities.

2. Management Oversight

Similar to the proposed required disclosures on board oversight, the proposed rules would require a registrant to disclose a number of items, as applicable, about management's role in assessing and managing any climate-related risks. For example, a registrant would be required to disclose, as applicable, whether certain management positions or committees are responsible for assessing and managing climate-related risks and, if so, to identify such positions or committees and disclose the relevant expertise of the position holders or members in such detail as necessary to fully describe the nature of the expertise.[282] This proposed requirement would give investors additional information to assess the extent to which management addresses climate-related risks, which could help them to make better informed investment or voting decisions.

Similar to the proposed board oversight provision described above, another proposed item would require disclosure about the processes by which the responsible managers or management committees are informed about and monitor climate-related risks.[283] Such a discussion might include, for example, whether there are specific positions or committees responsible for monitoring and assessing specific climate-related risks, the extent to which management relies on in-house staff with the relevant expertise to evaluate climate-related risks and implement related plans of action, and the extent to which management relies on third-party climate consultants for these same purposes.

The final proposed management governance item would require disclosure about whether the responsible positions or committees report to the board or board committee on climate-related risks and how frequently this occurs.[284] These proposed disclosure items could help investors evaluate whether management has adequately implemented processes to identify, assess, and manage climate-related risks. If applicable, a registrant may elect also to describe management's role in assessing and managing climate-related opportunities.

Several commenters recommended that we require a registrant to disclose whether it has connected a portion of its executive remuneration with the achievement of climate-related targets or goals.[285] Other commenters expressed the view that such a requirement is unnecessary, because a registrant could implement other measures to motivate progress towards climate-related targets [286] or connect executive remuneration with climate-related achievements as a discretionary matter for the registrant.[287] We are not proposing a compensation-related disclosure requirement at this time, because we believe that our existing rules requiring a compensation discussion and analysis should already provide a framework for disclosure of any connection between executive remuneration and achieving progress in addressing climate-related risks.[288]

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34. Should we require a registrant to describe, as applicable, the board's oversight of climate-related risks, as proposed? Should the required disclosure include whether any board member has expertise in climate-related risks and, if so, a description of the nature of the expertise, as proposed? Should we also require a registrant to identify the board members or board committee responsible for the oversight of climate-related risks, as proposed? Do our current rules, which require a registrant to provide the business experience of its board members, elicit adequate disclosure about a board member's or executive officer's expertise relevant to the oversight of climate-related risks?

35. Should we require a registrant to disclose the processes and frequency by which the board or board committee discusses climate-related risks, as proposed?

36. Should we require a registrant to disclose whether and how the board or board committee considers climate-related risks as part of its business strategy, risk management, and financial oversight, as proposed? Would the proposed disclosure raise competitive harm concerns? If so, how could we address those concerns while requiring additional information for investors about how a registrant's board oversees climate-related risks?

37. Should we require a registrant to disclose whether and how the board sets climate-related targets or goals, as proposed? Should the required disclosure include how the board oversees progress against those targets or goals, including whether it establishes any interim targets or goals, as proposed? Would the proposed disclosure raise competitive harm concerns? If so, how could we address those concerns while requiring additional information for investors about how a registrant's board oversees the setting of any climate-related targets or goals?

38. Should we require a registrant to describe, as applicable, management's role in assessing and managing climate-related risks, as proposed? Should the required disclosure include whether certain management positions or committees are responsible for assessing and managing climate-related risks and, if so, the identity of such positions or committees, and the relevant expertise of the position holders or members in such detail as necessary to fully describe the nature of the expertise, as proposed? Should we require a registrant to identify the executive officer(s) occupying such position(s)? Or do our current rules, which require a registrant to provide the business experience of its executive officers, elicit adequate disclosure about management's expertise relevant to the oversight of climate-related risks?

39. Should we require a registrant to describe the processes by which the management positions or committees responsible for climate-related risks are

[281] *See* proposed 17 CFR 229.1501(a)(1)(v).

[282] *See* proposed 17 CFR 229.1501(b)(1)(i).

[283] *See* proposed 17 CFR 229.1501(b)(1)(ii).

[284] *See* proposed 17 CFR 229.1501(b)(1)(iii).

[285] *See, e.g.,* letters from Baillie Gifford; Andrew Behar; CDP; Climate Governance Initiative; E3G (June 14, 2021); Interfaith Center on Corporate Responsibility; Majedie Asset Management; NEI Investments; NY State Comptroller; PRI (Consultation Response); RMI (June 11, 2021); Maria Stoica; and Value Balancing Alliance.

[286] *See* letter from Richard Love.

[287] *See* letter from Western Energy Alliance (June 12, 2021).

[288] *See* 17 CFR 229.402(b) (requiring disclosure of all material elements of a registrant's executive compensation, including the objectives of the registrant's compensation programs and what each compensation program is designed to reward). Further, the Commission recently decided to reopen the comment period on rules to implement section 953(a) of the Dodd-Frank Act, which requires disclosure of the relationship between executive compensation and the performance of the issuer. *See* Release No. 34–94074, *Reopening of Comment Period for Pay Versus Performance* (Jan. 27, 2021).

informed about and monitor climate-related risks, as proposed? Should we also require a registrant to disclose whether and how frequently such positions or committees report to the board or a committee of the board on climate-related risks, as proposed?

40. Should we specifically require a registrant to disclose any connection between executive remuneration and the achievement of climate-related targets and goals? Is there a need for such a requirement in addition to the executive compensation disclosure required by 17 CFR 229.402(b)?

41. As proposed, a registrant may disclose the board's oversight of, and management's role in assessing and managing, climate-related opportunities. Should we require a registrant to disclose these items?

E. Risk Management Disclosure

1. Disclosure of Processes for Identifying, Assessing, and Managing Climate-Related Risks

The proposed rules would require a registrant to describe any processes the registrant has for identifying, assessing, and managing climate-related risks.[289] Risk disclosure is a long-standing disclosure concept under our regulations.[290] Several commenters recommended that we adopt decision-useful disclosure requirements concerning a registrant's climate-related risk management practices.[291] More granular information regarding any climate-related risk management could allow investors to better understand how a registrant identifies, evaluates, and addresses climate-related risks that may materially impact its business. Such information could also permit investors to ascertain whether a registrant has made the assessment of climate-related risks part of its regular risk management processes. Despite the importance of climate-related risk management information, only a minority of registrants currently include such information in their voluntary climate reports.[292]

When describing the processes for identifying and assessing climate-related risks, the registrant would be required to disclose, as applicable:

- How it determines the relative significance of climate-related risks compared to other risks;
- How it considers existing or likely regulatory requirements or policies, such as GHG emissions limits, when identifying climate-related risks;
- How it considers shifts in customer or counterparty preferences, technological changes, or changes in market prices in assessing potential transition risks; and
- How it determines the materiality of climate-related risks, including how it assesses the potential size and scope of any identified climate-related risk.[293]

When describing any processes for managing climate-related risks, a registrant would be required to disclose, as applicable:

- How it decides whether to mitigate, accept, or adapt to a particular risk;
- How it prioritizes addressing climate-related risks; and
- How it determines how to mitigate a high priority risk.[294]

Together, these proposed disclosures would help investors evaluate whether a registrant has implemented adequate processes for identifying, assessing, and managing climate-related risks so that they may make better informed investment or voting decisions. As part of this risk management description, if a registrant uses insurance or other financial products to manage its exposure to climate-related risks, it may need to describe its use of these products.[295]

The proposed rules would also require a registrant to disclose whether and how climate-related risks are integrated into the registrant's overall risk management system or processes.[296] If a separate board or management committee is responsible for assessing and managing climate-related risks, a registrant would be required to disclose how that committee interacts with the registrant's board or management committee governing risks.[297] These proposed disclosures would help investors assess whether the registrant has centralized the processes for managing climate-related risks, which may indicate to investors how the board and management may respond to such risks as they unfold.

2. Transition Plan Disclosure

Adoption of a transition plan to mitigate or adapt to climate-related risks may be an important part of a registrant's climate-related risk management strategy, particularly if it operates in a jurisdiction that has made commitments under the Paris Agreement to reduce its GHG emissions. Many commenters recommended that we require disclosure regarding a registrant's transition plan, stating that such disclosure would help investors evaluate whether a registrant has an effective strategy to achieve its short-, medium-, or long-term climate-related targets or goals.[298]

The proposed rules would define a ''transition plan'' to mean a registrant's strategy and implementation plan to reduce climate-related risks.[299] A transition plan may include a plan to reduce its GHG emissions in line with a registrant's commitments or commitments of jurisdictions within which it has significant operations.[300] Transition plans may also be important to registrants and their shareholders to the extent transition risk arises from changes in customer or business counterparty preferences, technological change, or changes in market prices. If a registrant has adopted a transition plan, the proposed rules would require it to describe its plan, including the relevant metrics and targets used to identify and manage physical and transition risks.[301] This information could help investors understand how a registrant intends to address identified climate-related risks and any transition to a lower carbon economy while managing and assessing its business operations and financial condition.

[289] *See* proposed 17 CFR 229.1503(a).

[290] Risk factor disclosure has been part of the Commission's Securities Act disclosure requirements since prior to and from adoption of its integrated disclosure system. *See* Release No. 33–6383, *Adoption of Integrated Disclosure System* (Mar. 3, 1982). The Commission added risk factor disclosure to its Exchange Act registration and annual reporting requirements in 2005. *See* Release No. 33–8591, *Securities Offering Reform* (July 19, 2005) [70 FR 44722 (Aug. 3, 2005)].

[291] *See, e.g.,* letters from Rob Bonta, California Attorney General *et al.;* Boston Common Asset Management; Carbon Tracker Initiative; Confluence Philanthropy; Hermes Equity Ownership Services Ltd.; The Institute for Policy Integrity (''Policy Integrity'') at New York University School of Law, Environmental Defense Fund (''EDF''), the Initiative on Climate Risk and Resilience Law (''ICRRL''), and Professors Madison Condon, Jim Rossi, and Michael Vandenbergh (June 14, 2021) (''Institute for Policy Integrity, Environmental Defense Fund, Initiative on Climate Risk & Resilience Law''); and Total Energies.

[292] *See* TCFD, *2021 Status Report,* Section B (indicating that, during 2018–2020, 16–30% of surveyed public companies disclosed their climate risk identification and assessment processes, 14–29% disclosed their risk management processes, and 10–27% disclosed whether their climate risk management processes were integrated into their overall risk management).

[293] *See* proposed 17 CFR 229.1503(a)(1).

[294] *See* proposed 17 CFR 229.1503(a)(2).

[295] To the extent loss of insurance coverage or increases in premiums is reasonably likely to have a material impact on the registrant, the registrant would be required to disclose that risk pursuant to proposed Item 1502(a).

[296] *See* proposed 17 CFR 229.1503(b).

[297] *See id.*

[298] *See, e.g.,* letters from As You Sow; BlackRock; Clean Yield Asset Management; Climate Advisers; Climate Governance Initiative; Fiends of the Earth *et al.*; Institute for Governance and Sustainable Development; Miller/Howard Investments; Trillium Asset Management; and World Benchmarking Alliance.

[299] *See* proposed 17 CFR 229.1500(s).

[300] *See id.*

[301] *See* proposed 17 CFR 229.1503(c)(1).

Because transition planning inherently requires judgments and predictions about the future, forward-looking statements made as part of a registrant's discussion of its transition plan would be eligible for the PSLRA forward-looking statement safe harbors provided all applicable conditions are met.[302]

If a registrant has adopted a transition plan as part of its climate-related risk management strategy, the proposed rules would require the registrant to discuss, as applicable, how it plans to mitigate or adapt to any physical risks identified in the filing, including but not limited to those concerning exposure to sea level rise, extreme weather events, wildfires, drought, and severe heat.[303] For example, a company with significant operations in areas vulnerable to sea level rise might plan to relocate its vulnerable operations as part of any transition plan. A company operating in areas subject to severe storms might have a transition plan that includes reinforcing its physical facilities to better withstand such weather events, or a plan to relocate those facilities. An agricultural producer that operates in areas subject to increasing water stress might discuss its plans to adjust its business strategy or operations, for example by developing or switching to drought-resistant crops, developing technologies to optimize the use of available water, or acquiring land in other areas.[304]

The proposed rules would also require a registrant that has adopted a transition plan as part of its climate-related risk management strategy to discuss, as applicable, how it plans to mitigate or adapt to any identified transition risks, including the following:

- Laws, regulations, or policies that:
  - Restrict GHG emissions or products with high GHG footprints, including emissions caps; [305] or
  - Require the protection of high conservation value land or natural assets; [306]
- Imposition of a carbon price; [307] and
- Changing demands or preferences of consumers, investors, employees, and business counterparties.[308]

While each of these transition risks may not be applicable to each registrant and its particular transition plan, the above examples are intended to guide registrants in providing meaningful disclosure about its risk management strategies that is not generic or boilerplate. In this regard, it is important for investors to understand how a registrant plans to mitigate or adapt to any identified transition risks in its transition plan given the potential associated costs and burdens and their impact on the registrant's business.

The proposed rules would require a registrant that has adopted a transition plan as part of its climate-related management strategy to update its disclosure about its transition plan each fiscal year by describing the actions taken during the year to achieve the plan's targets or goals.[309] This is intended to provide investors with information that can help them better understand the registrant's effectiveness in implementing any transition plan and the potential risks and costs associated with what it still needs to accomplish.

A registrant that has adopted a transition plan as part of its climate-related risk management strategy may also describe how it plans to achieve any identified climate-related opportunities, such as:

- The production of products that facilitate the transition to a lower carbon economy, such as low emission modes of transportation and supporting infrastructure;
- The generation or use of renewable power;
- The production or use of low waste, recycled, or other consumer products that require less carbon intensive production methods;
- The setting of conservation goals and targets that would help reduce GHG emissions; and
- The provision of goods or services related to any transition to a lower carbon economy.[310]

For example, an energy company might discuss how, due to actual or potential regulatory constraints, it intends to take advantage of climate-related opportunities by increasing the amount of electricity purchased that is produced using renewable energy sources, reducing its medium and long-range fossil fuel exploration and production, increasing the percentage of its products consisting of biofuels and other lower emissions fuels, or investing in carbon capture and storage technologies. A transportation company might discuss how, to mitigate reputational risk, it plans to realize any climate-related opportunities presented by switching its existing fleet to one composed of low- or no-emission vehicles by a certain date.[311]

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42. Should we require a registrant to describe its processes for identifying, assessing, and managing climate-related risks, as proposed?

43. When describing the processes for identifying and assessing climate-related risks, should we require a registrant to disclose, as applicable, as proposed:

- How the registrant determines the relative significance of climate-related risks compared to other risks?
- How it considers existing or likely regulatory requirements or policies, such as emissions limits, when identifying climate-related risks?
- How it considers shifts in customer or counterparty preferences, technological changes, or changes in market prices in assessing potential transition risks?
- How the registrant determines the materiality of climate-related risks, including how it assesses the potential size and scope of an identified climate-related risk? Are there other items relevant to a registrant's identification and assessment of climate-related risks that we should require it to disclose instead of or in addition to the proposed disclosure items?

44. When describing the processes for managing climate-related risks, should we require a registrant to disclose, as applicable, as proposed:

- How it decides whether to mitigate, accept, or adapt to a particular risk?
- How it prioritizes climate-related risks?
- How it determines to mitigate a high priority risk?

Are there other items relevant to a registrant's management of climate-related risks that we should require it to disclose instead of or in addition to the proposed disclosure items?

45. Should we require a registrant to disclose whether and how the processes described in response to proposed 17 CFR 229.1503(a) are integrated into the registrant's overall risk management system or processes, as proposed? Should we specify any particular aspect of this arrangement that a registrant

[302] *See supra* note 219.

[303] *See* proposed 17 CFR 229.1503(c)(2)(i).

[304] A registrant would be required to disclose the expected impact of any potential reduction on its results of operations or financial condition pursuant to proposed 17 CFR 229.1502 to the extent it believes the likely impact would be material. Such quantified disclosure may be eligible for the PSLRA safe harbors if the conditions of the safe harbors are met.

[305] *See* proposed 17 CFR 229.1503(c)(2)(ii)(A)(*1*).

[306] *See* proposed 17 CFR 229.1503(c)(2)(ii)(A)(*2*).

[307] *See* proposed 17 CFR 229.1503(c)(2)(ii)(B).

[308] *See* proposed 17 CFR 229.1503(c)(2)(ii)(C).

[309] *See* proposed 17 CFR 229.1503(c)(1).

[310] *See* proposed 17 CFR 229.1503(c)(3)(i) through (v).

[311] A registrant would be required to disclose the expected impact of any transition opportunity on its results of operations or financial condition, *e.g.,* increased costs or expenditures, pursuant to proposed 17 CFR 229.1502 to the extent it believes they would be reasonably likely to have a material impact.

should disclose, such as any interaction between, and corresponding roles of, the board or any management committee responsible for assessing climate-related risks, if there is a separate and distinct committee of the board or management, and the registrant's committee in charge, generally, of risk assessment and management?

46. If a registrant has adopted a transition plan, should we require the registrant to describe the plan, including the relevant metrics and targets used to identify and manage physical and transition risks, as proposed? Would this proposed disclosure requirement raise any competitive harm concerns and, if so, how can we mitigate such concerns? Would any of the proposed disclosure requirements for a registrant's transition plan act as a disincentive to the adoption of such a plan by the registrant?

47. If a registrant has adopted a transition plan, should we require it, when describing the plan, to disclose, as applicable, how the registrant plans to mitigate or adapt to any identified physical risks, including but not limited to those concerning energy, land, or water use and management, as proposed? Are there any other aspects or considerations related to the mitigation or adaption to physical risks that we should specifically require to be disclosed in the description of a registrant's transition plan?

48. If a registrant has adopted a transition plan, should we require it to disclose, if applicable, how it plans to mitigate or adapt to any identified transition risks, including the following, as proposed:

- Laws, regulations, or policies that:
  - Restrict GHG emissions or products with high GHG footprints, including emissions caps; or
  - Require the protection of high conservation value land or natural assets?
- Imposition of a carbon price?
- Changing demands or preferences of consumers, investors, employees, and business counterparts?

Are there any other transition risks that we should specifically identify for disclosure, if applicable, in the transition plan description? Are there any identified transition risks that we should exclude from the plan description?

49. If a registrant has adopted a transition plan, when describing the plan, should we permit the registrant also to discuss how it plans to achieve any identified climate-related opportunities, including, as proposed:

- The production of products that facilitate the transition to a lower carbon economy, such as low emission modes of transportation and supporting infrastructure?
- The generation or use of renewable power?
- The production or use of low waste, recycled, or environmentally friendly consumer products that require less carbon intensive production methods?
- The setting of conservation goals and targets that would help reduce GHG emissions?
- The provision of services related to any transition to a lower carbon economy?

Should we require a registrant to discuss how it plans to achieve any of the above, or any other, climate-related opportunities when describing its transition plan?

50. If a registrant has disclosed its transition plan in a Commission filing, should we require it to update its transition plan disclosure each fiscal year by describing the actions taken during the year to achieve the plan's targets or goals, as proposed? Should we require a registrant to provide such an update more frequently, and if so, how frequently? Would the proposed updating requirement act as a disincentive to the adoption of a transition plan by the registrant?

51. To the extent that disclosure about a registrant's transition plan constitutes forward-looking information, the PSLRA safe harbors would apply. Should we adopt a separate safe harbor for transition plan disclosure? If so, what disclosures should such a safe harbor cover and what should the conditions be for such a safe harbor?

F. Financial Statement Metrics

1. Overview

If a registrant is required to file the disclosure required by subpart 229.1500 in a form that also requires audited financial statements,[312] under our proposal it would be required to disclose in a note to its financial statements certain disaggregated climate-related financial statement metrics that are mainly derived from existing financial statement line items.[313] In particular, the proposed rules would require disclosure falling under the following three categories of information:

- Financial Impact Metrics;
- Expenditure Metrics; and
- Financial Estimates and Assumptions.

The proposed financial statement metrics disclosures would involve estimation uncertainties that are driven by the application of judgments and assumptions, similar to other financial statement disclosures (*e.g.,* estimated loss contingencies, fair value measurement of certain assets, etc.). Accordingly, for each type of financial statement metric, the proposed rules would require the registrant to disclose contextual information to enable a reader to understand how it derived the metric, including a description of significant inputs and assumptions used, and if applicable, policy decisions made by the registrant to calculate the specified metrics.[314]

A number of existing accounting standards could elicit climate-related disclosure in the financial statements, as highlighted by the FASB in a Staff Educational Paper and by the IFRS in a similar document.[315] Nevertheless, we believe the proposed rules would benefit registrants by specifying when to provide such disclosures. Furthermore, the proposed rules may increase the consistency and comparability of such disclosures by prescribing accounting principles for preparing the proposed climate-related financial statement metrics disclosures, including, among other things, provisions that would specify the basis of calculation for such metrics and their presentation.[316]

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[312] For example, the climate-related note to the financial statements would not be required in a Form 10–Q filing. *See* proposed 17 CFR 210.14–01(a). *See infra* note 690 and accompanying text, which discusses the applicability of the proposed rules to foreign private issuers.

[313] *See* FASB Concepts Statement No. 8, Chapter 8, par. D8 (''[T]he primary purpose of notes to financial statements is to supplement or further explain the information on the face of financial statements by providing financial information relevant to existing and potential investors, lenders, and other creditors for making decisions about providing resources to an entity.'').

[314] *See* proposed 17 CFR 210.14–02(a). Inputs and assumptions may include the estimation methodology used to disaggregate the amount of impact on the financial statements between the climate-related events and activities and other factors. Policy decisions referenced herein may include a registrant's election to disclose the impacts from climate-related opportunities. *See also infra* Section II.F.2 for an example of contextual information that would be required.

[315] *See* FASB Staff Educational Paper, Intersection of Environmental, Social, and Governance Matters with Financial Accounting Standards (Mar. 2021), available at *https://fasb.org/jsp/FASB/Document_C/DocumentPage&cid=1176176379917. See also* IFRS, Effects of climate-related matters on financial statements (Nov. 2020), available at *https://www.ifrs.org/content/dam/ifrs/supporting-implementation/documents/effects-of-climate-related-matters-on-financial-statements.pdf#:~:text=IFRS%20Standards%20do%20not%20refer%explicitly%20to%20climate-related,significant%20judgements%20and%20estimates%20that%20%20has%20made.*

[316] The Commission has broad authority to set accounting standards and principles. *See, e.g.,* 15 U.S.C. 77s; 15 U.S.C. 7218(c); and *Policy Statement: Reaffirming the Status of the FASB as a Designated Private-Sector Standard Setter,* Release No. 33–8221

Continued

To avoid potential confusion, maintain consistency with the rest of the financial statements, and aid comparability, registrants would be required to calculate the proposed financial statement metrics using financial information that is consistent with the scope of the rest of the registrant's consolidated financial statements included in the filing.[317] Therefore, registrants would have to include in any such calculation financial information from consolidated subsidiaries.[318]

For the avoidance of doubt, and to further promote consistency in the preparation of the financial statements, the proposed basis of calculation requirements would also specify that a registrant would be required to apply the same set of accounting principles that it is required to apply in preparation of the rest of its consolidated financial statements included in the filing, whenever applicable.[319] Although 17 CFR 210.4–01(a)(1) already states that financial statements filed with the Commission that are not prepared in accordance with GAAP will be presumed misleading or inaccurate unless the Commission has otherwise provided, clarifying the application of this concept in the proposed rules may be helpful, given the possible confusion that may arise between the current body of GAAP and the proposed requirements.[320]

The proposed rules would also require disclosure to be provided for the registrant's most recently completed fiscal year and for the historical fiscal year(s) included in the registrant's consolidated financial statements in the applicable filing.[321] For example, a registrant that is required to include balance sheets as of the end of its two most recent fiscal years and income statements and cash flow statements at the end of its three most recent fiscal years would be required to disclose two years of the climate-related financial statement metrics that correspond to balance sheet line items and three years of the climate-related financial statement metrics that correspond to income statement or cash flow statement line items. If the registrant is an emerging growth company (''EGC'') [322] or SRC, only two years would be required.[323]

A registrant, however, would not need to provide a corresponding historical metric for a fiscal year preceding its current reporting fiscal year if it is eligible to take advantage of the accommodation in 17 CFR 230.409 (''Rule 409'') or 17 CFR 240.12b–21 (''Rule 12b–21''). For example, if a registrant has not previously presented such metric for such fiscal year and the historical information necessary to calculate or estimate such metric is not reasonably available to the registrant without unreasonable effort or expense, the registrant may be able to rely on Rule 409 or Rule 12b–21 to exclude a corresponding historical metric. Requiring disclosure of current and, when known or reasonably available, historical periods, should allow investors to analyze trends in the climate-related impacts on the consolidated financial statements and to better evaluate the narrative trend disclosure provided pursuant to proposed Subpart 1500 of Regulation S–K.[324]

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52. Should we require a registrant to provide contextual information, including a description of significant inputs and assumptions used, and if applicable, policy decisions made by the registrant to calculate the specified metrics, as proposed? Should we revise the proposed requirement to provide contextual information to require specific information instead? We provide some examples of contextual information disclosure in Sections II.F.2 and II.F.3 below. Would providing additional examples or guidance assist registrants in preparing this disclosure?

53. The proposed rules would specify the basis of calculation for the climate-related financial statement metrics. Is it clear how to apply these accounting principles when calculating the proposed climate-related financial statement metrics, or should we provide additional guidance? Should we require a registrant to report these metrics with reference to its consolidated financial statements, as proposed? If not, how should registrants report these metrics? If we were to establish accounting principles (*e.g.,* the basis for reporting these metrics) in a manner that differs from the principles applicable to the rest of the consolidated financial statements, would the application of those principles to the proposed metrics make climate-related disclosures less clear, helpful, or comparable for investors?

54. Should we also require such metrics to be calculated at a reportable segment level when a registrant has more than one reportable segment (as defined by the FASB ASC Topic 280 *Segment Reporting*)? In addition, should we require such metrics to be presented by geographic areas that are consistent with the registrant's reporting pursuant to FASB ASC Topic 280–10–50–41? How would investors use such information?

55. The proposed rules would require disclosure for the registrant's most recently completed fiscal year and for the corresponding historical fiscal years included in the registrant's consolidated financial statements in the filing. Should disclosure of the climate-related financial statement metrics be required for the fiscal years presented in the registrant's financial statements, as proposed? Instead, should we require the financial statement metrics to be calculated only for the most recently

(Apr. 25, 2003) [68 FR 23333 (May 1, 2003)], at 23334 (''While the Commission consistently has looked to the private sector in the past to set accounting standards, the securities laws, including the Sarbanes-Oxley Act, clearly provide the Commission with authority to set accounting standards for public companies and other entities that file financial statements with the Commission.''). *See also* FASB Accounting Standards Codification (''FASB ASC'') Topic 105–10–10–1 (''Rules and interpretive releases of the Securities and Exchange Commission . . . are also sources of authoritative GAAP for SEC registrants.'').

[317] *See* proposed 17 CFR 210.14–01(c)(1).

[318] *See, e.g.,* 17 CFR 210.3–01(a) (''There shall be filed, for the registrant and its subsidiaries consolidated, audited balance sheets as of the end of each of the two most recent fiscal years.'').

[319] *See* proposed 17 CFR 210.14–01(c)(2). Foreign private issuers that file consolidated financial statements under home country GAAP and reconcile to U.S. GAAP, would be required to use U.S. GAAP (including the provisions of the proposed rules) as the basis for calculating and disclosing the proposed climate-related financial statement metrics. Foreign private issuers that file consolidated financial statements under IFRS as issued by the IASB, would apply IFRS and the proposed rules as the basis for calculating and disclosing the proposed climate-related financial statement metrics. For simplicity, we do not refer to the corresponding IFRS in each instance where we refer to a FASB ASC. Accordingly, references in this release to a FASB ASC should be read to also refer to the corresponding IFRS for foreign private issuers applying those standards. *See also infra* note 690 which discusses proposed amendments to Form 20–F.

[320] *See also* 17 CFR 210.4–01(a)(2) (discussing the application of U.S. GAAP, IFRS, and the use of other comprehensive sets of accounting principles (with reconciliation to U.S. GAAP)).

[321] *See* proposed 17 CFR 210.14–01(d).

[322] An EGC is a registrant that had total annual gross revenues of less than $1.07 billion during its most recently completed fiscal year and has not met the specified conditions for no longer being considered an EGC. *See* 17 CFR 230.405; 17 CFR 240.12b–2; 15 U.S.C. 77b(a)(19); 15 U.S.C. 78c(a)(80); and *Inflation Adjustments and Other Technical Amendments under Titles I and III of the JOBS Act,* Release No. 33–10332 (Mar. 31, 2017) [82 FR 17545 (Apr. 12, 2017)].

[323] An EGC is only required to provide audited statements of comprehensive income and cash flows for each of the two fiscal years preceding the date of the most recent audited balance sheet (or such shorter period as the registrant has been in existence). *See* 17 CFR 210.3–02(a). A similar accommodation is provided to SRCs. *See* 17 CFR 210.8–02.

[324] *See supra* Section II.C.

completed fiscal year presented in the relevant filing? Would requiring historical disclosure provide important or material information to investors, such as information allowing them to analyze trends? Are there other approaches we should consider?

56. Should information for all periods in the consolidated financial statements be required for registrants that are filing an initial registration statement or providing climate-related financial statement metrics disclosure for historical periods prior to the effective date or compliance date of the rules? Would the existing accommodation in Rules 409 and 12b–21 be sufficient to address any potential difficulties in providing the proposed disclosures in such situations?

57. Should we provide additional guidance as to when a registrant may exclude a historical metric for a fiscal year preceding the current fiscal year?

58. In several instances, the proposed rules specifically point to existing GAAP and, in this release, we provide guidance with respect to the application of existing GAAP. Are there other existing GAAP requirements that we should reference? Are there instances where it would be preferable to require an approach based on TCFD guidance or some other framework, rather than requiring the application of existing GAAP?

2. Financial Impact Metrics

As discussed above, proposed Item 1502(d) of Regulation S–K would require a registrant to provide a narrative discussion of whether and how any of its identified climate-related risks have affected or are reasonably likely to affect the registrant's consolidated financial statements.[325] The term ''climate-related risks'' would be defined, in part, as the actual or potential negative impacts of climate-related conditions and events on a registrant's consolidated financial statements.[326] ''Climate-related risks'' would also be defined to include physical risks, such as extreme weather events, and transition risks.[327] To complement this proposed requirement in Regulation S–K to provide narrative disclosure about impacts on a registrant's consolidated financial statements, we are proposing to amend Regulation S–X to require a registrant to include disaggregated information about the impact of climate-related conditions and events, and transition activities, on the consolidated financial statements included in the relevant filing,[328] unless such impact is below a specified threshold.

We are proposing to require disclosure of the impacts from severe weather events and other natural conditions and transition activities, which should capture a broad spectrum of these two types of climate-related risks (physical risks and transition risks). In addition, the proposed rules would require disclosure of the impacts of any climate-related risks identified pursuant to proposed Item 1502(a)—both physical risks (''identified physical risks'') and transition risks (''identified transition risks'')—on any of the financial statement metrics.[329] Among the examples of severe weather events and other natural conditions that we have highlighted in the proposed rule are those that the Commission identified more than a decade ago in the 2010 Guidance as potentially affecting a registrant's operations and results.[330] In addition, although not specifically mentioned in the 2010 Guidance, we are including wildfires as an example because it is well recognized as another type of natural event that can have significant impacts on a registrant's financial statements.[331] Providing examples of severe weather events, other natural conditions, and transition activities in the proposed rule would aid in the comparability of the resulting disclosure while assisting issuers in making the disclosures.

Specifically, we are proposing that impacts on any relevant line item in the registrant's consolidated financial statements during the fiscal years presented arising from severe weather events and natural conditions, and the identified physical risks (collectively, ''climate-related events''), would trigger the proposed disclosure requirement discussed below. Specific examples of such severe weather events and natural conditions may include the following:

- Flooding;
- Drought;
- Wildfires;
- Extreme temperatures; and
- Sea level rise.[332]

As discussed, above, there has been increased recognition of the current and potential effects, both positive and negative, of these events and the associated physical risks on a registrant's business as well as its financial performance and position. For example, as mentioned above, the 2010 Guidance discusses the potential impacts on a registrant's business and financial performance from climate-related events, including, for example, severe weather events, that could negatively impact a registrant's supply chain or distribution chain and lead to higher input costs or delayed product deliveries.[333] The 2010 Guidance also points to credit risks for banks driven by borrowers with assets located in high risk coastal areas.[334] More recently, the FSOC's Report on Climate-Related Financial Risk 2021 discusses significant costs from the types of events included in proposed Rule 14–02(c).[335] The TCFD, in a recent publication, also discusses the potential financial impacts of such climate-related events.[336] Furthermore, the TCFD provides examples of disclosures already being made by some companies (including registrants) of the financial statement impact of the climate-related events discussed above in their standalone sustainability (or equivalent) reports.[337]

Generally, climate-related events such as severe weather events and other natural conditions, and climate-related risks more generally, are linked to negative impacts on a registrant's financial performance and position.

[325] *See* proposed 17 CFR 229.1502(d).

[326] *See supra* Section II.B.1 (discussing the definition of ''climate-related risks'').

[327] *See* proposed 17 CFR 229.1500(c) (defining ''climate related risks'' to include ''physical risks'' and ''transition risks'').

[328] For example, the impact on the income statement line items for the periods presented in the financial statements in a registrant's Form 10–K.

[329] *See* proposed 17 CFR 210.14–02(i).

[330] *See, e.g.,* 2010 Guidance, 26 (''Significant physical effects of climate change, such as effects on the severity of weather (for example, floods or hurricanes), [and] sea levels . . . have the potential to affect a registrant's operations and results.''). Temperature extremes and drought are also discussed in the 2010 Guidance. *See, e.g., id.* at 6–7.

[331] *See, e.g.,* Aurora A. Gutierrez et al., *Wildfire response to changing daily temperature extremes in California's Sierra Nevada,* Science Advances, Vol. 7, Issue 47 (Nov. 17, 2021) (''Our work supports the conclusion that considerable potential exists for an increase in fire activity as a consequence of climate warming in the absence of changes in fire and ecosystem management.''); U.S. Geological Survey, *Will global warming produce more frequent and more intense wildfires?* (''[R]esearchers have found strong correlations between warm summer temperatures and large fire years, so there is general consensus that fire occurrence will increase with climate change.''), available at *https://www.usgs.gov/faqs/will-global-warming-produce-more-frequent-and-more-intense-wildfires.*

[332] *See* proposed 17 CFR 210.14–02(c).

[333] *See* 2010 Guidance, 6.

[334] *See id.*

[335] *See, e.g.,* 2021 FSOC Report, Chapter 1: *From Climate-related Physical Risks to Financial Risks* (discussing the listed events and other risks).

[336] TCFD, Implementing the Recommendations of the Task Force on Climate-related Financial Disclosures (Oct. 2021), Section A.4 *Assessing Financial Impacts of Climate-Related Risks and Opportunities.*

[337] *See, e.g.,* TCFD, Guidance on Metrics, Targets, and Transition Plans (Oct. 2021), 23 (Figure C6), Appendix 2, available at *https://assets.bbhub.io/company/sites/60/2021/07/2021-Metrics_Targets_Guidance-1.pdf* (providing examples, mostly from sustainability (or equivalent) reports, that illustrate the feasibility of some of the disclosures that would be required by the proposed rules).

There could be situations, however, where such events result in positive impacts. For example, if a registrant's business is to conduct post-disaster cleanup and reconstruction, the occurrence of such severe weather events would generate additional revenues for the registrant.

In addition to the physical risks associated with climate change, registrants and investors also face climate-related transition risks. As government leaders across the globe have made public commitments to transition to a lower carbon economy, investors have sought information about the impact such a transition may have on registrants.[338] In addition to public commitments, these impacts may be prompted by regulatory, technological, market (including changing consumer, business counterparty, and investor preferences), liability, reputational, or other transition-related factors.[339] For example, significant shifts in modes of production may occur in GHG intensive economic sectors, such as the transportation, electricity generation, and heavy manufacturing sectors.[340] A registrant that is engaged in transition activities may experience business losses or, conversely, may benefit from such transition activities.[341] In response, some companies are already providing disclosure of the impact of transition-related activities on their financial statements and some have publicly made commitments related to this transition.[342] In light of these transition risks, the proposed rules would also require a registrant to disclose the financial impact of the impact of any identified transition risks and any efforts to reduce GHG emissions or otherwise mitigate exposure to transition risks (collectively, ''transition activities'') on any relevant line items in the registrant's consolidated financial statements during the fiscal years presented.[343]

A registrant may also disclose the impact of any opportunities arising from severe weather events and other natural conditions, any impact of efforts to pursue climate-related opportunities associated with transition activities, and the impact of any other climate-related opportunities, including those identified by the registrant pursuant to proposed Item 1502(a), on any of the financial statement metrics.[344] If a registrant makes a policy decision to disclose the impact of a climate-related opportunity on the proposed financial statement metrics, it must do so consistently (*e.g.,* for each fiscal year presented in the consolidated financial statements, for each financial statement line item, for all relevant opportunities identified by the registrant) and must follow the same presentation and disclosure threshold requirements applicable to the required disclosures related to financial impact metrics and expenditure metrics, as discussed below.[345]

The financial impact metric disclosure requirements in proposed Rules 14–02(c), (d), and (i) would require a registrant to disclose the financial impacts of severe weather events, other natural conditions, transition activities, and identified climate-related risks on the consolidated financial statements included in the relevant filing unless the aggregated impact of the severe weather events, other natural conditions, transition activities, and identified climate-related risks is less than one percent of the total line item for the relevant fiscal year.[346] The proposed threshold would provide a bright-line standard for registrants and should reduce the risk of underreporting such information. The proposed quantitative threshold could also promote comparability and consistency among a registrant's filings over time and among different registrants compared to a principles-based approach. The Commission has used similar one percent thresholds in other contexts.[347] More generally, in addition to the approach in Article 5 of Regulation S–X discussed below, other rules such as 17 CFR 229.103 and 17 CFR 229.404 use quantitative disclosure thresholds to facilitate comparability, consistency, and clarity in determining when information must be disclosed.[348]

A registrant would be required to determine the impacts of the severe weather events, other natural conditions, transition activities, and identified climate-related risks described above on each consolidated financial statement line item.[349] Within each category (*i.e.,* climate-related events or transition activities), impacts would, at a minimum, be required to be disclosed on an aggregated, line-by-line basis for all negative impacts and, separately, on an aggregated, line-by-line basis for all positive impacts.[350] However, for purposes of determining whether the disclosure threshold has been met, a registrant would be required to aggregate the absolute value of the positive and negative impacts on a line-by-line basis, which we believe would better reflect the significance of the impact of the climate-related events and transition activities on a registrant's financial performance and position.[351]

For example, when evaluating the line-by-line impact, a registrant may determine that its cost of revenue is impacted by Events A, B, and C, and Transition Activity D in the following manner:

- Cost of revenue was impacted negatively by Events A and B by $300,000, driven by increased input costs impacted by severe weather events that strained the registrant's main supplier;
- Cost of revenue was impacted positively by Event C by $70,000, driven by technology that improved the registrant's ability to manage the impact of severe heat on certain raw materials, which resulted in more efficient production; and
- Cost of revenue was impacted positively by Transition Activity D, which reduced production costs for certain products by $90,000 through advanced technology that improved energy efficiency during the production process.[352]

[338] *See supra* Section I.C.1.

[339] *See supra* Section II.B.

[340] *See, e.g.,* 2021 FSOC Report, Chapter 1, *From Climate-related Transition Risks to Financial Risks.*

[341] *See id.*

[342] *See, e.g.,* TCFD, Guidance on Metrics, Targets, and Transition Plans (Oct. 2021), Appendix 2.

[343] *See* proposed 17 CFR 210.14–02(d).

[344] *See* proposed 17 CFR 210.14–02(j).

[345] *See id.*

[346] *See* proposed 17 CFR 210.14–02(b). The registrant would be required to evaluate the impact on a line-by-line basis consistent with the line items presented in its consolidated financial statements. *See* proposed 17 CFR 210.14–02(c) and (d).

[347] The Commission currently uses a 1% threshold in other contexts for disclosure of certain items within the financial statements and without. *See, e.g.,* 17 CFR 210.5–03.1(a) (stating that if the total of sales and revenues reported under this caption includes excise taxes in an amount equal to 1% or more of such total, the amount of such excise taxes shall be shown on the face of the statement parenthetically or otherwise); 17 CFR 210.12–13 (requiring disclosure of open option contracts by management investment companies using a 1% of net asset value threshold, based on the notional amounts of the contracts); and 17 CFR 229.404(d) (requiring disclosure of transactions between a SRC and related persons in which the amount involved exceeds the lesser of $120,000 or 1% of the average of the SRC's total assets at year-end for the last two completed fiscal years).

[348] *See* 17 CFR 229.103(b)(2), (c)(3)(iii) and 17 CFR 229.404(a).

[349] Examples of such line items include revenue, cost of revenue, selling, general and administrative expenses, sale of property, plant, and equipment (in statement of cash flows), inventories, intangible assets, long-term debt, or contingent liabilities.

[350] *See* proposed 17 CFR 210.14–02(c) and (d).

[351] *See* proposed 17 CFR 210.14–02(b).

[352] This example illustrates a situation where the registrant has elected to include impacts from transition opportunities.

For purposes of determining whether the impacts from the example above would trigger the disclosure threshold requirements, the registrant would perform the analysis illustrated in the following table:

F/S line-item	F/S balance (from consolidated financial statements)	Impact of events A and B	Impact of event C	Impact of transition activity D	Absolute value of impacts	Percentage impact
Cost of revenue	$10,000,000	−$300,000	+$70,000	+$90,000	$460,000	4.6%

Although some of the impacts (*e.g.,* impact of Event C, impact of Transition Activity D) do not individually meet the one percent threshold, the absolute value of the aggregated impacts from the events and transition activities on the line item in the above example is $460,000 and thus exceeds one percent of the corresponding line-item threshold; therefore, disclosure for that specific line item would be required. The registrant's disclosure of such impacts may be provided, for example, as illustrated in the following table (excluding disclosure of contextual information):

Note X. Climate-related financial metrics:

F/S line-item	Total negative impact from climate-related events	Total positive impact from climate-related events	Total negative impact from climate-related transition activities	Total positive impact from climate-related transition activities and climate-related opportunities *
Cost of revenue	(Debit) $300,000	(Credit) $70,000		(Credit) $90,000

* As discussed earlier, a registrant may elect to include the impact of climate-related opportunities when calculating its climate-related financial impact metrics. This example illustrates a situation where the registrant has elected to include impacts from transition opportunities.

In this example, contextual information may include disclosure such as the registrant's election to include the impact from opportunities in its disclosure analysis and calculation, the specific events that were aggregated for purposes of determining the impact on the cost of revenue and, if applicable, a discussion of the estimation methodology used to disaggregate the amount of impact on the cost of revenue between the climate-related events, transition activities, and other factors.

To provide additional clarity, the proposed rule would include the following examples of disclosures that may be required to reflect the impact of the severe weather events and other natural conditions on each line item of the registrant's consolidated financial statements (*e.g.,* line items of the consolidated income statement, balance sheet, or cash flow statement): [353]

- Changes to revenue or costs from disruptions to business operations or supply chains;
- Impairment charges and changes to the carrying amount of assets (such as inventory, intangibles, and property, plant and equipment) due to the assets being exposed to severe weather, flooding, drought, wildfires, extreme temperatures, and sea level rise;
- Changes to loss contingencies or reserves (such as environmental reserves or loan loss allowances) due to impact from severe weather events; and
- Changes to total expected insured losses due to flooding or wildfire patterns.[354]

With respect to the financial impacts of transition activities, the proposed rule would include the following examples of potential impacts:

- Changes to revenue or cost due to new emissions pricing or regulations resulting in the loss of a sales contract;
- Changes to operating, investing, or financing cash flow from changes in upstream costs, such as transportation of raw materials;
- Changes to the carrying amount of assets (such as intangibles and property, plant, and equipment), for example, due to a reduction of the asset's useful life or a change in the asset's salvage value by being exposed to transition activities; and
- Changes to interest expense driven by financing instruments such as climate-linked bonds issued where the interest rate increases if certain climate-related targets are not met.[355]

Many commenters stated that climate-related financial disclosure is material and should be reflected separately in the financial statements.[356] For example, one commenter stated that it is critical to investors and others in assessing a company's risk profile, estimating its risk-adjusted returns, and completing other relevant financial analyses to include information on how climate-related risks and climate-related opportunities may affect companies' income statements, cash flow statements, and balance sheets.[357]

Other commenters, however, generally expressed the view that if such disclosures are material, they would already be required by existing financial statement disclosure requirements.[358] For example, some of these commenters stated that they opposed new climate-specific disclosure rules because, in their view, the traditional concept of materiality already requires the disclosure of climate-related impacts that materially

[353] The examples below, like all of the examples in this release (including examples in the text of the proposed rules), are non-exclusive and should not be interpreted as a checklist for compliance with any proposed rule.

[354] *See* proposed 17 CFR 210.14–02(c)(1) through (4).

[355] *See* proposed 17 CFR 210.14–02(d)(1) through (4).

[356] *See, e.g.,* letters from Americans for Financial Reform Education Fund *et al.;* BlackRock; CalPERS; Ceres; Climate Accounting Project; Climate Governance Initiative; Eni SpA; Friends of the Earth, Amazon Watch and RainForest Coalition; Initiative on Climate Risk and Resilience Law; International Corporate Governance Network; Investment Company Institute; Natural Resources Defense Council; Policy Working Group; Sens. Brian Schatz and Sheldon Whitehouse (June 10, 2021); Ted Atwood; The Forum for Sustainable and Responsible Investment; The Revolving Door Project; The Washington State Investment Board; UNEP—FI; Union of Concerned Scientists; and WBCSD.

[357] *See* letter from Bloomberg.

[358] *See, e.g.,* letters from the American Fuel Petrochemical Manufacturers (June 13, 2021); Environmental Bankers Association; Heritage Foundation; National Mining Association (June 11, 2021); Society for Mining, Metallurgy, & Exploration (June 13, 2021); and The Associated General Contractors of America.

affect the issuer's financial condition and results of operations.[359]

Although we agree that registrants are currently required to disclose material financial impacts on the financial statements, the proposed climate-related financial statement metrics should provide additional transparency into the impact of climate-related events on information reported in the financial statements that would be relevant to investors when making investment or voting decisions.[360] Such disclosure would also provide investors with additional insights into the nature of a registrant's business, the implementation of the registrant's targets and goals, and material trends in climate-related impacts. Furthermore, separately stating the financial statement impacts from the climate-related events and transition activities could improve comparability across both the registrant's year-to-year disclosures and the disclosures of different registrants.

We further note that the proposed requirement to separately disclose the financial impacts of the climate-related events and transition activities may be necessary not only because climate-related risks may have significant impacts on individual registrants, but also because the risks presented by the climate-related events and transition activities may be correlated across different, similarly situated registrants.[361] Climate-related risks present the potential for a high correlation and therefore concentration of risk within a portfolio. Separate disclosure of climate-related risks could help to provide investors with information to help them more effectively evaluate their portfolio risk. In this regard, we note that an analogous approach to disaggregated, or separately stated, disclosure has been taken in other contexts within the financial statements and elsewhere.[362] For example, in segment reporting, a registrant must present within its consolidated financial statements a separate presentation of certain financial statement line items for each segment.[363] The Commission has noted the importance of disaggregated disclosure in the segment reporting context, stating that it ''has long been aware of the importance of meaningful segment information to reasoned investment decision-making.'' [364]

The importance of disaggregated disclosure in a registrant's financial statements is also supported by the concepts set forth in FASB ASC Topic 606 *Revenue from Contracts with Customers* and IFRS 15 *Revenue from Contracts with Customers,* which require, among other things, disclosure of disaggregated revenue recognized from contracts with customers into categories that depict how the nature, amount, timing, and uncertainty of revenue and cash flows are affected by economic factors. As noted earlier, the Commission also requires disaggregation of certain financial statement line items in Article 5 of Regulation S–X. Specifically, Article 5 requires separate disclosures of specific balance sheet and income statement line items when practicable or when certain percentage thresholds are met, depending on the nature of the information.[365] Those conditions on when separate disclosure is required are analogous to the proposed condition that financial impacts result from the climate-related events and transition activities.

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59. Should we require registrants to disclose the financial impact metrics, as proposed? Would presenting climate-specific financial information on a separate basis based on climate-related events (severe weather events and other natural conditions and identified physical risks) and transition activities (including identified transition risks) elicit decision-useful or material information for investors? Are there different metrics that would result in disclosure of more useful information about the impact of climate-related risks and climate-related opportunities on the registrant's financial performance and position?

60. Would the impact from climate-related events and transition activities yield decision-useful information for investors? Would the climate-related events (including the examples provided) and transition activities result in impacts that are easier to quantify or disaggregate than climate-related risks more generally? Would a registrant be able to quantify and provide the proposed disclosure when the impact may be the result of a mixture of factors (*e.g.,* a factory shutdown due to an employee strike that occurs simultaneously with a severe weather event)? If there are situations where disaggregation would not be practicable, should we require a registrant to disclose that it was unable to make the required determination and why, or to make a reasonable estimate and provide disclosure about the assumptions and information that resulted in the estimate?

61. Alternatively, should we not require disclosure of the impacts of identified climate-related risks and only require disclosure of impacts from

[359] *See* letters from American Fuel Petrochemical Manufacturers; Environmental Bankers Association; and The Associated General Contractors of America.

[360] Certain commenters, in response to FASB's 2021 Agenda Consultation, were also supportive of more disaggregated disclosures within the financial statements. *See, e.g.,* letters from CalPERS (Sept. 22, 2021); CFA Institute (Oct. 7, 2021); and CII (Sept. 16, 2021). Comment letters in response to FASB's invitation to comment are available at *https://www.fasb.org/jsp/FASB/CommentLetter_C/CommentLetterPage&cid=1218220137090&project_id=2021-004&page_number=1.*

[361] *See, e.g.,* Madison Condon, *Market Myopia's Climate Bubble,* 2022 Utah L. Rev. 63 (2021). *See also* 2020 CFTC Advisory Subcommittee Report (''Climate change is expected to affect multiple sectors, geographies, and assets in the United States, sometimes simultaneously and within a relatively short timeframe. As mentioned earlier, transition and physical risks—as well as climate and non-climate-related risks—could interact with each other, amplifying shocks and stresses. This raises the prospect of spillovers that could disrupt multiple parts of the financial system simultaneously.'').

[362] The analogies presented are not intended to imply that FASB ASC Topic 280, IFRS 8 or other concepts would have to be applied when accounting for and disclosing the climate-related financial statement metrics. The analogies are also not intended to imply that the determination of when disclosure may be required and how that determination is made is the same across all of these concepts. *See, e.g., infra* note 363 (discussing management's evaluation under FASB ASC Topic 280 *Segment Reporting* and IFRS 8 *Operating Segments*) and the discussion below of FASB ASC Topic 606, IFRS 15, and Article 5 of Regulation S–X.

[363] *See* FASB ASC Topic 280 *Segment Reporting* and IFRS 8 *Operating Segments* (requiring segment reporting disclosures to be included in the audited financial statements). FASB ASC 280–10–10–1 states that the objective of segment reporting is to provide information about the different types of business activities in which a registrant engages and the different economic environments in which it operates to help users of financial statements: (i) Better understand the public entity's performance; (ii) better assess its prospects for future net cash flows; and (iii) make more informed judgments about the public entity as a whole. FASB ASC Topic 280 and IFRS 8 focus on the chief operating decision maker's view when evaluating the registrant and prescribes certain qualitative and quantitative considerations when determining what constitutes an operating segment. Similarly, the proposed rule would require an initial determination by the registrant of the relevant climate-related events and transition activities, and their impact on the registrant's financial statements.

[364] *See Industry and Homogenous Geographic Segment Reporting,* Release No. 33–6514 (Feb. 15, 1984) [49 FR 6737–01 (Feb. 23, 1984)], at 6738. Robust segment reporting disclosures are important as they can provide crucial transparency to investors that are reviewing financial statements. *See also* Gary Buesser, *For the Investor: Segment Reporting,* FASB OUTLOOK (Apr. 2019) (''[I]nvestors normally model a company at the segment level rather than at the consolidated level. More segments and greater information about an operating segment improve an analyst's ability to forecast a company's revenue, margins and assets—which serves as the basis for valuing a company.'').

[365] *See supra* note 347 for examples of the Commission's use of a 1% threshold in other contexts.

severe weather events and other natural conditions? Should we require a registrant to disclose the impact on its consolidated financial statements of only certain examples of severe weather events and other natural conditions? If so, should we specify which severe weather events and other natural conditions the registrant must include? Would requiring disclosure of the impact of a smaller subset of climate-related risks be easier for a registrant to quantify without sacrificing information that would be material to investors?

62. Should impact from climate-related opportunities be required, instead of optional, as proposed? We are proposing to require a registrant that elects to disclose the impact of an opportunity to do so consistently (*e.g.,* for each fiscal year presented in the consolidated financial statements, for each financial statement line item, and for all relevant opportunities identified by the registrant). Are there any other requirements that we should include to enhance consistency? Should we only require consistency between the first fiscal period in which opportunities were disclosed and subsequent periods?

63. Is it clear which climate-related events would be covered by ''severe weather events and other natural conditions''? If not, should we provide additional guidance or examples about what events would be covered? Should we clarify that what is considered ''severe weather'' in one region may differ from another region? For example, high levels of rainfall may be considered ''severe weather'' in a typically arid region.

64. Are the proposed requirements for calculating and presenting the financial impact metrics clear? Should the analysis be performed and disclosed in a manner other than on a line-by-line basis referring to the line items of the registrant's consolidated financial statements?

65. We are proposing to allow a registrant to aggregate the absolute value of negative and positive impacts of all climate-related events and, separately, transition activities on a financial statement line item. Should we instead require separate quantitative disclosure of the impact of each climate-related event or transition activity? Should we require separate disclosure of the impact of climate-related opportunities that a registrant chooses to disclose?

66. The proposed financial impact metrics would not require disclosure if the absolute value of the total impact is less than one percent of the total line item for the relevant fiscal year. Is the proposed threshold appropriate? Should we use a different percentage threshold (*e.g.,* three percent, five percent) or use a dollar threshold (*e.g.,* less than or greater than $1 million)? Should we use a combination of a percentage threshold and a dollar threshold? Should we only require disclosure when the financial impact exceeds the threshold, as proposed, or should we also require a determination of whether an impact that falls below the proposed quantitative threshold would be material and should be disclosed?

67. For purposes of determining whether the disclosure threshold has been met, should impacts on a line item from climate-related events and transition activities be permitted to offset (netting of positive and negative impacts), instead of aggregating on an absolute value basis as proposed? Should we prescribe how to analyze positive and negative impacts on a line item resulting from the same climate-related event or the same transition activity (*e.g.,* whether or not netting is permitted at an event or activity level)? Should we permit registrants to determine whether or not to offset as a policy decision (netting of the positive and negative impact within an event or activity) and provide relevant contextual information? Should we require the disclosure threshold to be calculated separately for the climate-related events and transition activities, rather than requiring all of the impacts to be aggregated as proposed?

68. Instead of including a quantitative threshold, as proposed, should we require disaggregated disclosure of *any* impact of climate-related risks on a particular line item of the registrant's consolidated financial statements? Alternatively, should we just use a materiality standard?

69. Should we require a registrant to disclose changes to the cost of capital resulting from the climate-related events? If so, should we require a registrant to disclose its weighted average cost of capital or any internal cost of capital metrics? Would such disclosure elicit decision-useful or material information for investors?

70. We have not proposed defining the term ''upstream costs'' as used in the proposed examples for the financial impact metrics and elsewhere. Should we define that term or any others? If so, how should we define them?

71. Are the proposed examples in the financial impact metrics helpful for understanding the types of disclosure that would be required? Should we provide different or additional examples or guidance?

3. Expenditure Metrics

The proposed expenditure metrics would refer to the positive and negative impacts associated with the same climate-related events, transition activities, and identified climate-related risks as the proposed financial impact metrics.[366] As proposed, the expenditure metrics would require a registrant to separately aggregate amounts of (i) expenditure expensed and (ii) capitalized costs incurred during the fiscal years presented.[367] For each of those categories, a registrant would be required to disclose separately the amount incurred during the fiscal years presented (i) toward positive and negative impacts associated with the climate-related events (*i.e.,* severe weather events and other natural conditions and identified physical risks) and (ii) toward transition activities, specifically, to reduce GHG emissions or otherwise mitigate exposure to transition risks (including identified transition risks).[368] The registrant may also choose to disclose the impact of efforts to pursue climate-related opportunities associated with transition activities.[369] As discussed above, if a registrant elects to disclose the impact of an opportunity, it must do so consistently and must follow the same presentation and disclosure threshold requirements applicable to the required disclosures of expenditure metrics associated with transition risks. The amount of expenditure disclosed pursuant to the proposed metrics would be a portion, if not all, of the registrant's total recorded expenditure (expensed or capitalized), as calculated pursuant to the accounting principles applicable to the registrant's financial statements.[370]

The proposed expenditure metrics would be subject to the same disclosure threshold as the financial impact metrics, which we believe would promote comparability, consistency, and clarity in determining when information must be disclosed. For purposes of calculating the disclosure threshold for the expenditure metrics, a registrant would be permitted to separately determine the amount of expenditure expensed and the amount of expenditure capitalized; however, a registrant would be required to

[366] *See* proposed 17 CFR 210.14–02(e), (f), and (i).

[367] *See id.* These metrics are focused on expenditures (spending) incurred in each reported fiscal year(s). We therefore believe the number of periods of the expenditure metrics should correspond to the number of years of income statement or cash flow statement presented in the consolidated financial statements.

[368] *See id.*

[369] *See* proposed 17 CFR 210.14–02(j).

[370] *See* 17 CFR 210.4–01(a)(1) and (2).

aggregate expenditure related to climate-related events and transition activities within the categories of expenditure (*i.e.,* amount capitalized and amount expensed). This approach should better reflect the significance of climate-related expenditure compared to a calculation approach that would allow for a disclosure threshold to be measured at the individual event or activity level, which may result in more limited disclosures.

For example, assume a registrant capitalized $200,000 of expenditure incurred related to Event D and capitalized another $100,000 of expenditure incurred related to Activity E. The registrant also expensed $25,000 of expenditure incurred related to Event F (which is an identified transition risk disclosed by the registrant). The registrant would determine whether the impacts would trigger the disclosure requirements based on the proposed thresholds, as illustrated below:

Expenditure category	Current fiscal year balances (from consolidated financial statements) *	Event D	Activity E	Event F	Percentage impact
Capitalized costs (total expenditure incurred during the year that was capitalized)	$8,000,000	$200,000	$100,000	.....	** 3.85%
Expense (total expenditure incurred during the year that was expensed)	$3,000,000	.....	.....	$25,000	0.8%

* As expenditures capitalized and expensed are recorded in various financial statement line items, we expect the ''total'' to be used for disclosure threshold calculation purposes for each category to represent the aggregated expenditures capitalized during the fiscal year and aggregated expenditures expensed during the fiscal year. See below for additional discussion regarding associated contextual information that may be required.

** Calculated based on total impact on capitalized costs from Event D ($200,000), Activity E ($100,000), and Event F ($0): $300,000/$8,000,000.

In the above example, the expenditure incurred toward Event D was $200,000 (capitalized) and the expenditure incurred toward Activity E and Event F were $100,000 (capitalized) and $25,000 (expensed). The amount of capitalized costs equaled the proposed one percent threshold, and thus the disclosure would be required for that category of expenditure. No disclosure would be required for the expenditure incurred that was expensed (related to Event F in this example), because it was below the one percent threshold. The registrant's resulting disclosure of such expenditure (capitalized or expensed) may be provided, for example, as illustrated in the following table (excluding disclosure of contextual information):

Note X. Climate-related financial metrics:

	Expenditure incurred for climate-related events	Expenditure incurred for climate-related transition activities
Capitalized costs	$200,000	$100,000

In this example, contextual information may include disclosure such as the specific climate-related events and transition activities that were aggregated for purposes of determining the impacts on the capitalized or expensed expenditure amounts and, if applicable, policy decisions made by a registrant to determine the amount of climate-related events or transition activities that are categorized as expenditure capitalized versus expenditure expensed or whether impact from pursuing any climate-related opportunities are included in the analysis. Contextual information may also include a discussion of the composition of the total expenditure expensed and total expenditure capitalized, which were used to calculate whether the disclosure threshold was met, and, if applicable, a discussion of the estimation methodology used to disaggregate the amount of impact between the climate-related events, transition activities, and other factors, including if an event or an activity impacted both capitalized and expensed costs.

The proposed rules would clarify that a registrant may be required to disclose the amount of expenditure expensed or capitalized costs, as applicable, incurred for the climate-related events to increase the resilience of assets or operations, retire or shorten the estimated useful lives of impacted assets, relocate assets or operations at risk, or otherwise reduce the future impact of severe weather events and other natural conditions on business operations.[371] The proposed rules would also clarify that a registrant may be required to disclose the amount of expenditure expensed or capitalized costs, as applicable, incurred for climate-related transition activities related to research and development of new technologies, purchase of assets, infrastructure, or products that are intended to reduce GHG emissions, increase energy efficiency, offset emissions (purchase of energy credits), or improve other resource efficiency.[372]

Several commenters recommended taking a similar approach, stating that we should require disclosure of climate-related capital expenditure (*i.e.,* capitalized assets),[373] or both climate-related expenses and capitalized assets.[374] Consistent with these comments, and for similar reasons to those stated above with respect to the financial impact metrics, separate disclosure of total expense and total capitalized costs incurred toward the climate-related events and transition activities should provide important

[371] *See* proposed 17 CFR 210.14–02(e).

[372] *See* proposed 17 CFR 210.14–02(f).

[373] *See, e.g.,* letters from Amalgamated Bank; Interfaith Center on Corporate Responsibility; and Natural Resources Defense Council.

[374] *See, e.g.,* letters from Calvert; Climate Risk Disclosure Lab; and World Benchmarking Alliance.

information to help investors make better informed investment or voting decisions. Moreover, the financial impacts of expenditure typically appear in different places within the financial statements (*e.g.,* in an asset line item(s) on the balance sheet or in an expense line item(s) in the income statement). The proposed approach is intended to address this dispersed presentation by requiring registrants to first identify the relevant climate-related expenditures and then compile those impacts in one location. Similar to the proposed financial impact metrics, such an approach should provide insight into, and context for understanding, the nature of a registrant's business, including any disclosed strategy for addressing and managing the specified risks—particularly in the context of transition planning.[375]

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72. Should we require registrants to disclose the expenditure metrics, as proposed? Would presenting the expenditure metrics separately in one location provide decision-useful information to investors? Is there a different type of metric that would result in more useful disclosure of the expense or capitalized costs incurred toward climate-related events and transition activities or toward climate-related risks more generally?

73. Would the disclosure required by the expenditure metrics overlap with the disclosure required by the financial impact metrics? If so, should we require the disclosure to be provided pursuant to only one of these types of metrics?

74. Should the same climate-related events (including severe weather events and other natural conditions and identified physical risks) and transition activities (including identified transition risks) that we are proposing to use for the financial impact metrics apply to the expenditure metrics, as proposed? Alternatively, should we not require a registrant to disclose expenditure incurred towards identified climate-related risks and only require disclosure of expenditure relating to severe weather events and other natural conditions? Should we require a registrant to disclose the expenditure incurred toward only certain examples of severe weather events and other natural conditions? If so, should we specify which severe weather events and other natural conditions the registrant must include? Would requiring disclosure of the expenditure relating to a smaller subset of climate-related risks be easier for a registrant to quantify without sacrificing information that would be material to investors?

75. Should the proposed rules instead require a registrant to disclose the aggregate amounts of expensed and capitalized costs incurred toward *any* climate-related risks? Should expenditures incurred towards climate-related opportunities be optional based on a registrant's election to disclose such opportunities, as proposed?

76. Should we apply the same disclosure threshold to the expenditure metrics and the financial impact metrics? Is the proposed threshold for expenditure metrics appropriate? Should we use a different percentage threshold (*e.g.,* three percent, five percent) or use a dollar threshold (*e.g.,* less than or greater than $1 million)? Should we use a combination of a percentage threshold and a dollar threshold? Should we only require disclosure when the amount of climate-related expenditure exceeds the threshold, as proposed, or should we also require a determination of whether an amount of expenditure that falls below the proposed quantitative threshold would be material and should be disclosed? Should we require separate aggregation of the amount of expense and capitalized costs for purposes of the threshold, as proposed? Should we require separate aggregation of expenditure relating to the climate-related events and transition activities, as proposed?

77. Instead of including a quantitative threshold, as proposed, should we require disaggregated disclosure of *any* amount of expense and capitalized costs incurred toward the climate-related events and transition activities, during the periods presented? Alternatively, should we just use a materiality standard?

78. Are the proposed requirements for calculating and presenting the expenditure metrics clear? Should the analysis be performed and disclosed in a different manner, other than separately based on capitalized costs and amount of expenditure expensed and separately based on the climate-related events and transition activities? Should disclosure of expenditure incurred be required for both the amount of capitalized costs and the amount of expenditure expensed if only one of the two types of expenditure meets the disclosure threshold? Should we require separate disclosure of expenditure incurred toward each climate-related event and transition activity?

79. The proposed rule does not specifically address expensed or capitalized costs that are *partially* incurred towards the climate-related events and transition activities (*e.g.,* the expenditure relates to research and development expenses that are meant to address both the risks associated with the climate-related events and other risks). Should we prescribe a particular approach to disclosure in such situations? Should we require a registrant to provide a reasonable estimate of the amount of expense or capitalized costs incurred toward the climate-related events and transition activities and to provide disclosure about the assumptions and information that resulted in the estimate?

80. Are the proposed terms and examples used in the expenditure metrics helpful for understanding the types of disclosures that would be required? Should we provide different or additional examples?

4. Financial Estimates and Assumptions

The proposed rules would require a registrant to disclose whether the estimates and assumptions used to produce the consolidated financial statements were impacted by exposures to risks and uncertainties associated with, or known impacts from, climate-related events (including identified physical risks and severe weather events and other natural conditions), such as flooding, drought, wildfires, extreme temperatures, sea level rise.[376] If so, the registrant would be required to provide a qualitative description of how such events have impacted the development of the estimates and assumptions used by the registrant in the preparation of such financial statements. Similar to the other proposed financial statement metrics, the proposed rules would include a provision that would require separate disclosure focused on transition activities (including identified transition risks).[377] Further, if a registrant elects to disclose the impact of an opportunity on its financial estimates and assumptions, it must do so consistently and must follow the same presentation and disclosure requirements applicable to the required disclosures herein.[378]

If the estimates and assumptions a registrant used to produce the consolidated financial statements were

[375] *See supra* Section II.C, which discusses our proposals to require the registrant to describe the actual and potential impacts of the identified climate-related risks (and climate-related opportunities if the registrant elects to do so) on its strategy, business model, and outlook. Further, such disclosure could also provide additional context to other narrative disclosures such as the discussion of risk factors required by 17 CFR 229.105.

[376] *See* proposed 17 CFR 210.14–02(g) and (i).

[377] *See* proposed 17 CFR 210.14–02(h) and (i).

[378] *See* proposed 17 CFR 210.14–02(j).

impacted by risks and uncertainties associated with, or known impacts from, a potential transition to a lower carbon economy or any climate-related targets it has disclosed, the registrant would be required to provide a qualitative description of how the development of the estimates and assumptions were impacted by such a potential transition or the registrant's disclosed climate-related targets.

Estimates and assumptions are currently required for accounting and financial reporting purposes (*e.g.,* projected financial information used in impairment calculations, estimated loss contingencies, estimated credit risks, commodity price assumptions, etc.). The proposed disclosures could provide decision-useful information and transparency to investors about the impact of the climate-related events and transition activities, including disclosed targets and goals,[379] on such estimates and assumptions. Moreover, in addition to providing insight into impacts on the registrant's financial statements, such disclosure could allow investors to evaluate the reasonableness of the registrant's estimates and assumptions, which are used to prepare the registrant's financial statements. Although current accounting standards require registrants to consider how climate-related matters may intersect with and affect the financial statements, including their impact on estimates and assumptions,[380] the nature of the climate-related events and transition activities discussed in the proposed rules, which may manifest over a longer time horizon, necessitate targeted disclosure requirements to elicit decision-useful information for investors in a consistent manner. We also note that some registrants have already provided disclosure along the lines of the proposed requirements, which lends support to the feasibility of making such disclosures.[381]

By way of example, the proposed climate-related events and impacts relating to a transition away from greenhouse gas producing products and activities could affect a registrant's asset values and may result in asset impairments. The effect on asset values and the resulting impairments could, in turn, affect a registrant's assumptions when calculating depreciation expenses or asset retirement obligations associated with the retirement of tangible, long-lived assets. Providing related disclosure could help an investor understand if a registrant would be responsible for removing equipment or cleaning up hazardous materials sooner than originally planned due to a severe weather event. Similarly, a registrant's climate-related targets and related commitments, such as a commitment to achieve net-zero emissions by 2040, may impact certain accounting estimates and assumptions. For example, if a registrant announced a commitment that would require decommissioning an asset by a target year, then the registrant's depreciation expense should reflect alignment with that commitment. If the registrant believes it can execute a strategy that would allow it to meet the commitment and continue to operate the asset past the target date, then the proposed disclosure requirement could facilitate an investor's understanding and own assessment of the feasibility of that strategy. Other financial statement estimates and assumptions that may require disclosure pursuant to the proposed rules may include those related to the estimated salvage value of certain assets, estimated useful life of certain assets, projected financial information used in impairment calculations, estimated loss contingencies, estimated reserves (such as environmental reserve or loan loss allowances), estimated credit risks, fair value measurement of certain assets, and commodity price assumptions.

Several commenters stated that it was important to provide investors with an understanding of how climate-related events and activities are considered when a registrant develops the assumptions and estimates used to prepare its financial statements.[382] In particular, one commenter stated that investors may face ''substantial risk'' if disclosure on the impact of ''decarbonization'' on the estimates and assumptions underlying asset valuations is not disclosed.[383] Another commenter stated that ''current corporate disclosure is not sufficient, is not readily available in existing financial disclosures, and does not allow investors to make comparable assessments of how companies are evaluating and responding to climate-related risks and opportunities.'' [384]

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81. Should we require disclosure of financial estimates and assumptions impacted by the climate-related events and transition activities (including disclosed targets), as proposed? How would investors use this information?

82. Should we instead require disclosure of only significant or material estimates and assumptions that were impacted by the climate-related events and transition activities? Alternatively, should we require disclosure of only estimates and assumptions that were materially impacted by the climate-related events and transition activities?

83. Should we instead require disclosure of financial estimates and assumptions impacts by a subset of climate-related events and transition activities, such as not requiring disclosure related to identified climate-related risks or only requiring disclosure with respect to a subset of severe weather events and natural conditions? If so, how should the subset be defined?

84. Should we instead utilize terminology and thresholds consistent with the critical accounting estimate disclosure requirement in 17 CFR 229.303(b)(3), such as ''estimates made in accordance with generally accepted accounting principles that involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on the financial condition or results of operations of the registrant''? If so, should we only require disclosures of whether and how the climate-related events and transition activities impacted such critical accounting estimates? Should we require only a qualitative description of how the estimates and assumptions were impacted by the climate-related events and transition activities, as proposed? Should we require quantitative disclosures as well? If so, should we require such disclosure

[379] *See* proposed 17 CFR 229.1506.

[380] *See* FASB Staff Educational Paper, Intersection of Environmental, Social and Governance Matters with Financial Accounting Standards (Mar. 2021), available at *https://fasb.org/jsp/FASB/Document_C/DocumentPage&cid=1176176379917. See also* IFRS, Effects of climate-related matters on financial statements (Nov. 2020), available at *https://www.ifrs.org/content/dam/ifrs/supporting-implementation/documents/effects-of-climate-related-matters-on-financial-statements.pdf#:~:text=IFRS%20Standards%20do%20not%20refer%explicitly%20to%20climate-related,significant%20judgements%20and%20estimates%20that%20%20has%20made.* We also remind registrants of the requirements under FASB ASC Topic 250–10–50–4 for disclosures of changes in accounting estimates, including the requirement that if a change in estimate does not have a material effect in the period of change, but is reasonably certain to have a material effect in later periods, a description of that change in estimate must be disclosed whenever the financial statements of the period of change are presented.

[381] *See* letter from Carbon Tracker (stating that some companies in the European Union and United Kingdom (several of which are registrants) are already providing this information and providing examples).

[382] *See, e.g.,* letters from Carbon Tracker; Climate Accounting Project; ICCR; and Institute for Policy Integrity, Environmental Defense Fund, Initiative on Climate Risk & Resilience Law.

[383] *See* letter from Carbon Tracker.

[384] *See* letter from ICCR.

only if practicable or subject to another qualifier?

85. Should the disclosure of financial estimates and assumptions impacted by climate-related opportunities be optional, as proposed?

86. For the proposed financial statement metrics, should we require a registrant to disclose material changes in estimates, assumptions, or methodology among fiscal years and the reasons for those changes? If so, should we require the material changes disclosure to occur on a quarterly, or some other, basis? Should we require disclosure beyond a discussion of the material changes in assumptions or methodology and the reasons for those changes? Do existing required disclosures already elicit such information? What other approaches should we consider?

5. Inclusion of Climate-Related Metrics in the Financial Statements

The proposed financial statement metrics would be required in the financial statements, and therefore would be (i) included in the scope of any required audit of the financial statements in the relevant disclosure filing, (ii) subject to audit by an independent registered public accounting firm, and (iii) within the scope of the registrant's ICFR.

As discussed above, the proposed disclosures share many characteristics with other complex financial statement disclosures. The financial statement metrics present financial data that is derived from the registrant's consolidated balance sheets, income statements, and statements of cash flows, and would be presented in a similar way to existing financial statement disclosures.[385] Requiring certain climate-related information to be included in a note to the financial statements, and therefore subject to audit and within the scope of ICFR, should enhance the reliability of the proposed financial statement metrics.

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87. We are proposing to require the financial statement metrics to be disclosed in a note to the registrant's audited financial statements. Should we require or permit the proposed financial statement metrics to be disclosed in a schedule to the financial statements? If so, should the metrics be disclosed in a schedule to the financial statements, similar to the schedules required under Article 12 of Regulation S–X, which would subject the disclosure to audit and ICFR requirements? Should we instead require the metrics to be disclosed as supplemental financial information, similar to the disclosure requirements under FASB ASC Topic 932–235–50–2 for registrants that have significant oil- and gas-producing activities? If so, should such supplemental schedule be subject to assurance or ICFR requirements?

88. Instead of requiring the financial statement metrics to be disclosed in a note to the registrant's audited financial statements, should we require a new financial statement for such metrics? For example, should a ''consolidated climate statement'' be created in addition to the consolidated balance sheets, statements of comprehensive income, cash flows, and other traditional financial statements? Would including the proposed metrics in a new financial statement provide more clarity to investors given that the metrics are intended to follow the structure of the existing financial statements (including the line items)? What complications or unintended consequences may arise in practice if such a climate statement is created?

89. Should we require the disclosure to be provided outside of the financial statements? Should we require all of the disclosure to be provided in the proposed separately captioned item in the specified forms?

90. Should we require any additional metrics or disclosure to be included in the financial statements and subject to the auditing and ICFR requirements as described above? For example, should any of the disclosures we are proposing to require outside of the financial statements (such as GHG emissions metrics) be included in the financial statements? If so, should such metrics be disclosed in a note or a schedule to the financial statements? If in a schedule, should such schedule be similar to the schedules required under Article 12 of Regulation S–X and subject to audit and ICFR requirements? Should we instead require the metrics to be disclosed as supplemental financial information in a supplemental schedule? If so, should such supplemental schedule be subject to assurance or ICFR requirements?

91. Under the proposed rules, PCAOB auditing standards would be applicable to the financial statement metrics that are included in the audited financial statements, consistent with the rest of the audited financial statements. What, if any, additional guidance or revisions to such standards would be needed in order to apply PCAOB auditing standards to the proposed financial statement metrics? For example, would guidance on how to apply existing requirements, such as materiality, risk assessment, or reporting, be needed? Would revisions to the auditing standards be necessary? What additional guidance or revisions would be helpful to auditors, preparers, audit committee members, investors, and other relevant participants in the audit and financial reporting process?

92. Would it be clear that the climate-related financial statement metrics would be included in the scope of the audit when the registrant files financial statements prepared in accordance with IFRS as issued by the IASB? Would it be clear that the proposed rules would not alter the basis of presentation of the financial statements as referred to in an auditor's report? Should we amend Form 20–F, other forms, or our rules to clarify the scope of the audit or the basis of presentation in this context? For example, should we amend Form 20–F to state specifically that the scope of the audit must include any notes prepared pursuant to Article 14 of Regulation S–X? What are the costs for accounting firms to provide assurance with respect to the financial statement metrics? Would those costs decrease over time?

G. GHG Emissions Metrics Disclosure

1. GHG Emissions Disclosure Requirement

a. Overview

In addition to the other proposed climate-related disclosures, the proposed rules would require a registrant to disclose its GHG emissions for its most recently completed fiscal year.[386] As institutional investors and other commenters have indicated, GHG emissions information is important to investment decisions for various reasons, including because GHG emissions data is quantifiable and comparable across industries and can be particularly useful in conducting a transition risk analysis;[387] it can be used to evaluate the progress in meeting net-zero commitments and assessing any associated risks;[388] and it may be relevant to investment or voting decisions because GHG emissions could impact the company's access to financing, as well as its ability to reduce

[385] *See supra* Section II.F.2 for additional discussion of shared characteristics that the financial statement metrics have with existing financial statement disclosures and commenters' views.

[386] *See proposed* 17 CFR 229.1504(a). As discussed below, the proposed rules would also require a registrant to disclose its GHG emissions for the historical fiscal years included in its consolidated financial statements.

[387] *See, e.g., infra* note 432 and accompanying text.

[388] *See, e.g., infra,* note 433 and accompanying text.

its carbon footprint in the face of regulatory, policy, and market constraints.[389] Thus, while the justifications for the proposed GHG emissions disclosures overlap in some respects with the justifications for the other proposed climate-related disclosure rules, the GHG emissions requirements are intended to address separate challenges and are supported by the particular justifications discussed in detail in the following sections.

The proposed rules would establish certain requirements regarding the measurement and reporting of GHG emissions that would promote the comparability of such disclosure. We have based the proposed GHG emissions disclosure rules on the concept of scopes, which are themselves based on the concepts of direct and indirect emissions, developed by the GHG Protocol. We also have proposed definitions of Scope 1, Scope 2, and Scope 3 emissions that are substantially similar to the corresponding definitions provided by the GHG Protocol. Commenters indicated that the GHG Protocol has become the leading accounting and reporting standard for GHG emissions.[390] By sharing certain basic concepts and a common vocabulary with the GHG Protocol, the proposed rules should help limit the compliance burden for those registrants that are already disclosing their GHG emissions pursuant to the GHG Protocol.[391] Similarly, to the extent that registrants elect to follow GHG Protocol standards and methodologies, investors already familiar with the GHG Protocol may also benefit.

The proposed rules would define ''greenhouse gases'' as carbon dioxide (''CO_2''); methane (''CH_4''); nitrous oxide (''N_2O''); nitrogen trifluoride (''NF_3''); hydrofluorocarbons (''HFCs''); perfluorocarbons (''PFCs''); and sulfur hexafluoride (''SF_6'').[392] The greenhouse gases included in the proposed definition reflect the gases that are currently commonly referenced by international, scientific, and regulatory authorities as having significant climate impacts. In addition to being consistent with the GHG Protocol,[393] the list of constituent greenhouse gases would be consistent with the gases identified by widely used frameworks, such as the Kyoto Protocol, the UN Framework Convention on Climate Change, the U.S. Energy Information Administration, and the EPA.[394]

The proposed rules would define GHG emissions to mean direct and indirect emissions of greenhouse gases.[395] Pursuant to the proposed definition of GHG emissions, direct emissions are GHG emissions from sources that are owned or controlled by a registrant,[396] whereas indirect emissions are GHG emissions that result from the activities of the registrant, but occur at sources not owned or controlled by the registrant.[397] Similar to the GHG Protocol, the proposed rules would define: [398]

- Scope 1 emissions as direct GHG emissions from operations that are owned or controlled by a registrant; [399]
- Scope 2 emissions as indirect GHG emissions from the generation of purchased or acquired electricity, steam, heat, or cooling that is consumed by operations owned or controlled by a registrant; [400] and
- Scope 3 emissions as all indirect GHG emissions not otherwise included in a registrant's Scope 2 emissions, which occur in the upstream and downstream activities of a registrant's value chain.[401] Upstream emissions include emissions attributable to goods and services that the registrant acquires, the transportation of goods (for example, to the registrant), and employee business travel and commuting. Downstream emissions include the use of the registrant's products, transportation of products (for example, to the registrant's customers), end of life treatment of sold products, and investments made by the registrant.

As previously noted, the EPA uses the concept of scopes, and refers to the GHG Protocol, when providing guidance to companies regarding their GHG emissions inventories.[402] Because GHG emissions data compiled for the EPA's own GHG emissions reporting program would be consistent with the GHG Protocol's standards, and thus with the proposed rules, a registrant may use that data in partial fulfillment of its GHG emissions disclosure obligations pursuant to the proposed rules.

The proposed rules would require a registrant to disclose its total Scope 1 emissions separately from its total Scope 2 emissions after calculating them from all sources that are included in the registrant's organizational and operational boundaries.[403] A registrant would also be required to disclose separately its total Scope 3 emissions for the fiscal year if those emissions are material, or if it has set a GHG emissions reduction target or goal that includes its Scope 3 emissions.[404] For each of its Scopes 1, 2, and 3 emissions, the proposed rules would require a registrant to disclose the emissions both disaggregated by each constituent greenhouse gas (*e.g.,* by carbon dioxide

[389] *See, e.g., infra* note 455 and accompanying text.

[390] *See supra* note 112 and accompanying text.

[391] In addition, as discussed in Section II.G.2.d, the proposed rules would permit a registrant, if actual reported data is not reasonably available, to use a reasonable estimate of its GHG emissions for its fourth fiscal quarter, together with actual, determined GHG emissions data for the first three fiscal quarters, as long as the registrant promptly discloses in a subsequent filing any material difference between the estimate used and the actual, determined GHG emissions data for the fourth fiscal quarter. *See* proposed 17 CFR 229.1504(e)(4)(i). This proposed provision should also help mitigate the GHG emissions compliance burden for registrants.

[392] *See* proposed 17 CFR 229.1500(g).

[393] In Feb. 2013 the GHG Protocol amended the required greenhouse gas inventory list to align with the seven gases required by the Kyoto Protocol (consistent with the proposed definition of greenhouse gases). *See* GHG Protocol, *Required Greenhouse Gases in Inventories: Accounting and Reporting Standard Amendment* (Feb. 2013), *available at https://www.ghgprotocol.org/sites/default/files/ghgp/NF3-Amendment_052213.pdf.* Nevertheless, the GHG Protocol's Corporate Accounting and Reporting Standard, which was updated in 2015, continues to refer to only six greenhouse gases. We believe the common understanding of the GHG Protocol's Corporate Accounting and Reporting Standard is that the earlier amendment (reflecting seven gases) applies despite the subsequent 2015 update to the standard.

[394] *See* UN Framework Convention on Climate Change (''UNFCCC'')—*Reporting requirements* (last visited Nov. 4, 2021), *available at https://unfccc.int/process-and-meetings/transparency-and-reporting/reporting-and-review-under-the-convention/greenhouse-gas-inventories-annex-i-parties/reporting-requirements.* The Kyoto Protocol is the international agreement linked to the UNFCCC. *See also* U.S. Energy Information Administration—*Where greenhouse gases come from* (last updated May 21, 2021), *available at https://www.eia.gov/energyexplained/energy-and-the-environment/where-greenhouse-gases-come-from.php;* and EPA—*Overview of Greenhouse Gases* (last visited Nov. 4, 2021), *available at https://www.epa.gov/ghgemissions/overview-greenhouse-gases.*

[395] *See* proposed 17 CFR 229.1500(h).

[396] *See* proposed 17 CFR 229.1500(h)(1).

[397] *See* proposed 17 CFR 229.1500(h)(2).

[398] Sources of emissions can include transportation, electricity production, industrial processes, commercial and residential use, agriculture, and land use changes (including deforestation). *See, e.g.,* EPA, *Sources of Greenhouse Gas Emissions,* available at *https://www.epa.gov/ghgemissions/sources-greenhouse-gas-emissions.*).

[399] *See* proposed 17 CFR 229.1500(p).

[400] *See* proposed 17 CFR 229.1500(q).

[401] *See* proposed 17 CFR 229.1500(r).

[402] *See supra* note 113. The EPA requires the disclosure of direct GHG emissions primarily from large industrial sources as well as emissions from fuel and industrial gas suppliers and CO_2 injection sites in the United States. *See* EPA, *Greenhouse Gas Reporting Program,* available at *https://www.epa.gov/ghgreporting.*

[403] *See* proposed 17 CFR 229.1504(b)(1). We discuss the setting of a registrant's organizational and operational boundaries in Section II.G.2. below.

[404] *See* proposed 17 CFR 229.1504(c)(1). As discussed in greater detail below, for many companies, these emissions may be material for assessing the companies' exposure to climate-related risks, particularly transition risks, and their strategy to reduce their carbon footprint in the face of regulatory, policy, and market constraints. *See infra* Section II.G.1.b.

(CO_2), methane (CH_4), nitrous oxide (N_2O), nitrogen trifluoride (NF_3), hydrofluorocarbons (HFCs), perfluorocarbons (PFCs), and sulfur hexafluoride (SF_6)) and in the aggregate.[405] By requiring the disclosure of GHG emissions both disaggregated by the constituent greenhouse gases and in the aggregate, investors could gain decision-useful information regarding the relative risks to the registrant posed by each constituent greenhouse gas in addition to the risks posed by its total GHG emissions by scope. For example, if a government targets reduction of a specific greenhouse gas, knowing that a registrant has significant emissions of such gas would provide insight into potential impacts on the registrant's business.[406] Because measuring the constituent greenhouse gases is a necessary step in calculating a registrant's total GHG emissions per scope, the proposed disaggregation by each constituent greenhouse gas should not create significant additional burdens.

Consistent with the GHG Protocol, the proposed rules would require a registrant to express each scope of its GHG emissions in terms of carbon dioxide equivalent (''CO_2e'').[407] CO_2e is the common unit of measurement used by the GHG Protocol to indicate the global warming potential (''GWP'')[408] of each greenhouse gas, expressed in terms of the GWP of one unit of carbon dioxide (CO_2).[409] Requiring a standard unit of measurement for GHG emissions, rather than different units of measurement for the different greenhouse gases, should simplify the disclosure for investors and enhance its comparability across registrants with different types of GHG emissions.

For all scopes of GHG emissions, the proposed rules would require a registrant to disclose GHG emissions data in gross terms, excluding any use of purchased or generated offsets.[410] Because the value of offsets can vary depending on restrictions that are or may be imposed by regulation or market conditions, disclosing GHG emissions data in this manner would allow investors to assess the full magnitude of climate-related risk posed by a registrant's GHG emissions and the registrant's plans for managing such risk. This proposed approach also is consistent with the approach taken by the GHG Protocol.[411]

Commenters generally supported requiring disclosure of a registrant's Scope 1 and Scope 2 emissions, with many also supporting disclosure of Scope 3 emissions.[412] A common reason asserted by commenters for requiring GHG emissions disclosure is that quantitative data, such as GHG emissions data, is useful for assessing a registrant's exposure to climate-related risks and accordingly its ability to transition to a lower carbon economy.[413] Investors that are currently using GHG emissions data do so because the data provides insight into a registrant's exposure to climate-related risks, and transition risks in particular—risks that have implications for a registrant's financial condition and results of operations.[414] An increasing number of investors have identified GHG emissions as material to their investment decision-making and are either purchasing this information from third-party providers or engaging with companies to obtain the information directly. In each situation, there is a lack of consistency, comparability, and reliability in those data that our proposal seeks to address.[415]

[405] *See* proposed 17 CFR 229.1504(a)(1).

[406] For example, the White House has recently launched an initiative to reduce methane emissions in the United States. *See* the White House Office of Domestic Climate Policy, *U.S. Methane Emissions Reductions Action Plan* (Nov. 2021), available at *https://www.whitehouse.gov/wp-content/uploads/2021/11/US-Methane-Emissions-Reduction-Action-Plan-1.pdf.*

[407] *See id.*

[408] The proposed rules would define global warming potential to mean a factor describing the global warming impacts of different greenhouse gases. It is a measure of how much energy will be absorbed in the atmosphere over a specified period of time as a result of the emission of one ton of a greenhouse gas, relative to the emissions of one ton of carbon dioxide (CO_2). *See* proposed 17 CFR 229.1500(f).

[409] *See* proposed 17 CFR 229.1500(d).

[410] *See* proposed 17 CFR 229.1504(a)(2). The proposed rules would define carbon offsets to represent an emissions reduction or removal of greenhouse gases in a manner calculated and traced for the purpose of offsetting an entity's GHG emissions. *See* proposed 17 CFR 229.1500(a).

[411] *See* GHG Protocol, *Corporate Accounting and Reporting* Standard, Chapter 9.

[412] *See, e.g.,* letters from Actual Systems, Inc.; Adobe Inc.; AICPA; Curt Albright (June 13, 2021); AllianceBernstein; Alphabet *et al.;* Amalgamated Bank; Americans for Financial Reform Education Fund; Andrew Behar; Apple; Ted Atwood; Baillie Gifford; Bank of America Corporation; BlackRock; Bloomberg, LP; Blueprint Financial; BNP Paribas; Rob Bonta, California Attorney General *et al.*; Boston Common Asset Management; BSR; CalPERS; CALSTRS; Calvert Research and Management; Carbon4 Finance (June 14, 2021); Carbon180 (June 13, 2021); Carbon Tracker Initiative; Cardano Risk Management Ltd.; Carolyn Kohoot; CDP NA; Center for American Progress; Center for Climate and Energy Solutions; Center for Law and Social Policy and a New Deal for Youth (June 15, 2021); Ceres *et al.*; Certified B Corporations; Chevron; Christopher Lish; Clean Yield Asset Management; Climate Advisers; Climate Governance Initiative Climate Risk Disclosure Law and Policy Lab; Climate Policy Ocean Conservancy (June 14, 2021); Coalition on Material Emissions Transparency (COMET) (June 10, 2021); Confluence Philanthropy; Consumer Federation of America; Crake Asset Management (June 4, 2021); Credit Suisse (June 11, 2021); Daniel Cain; Katherine DiMatteo; Domini Impact Investments LLC; Douglas Hileman Consulting, LLC; Dow (June 4, 2021); Dynamhex Inc.; Energy Infrastructure Council (June 14, 2014); Environmental Bankers Association; E2; E3G; ERM CVS; Etsy, Inc.; FAIRR Initiative; First Affirmative Financial Network; Regenerative Crisis Response Committee; the Forum for Sustainable and Responsible Investment; Friends of the Earth, Amazon Watch, and RainForect Action Network; Generation Investment Management LLP (June 14, 2021); Georgetown Climate Center (June 14, 2021); George S. Georgiev; Emmanuelle Haack; Hannon Armstrong; Hermes Equity Ownership Services Limited; HP, Inc.; IHS Markit; Impact Investors, Inc.; Impax Asset Management; Institute for Governance and Sustainable Development; Institute for Market Transformation; Interfaith Center on Corporate Responsibility; International Corporate Governance Network; Invesco; Investment Consultants Sustainability Working Group-U.S.; Investor Advocates for Social Justice (June 14, 2021); Janice Shade (June 22, 2021); Japanese Bankers Association; Keramida *et al.*; Majedie Asset Management; Manifest Climate; Mercy Investment Services, Inc.; Microsoft Corporation; Miller/Howard Investments; Mirova US LLC; Morningstar, Inc.; MSCI Inc.; Natural Resources Defense Council; NEI Investments; Newground Social Investment (June 14, 2021); New York City Comptroller; New York State Society of Certified Public Accountants; Nia Impact Capital (June 14, 2021); Norges Bank Investment; NY State Comptroller; Oxfam America (June 13, 2021); Paradice Investment Management; PayPal Holdings, Inc.; Pension Investment Association of Canada (June 14, 2021); Michael S. Pieciak, Vermont Commissioner of Financial Regulation (June 14, 2021); PRI (Consultation Response); Private Equity Stakeholder Project (June 14, 2021); Public Citizen and 57 other signatories (June 14, 2021); Publish What you Pay (US) (June 13, 2021); Revolving Door Project; RMI; Salesforce.com, Inc.; SASB; Schroder Investment Management North America (June 14, 2021); Seventh Generation Interfaith, Inc.; State Street Global Advisors; Maria Stoica; Stray Dog Capital; Sunrise Bay Area; Sustainable Inclusive Solutions (June 13, 2021); Terra Alpha Investor Group; the organization Green America and 14,600 Individual Americans (June 14, 2021); TotalEnergies; Trillium Asset Management; Union of Concerned Scientists (June 14, 2021); Unovis Asset Management (June 11, 2021); Value Balancing Alliance; Vert Asset Management LLC; Wellington Management Co.; Wespath Benefits and Investments; William and Flora Hewlett Foundation; W.K. Associates, Inc. (June 14, 2021); World Benchmarking Alliance; and WBCSD.

[413] *See, e.g.,* letters from Calvert Research and Management; Ceres *et al.*; NY State Comptroller; and SASB.

[414] *See, e.g.,* letters from Bloomberg, LP (stating that GHG emissions are critical components of any climate-related financial disclosure scheme, and that understanding the emissions contributions of a company is an important factor for understanding how financially vulnerable they may be to shifts in regulation, technology, and markets during any transition to a lower-carbon economy); CalPers (indicating the use of GHG emissions data by asset managers to evaluate potential transition risks); and Credit Suisse (supporting mandatory disclosure of Scopes 1, 2, and 3 emissions for key industries as such information is critical for financial market participants to have a better understanding of their total climate-related exposure to the highest emitting sectors).

[415] *See, e.g.,* letters from CALSTRS (indicating the use by asset managers of third-party derived climate data, the expense and lack of consistency regarding such data, and the need for publicly available climate data so that the commenter may more efficiently and cost-effectively allocate capital to lower climate risk assets in line with its investment

Continued

Some of these commenters supported requiring disclosure of Scope 1 emissions at the individual greenhouse gas level.[416] Although commenters noted an increase in the voluntary reporting of climate-related disclosure, several also stated that significant gaps remain in the disclosure, particularly regarding Scope 3 emissions, which, for certain industries, can comprise a majority of GHG emissions.[417]

Many commenters recommended basing any GHG emissions disclosure requirement on the GHG Protocol.[418] Several of these commenters stated that the GHG Protocol's framework for reporting GHG emissions, delineated as Scopes 1, 2, and 3 emissions, has become the globally-accepted standard used by numerous companies for reporting their GHG emissions.[419] Commenters also indicated that a mandatory standard for reporting GHG emissions based on the GHG Protocol would help in producing consistent, comparable, and reliable climate-related information for investors.[420] Some commenters also stated that mandating GHG emissions pursuant to a standardized approach, such as the GHG Protocol, would help mitigate instances of greenwashing.[421]

Some commenters indicated that the Commission should mandate disclosure of only Scopes 1 and 2 emissions.[422] Other commenters suggested limiting the mandatory disclosure of Scope 3 emissions to registrants in certain industries,[423] larger registrants, or when a registrant's Scope 3 emissions comprise 40 percent of its total emissions.[424] These commenters pointed to difficulties in obtaining the necessary data from third parties and methodological uncertainties as reasons for limiting or not requiring disclosure of Scope 3 emissions. Other commenters and research support a requirement for disclosure of Scope 3 emissions that is independent of an individual company's materiality assessment.[425]

A few commenters stated that the Commission should require the disclosure of only Scope 1 emissions.[426] One commenter stated that this approach would be consistent with the Greenhouse Gas Reporting Program overseen by the EPA, which they stated requires the tracking of facility-level Scope 1 emissions from ''large greenhouse gas emitters.'' [427] Another commenter opposed a requirement to disclose any GHG emissions, asserting that GHG emissions do not serve as adequate indicators for the actual risks faced by a registrant.[428]

We agree with the many commenters that indicated that GHG emissions disclosure could provide important information for investors to help them evaluate the climate-related risks faced by registrants and to understand better how registrants are planning to mitigate or adapt to those risks.[429] The proposed GHG emissions disclosures could be important to an investor's understanding of other disclosures that would be required by the proposed rules, such as disclosure of the likely impacts of climate-related risks as well as any targets and goals disclosure.[430]

We propose requiring disclosure of registrants' Scopes 1 and 2 emissions because, as several institutional investor commenters stated, investors need and many investors currently use this information to make investment or voting decisions.[431] One of those commenters stated that GHG emissions information serves as the starting point for transition risk analysis because it is quantifiable and comparable across companies and industries.[432] The commenter, an institutional investor, indicated that it uses GHG emissions data to rank companies within industries based on their GHG emissions intensity to better assess transition risk exposure of companies in its portfolio and make informed investment decisions. This commenter also indicated that Scopes 1 and 2 emissions information is more broadly available than Scope 3 emissions data because of the challenges of collecting the latter data.

As previously mentioned, several large institutional investors and financial institutions, which collectively have trillions of dollars in assets under management, have formed initiatives and made commitments to achieve a net-zero economy by 2050, with interim targets set for 2030.[433] These initiatives further support the notion that investors currently need and use GHG emissions data to make informed investment decisions. These investors and financial institutions are working to reduce the GHG emissions of companies in their portfolios or of their counterparties and need GHG emissions data to evaluate the progress made regarding their net-zero commitments and to assess any

objectives); Credit Suisse (stating that the lack of consistent and reliable climate-related data has created significant challenges in the ability of financial market participants to adequately assess and compare the performance of reporting companies, as well as efficiently allocate capital towards low-carbon solutions); and Norges Bank Investment Management (indicating their reliance on companies' climate-related data to assess their exposure to the effects of climate and how they manage climate-related risks and opportunities, and stating that the scope and quality of companies' climate-related disclosures varies significantly and that their climate-related data is often incomplete and/or not comparable).

[416] *See, e.g.,* letters from Amazon Watch and Rainforest Action Network; Dimensional; Friends of the Earth; and ICCR.

[417] *See, e.g.,* letters from Ceres (''In land-intensive sectors, deforestation, forest degradation, and land-use change are important financial risks associated with climate change. In these sectors—for example food and forest management—currently Scope 3 GHG emissions are not regularly disclosed, despite comprising upwards of 90% of emissions from companies.''); *see also* letters from Apple (stating that Scope 3 emissions ''represent the overwhelming majority of most companies' carbon footprint and are therefore critical to include''); Natural Resources Defense Council; NY State Comptroller; and Teachers Insurance and Annuity Association of America.

[418] *See, e.g.,* letters from Apple; bp; Carbon Tracker Initiative; Consumer Federation of America; ERM CVS; Ethic Inc.; First Affirmative Financial Network; Regenerative Crisis Response Committee; MSCI, Inc.; Natural Resources Defense Council; New York State Society of Certified Public Accountants; Paradice Investment Management; Stray Dog Capital; and Huw Thomas.

[419] *See, e.g.,* letters from ERM CVS; and Natural Resources Defense Council.

[420] *See, e.g.,* letters from BNP Paribas; Natural Resources Defense Council; and New York State Society of Certified Public Accountants.

[421] *See, e.g.,* letters from BNP Paribas; Center for Law and Social Policy (June 15, 2021); and Dimensional Fund Advisors. *See also* Section IV.C below for further discussion of the practice of greenwashing.

[422] *See, e.g.,* letters from Acadian Asset Management LLC; American Bankers Association; American Exploration Production Council (June 11, 2021); Seema Arora; Bank Policy Institute; Biotechnology Innovation Organization; Business Roundtable (June 11, 2021); Cisco (June 11, 2021); Conning (June 11, 2021); CPP Investments; Decatur Capital Management; Dimensional Fund Advisors; Ethic Inc.; Freeport-McMoran (June 11, 2021); Harvard Management Company; Information Technology Industry Council; Institute of International Bankers; Investment Adviser Association; Manulife Investment Management; PGIM; PIMCO; Real Estate Roundtable (June 9, 2021); Matthew Roling and Samantha Tirakian; SIFMA Asset Management Group; the Vanguard Group, Inc.; and Walmart, Inc.

[423] *See, e.g.,* letters from Teachers Insurance and Annuity Association of America (recommending requiring Scope 3 disclosure from issuers in the financial, energy, transportation, materials and buildings, and agriculture, food, and forest products sectors; and Sens. Schatz and Whitehouse (recommending requiring Scope 3 disclosure for financed emissions).

[424] *See* letter from Catavento Consultancy.

[425] *See, e.g.,* letters from Uber Technologies (Apr. 27, 2021); and Americans for Financial Reform Education Fund. *See also* TCFD, *Guidance on Metrics, Targets, and Transition Plans* (stating that 47% of respondents surveyed supported disclosure of Scope 3 GHG emissions independent of a materiality assessment).

[426] *See* letters from American Petroleum Institute; Virginia Harper Ho; and David Marriage.

[427] *See* letter from American Petroleum Institute.

[428] *See* letter from Richard Love.

[429] *See supra* notes 412 and 413.

[430] *See supra* Section II.C and *infra* Section II.I.

[431] *See, e.g.,* letters from PIMCO; State Street Global Advisors; Trillium Asset Management; and Wellington Management Co.

[432] *See* Wellington Management Co.

[433] *See supra* Section I.C.1 (discussing, in particular, Climate Action 100+ and GFANZ).

associated potential asset devaluation or loan default risks.[434] A company's GHG emissions footprint also may be relevant to investment or voting decisions because it could impact the company's access to financing or signal potential changes in its financial planning as governments, financial institutions, and other investors make demands to reduce GHG emissions.

We also agree with commenters that basing the Commission's proposed GHG emissions disclosure rules on concepts used in the GHG Protocol could help provide investors with consistent, comparable, and reliable information about a registrant's GHG emissions.[435] In this regard, we note that several studies have found that GHG emissions data prepared pursuant to the GHG Protocol have become the most commonly referenced measurements of a company's exposure to climate-related risks.[436]

However, we are not proposing to adopt all of the features of the GHG Protocol into the Commission's proposed climate-related disclosure rules. As explained in greater detail below, in one significant respect the proposed rules differ from the approach taken by the GHG Protocol regarding the methodology that a registrant would be required to use when calculating its GHG emissions. This difference better suits the U.S. financial reporting regime and the needs of investors.[437] We recognize that the methodologies pertaining to the measurement of GHG emissions, particularly Scope 3 emissions, are evolving. While we expect that many registrants would choose to follow the standards and guidance provided by the GHG Protocol when calculating their GHG emissions, the proposed rules would not require registrants to do so. Allowing for some flexibility in the choice of GHG emissions methodologies would permit registrants to adapt to new approaches, such as those pertaining to their specific industry, as they emerge.

b. The Treatment of Scopes 1 and 2 Emissions Compared to Scope 3 Emissions

We are proposing to require all registrants to disclose their Scopes 1 and 2 emissions. Those types of emissions result directly or indirectly from facilities owned or activities controlled by a registrant. The relevant data for calculating Scopes 1 and 2 emissions should be reasonably available to registrants, and the relevant methodologies are fairly well-developed. Registrants with large stationary sources of emissions already report Scope 1 emissions data to the EPA, and the EPA provides detailed methodologies for a range of industries with significant Scope 1 emissions.[438] The EPA also provides detailed guidance for the calculation of Scope 2 emissions, which, although classified as ''indirect emissions,'' are generated by direct activities of the registrant in using purchased energy.[439]

Unlike Scopes 1 and 2 emissions, Scope 3 emissions typically result from the activities of third parties in a registrant's value chain[440] and thus collecting the appropriate data and calculating these emissions would potentially be more difficult than for Scopes 1 and 2 emissions. At the same time, in many cases Scope 3 emissions disclosure may be necessary to present investors a complete picture of the climate-related risks—particularly transition risks—that a registrant faces and how GHG emissions from sources in its value chain, which are not included in its Scopes 1 and 2 emissions, may materially impact a registrant's business operations and associated financial performance. Scope 3 emissions can augment the information provided in Scopes 1 and 2 emissions and help to reflect the total emissions associated with a registrant's operations, including inputs from upstream activities, such as those of its suppliers, and outputs from downstream activities, such as those involving the distribution, use, and disposal of a registrant's products or services.[441]

Scope 3 emissions are indirect, but registrants can and do take steps to limit Scope 3 emissions and the attendant risks. Although a registrant may not own or control the operational activities in its value chain that produce Scope 3 emissions, it nevertheless may influence those activities, for example, by working with its suppliers and downstream distributors to take steps to reduce those entities' Scopes 1 and 2 emissions (and thus help reduce the registrant's Scope 3 emissions) and any attendant risks. As such, a registrant may be able to mitigate the challenges of collecting the data required for Scope 3 disclosure.[442] Such data may reveal changes in a registrant's Scope 3 emissions over time that could be informative for investors in discerning how the registrant is managing transition risks. For example, a registrant could seek to reduce the potential impacts on its business of its upstream emissions by choosing to purchase from more GHG emission-efficient suppliers or by working with existing suppliers to reduce emissions. A registrant could also seek to reduce the potential impacts on its business of downstream emissions by producing products that are more energy efficient or involve less GHG emissions when consumers use them, or by contracting with distributors that use shorter transportation routes. Being able to compare Scope 3 emissions over time could thus be a valuable tool for investors in tracking a registrant's progress in mitigating transition and other climate-related risks.

To balance the importance of Scope 3 emissions with the potential relative difficulty in data collection and measurement, the proposed rules would require disclosure of Scope 3 emissions only if those emissions are material, or if the registrant has set a GHG emissions reduction target or goal that includes its

[434] *See, e.g.,* Climate Action 100+, *The Three Asks.*

[435] *See supra* note 420.

[436] *See, e.g.,* Kauffmann, C., C. Tébar Less and D. Teichmann (2012), *Corporate Greenhouse Gas Emission Reporting: A Stocktaking of Government Schemes,* OECD Working Papers on International Investment, 2012/01, OECD Publishing, at 8, *available at http://dx.doi.org/10.1787/5k97g3x674lq-en* (''For example, the use of scope 1, 2, 3 to classify emissions as defined by the GHG Protocol has become common language and practice today.'').

[437] *See infra* Section II.G.2 (discussing the proposed treatment for determining ownership or control for the purpose of setting a registrant's organizational boundaries when measuring its Scopes 1 and 2 emissions).

[438] *See* EPA, *Direct Emissions from Stationary Combustion Sources* (Dec. 2020), available at *https://www.epa.gov/sites/default/files/2020-12/documents/stationaryemissions.pdf.*

[439] *See* EPA, *Indirect Emissions from Purchased Electricity* (Dec. 2020), available at *https://www.epa.gov/sites/default/files/2020-12/documents/electricityemissions.pdf.*

[440] As previously mentioned, the proposed rules would define a registrant's value chain to mean the upstream and downstream activities related to a registrant's operations. Upstream activities include activities that relate to the initial stages of producing a good or service (*e.g.,* materials sourcing, materials processing, and supplier activities). Downstream activities include activities that relate to processing materials into a finished product and delivering it or providing a service to the end user (*e.g.,* transportation and distribution, processing of sold products, use of sold products, end of life treatment of sold products, and investments). *See* proposed 17 CFR 229.1500(t).

[441] *See, e.g.,* letter from Wellington Management Co.

[442] *See, e.g.,* letter from Apple (referencing its *2021 Environmental Progress Report,* available at *https://www.apple.com/environment/pdf/Apple_Environmental_Progress_Report_2021.pdf,* which states that 109 suppliers across 24 countries have committed to manufacturing Apple products with 100 percent renewable energy, and indicating Apple's development of detailed life cycle assessment models, which help the company identify its top product component contributors of carbon emissions and facilitate its providing a comprehensive account of its relevant Scope 3 emissions).

Scope 3 emissions.[443] As explained in greater detail below, this latter proposed disclosure requirement could assist investors in tracking the progress of the registrant toward reaching the target or goal so that investors can better understand potential associated costs.[444]

Consistent with the Commission's definition of ''material'' and Supreme Court precedent, a registrant would be required to disclose its Scope 3 emissions if there is a substantial likelihood that a reasonable investor would consider them important when making an investment or voting decision.[445] In articulating this materiality standard, the Supreme Court recognized that ''[d]oubts as to the critical nature'' of the relevant information ''will be commonplace.'' But ''particularly in view of the prophylactic purpose'' of the securities laws,'' and ''the fact that the content'' of the disclosure ''is within management's control, it is appropriate that these doubts be resolved in favor of those the statute is designed to protect,'' namely investors.[446]

When recommending that the Commission require the disclosure of Scope 3 emissions, some commenters indicated that Scope 3 emissions represent the relatively large source of overall GHG emissions for many companies.[447] Given their relative magnitude, we agree that, for many registrants, Scope 3 emissions may be material to help investors assess the registrants' exposure to climate-related risks, particularly transition risks,[448] and whether they have developed a strategy to reduce their carbon footprint in the face of regulatory, policy, and market constraints.[449]

Scope 3 emissions information may be material in a number of situations to help investors gain a more complete picture of the transition risks to which a registrant may be exposed. In certain industries, a transition to lower-emission products or processes may already be underway, triggered by existing laws or regulations, changes in weather, policy initiatives, a shift in consumer preferences, technological changes, or other market forces, such that financial risks are reasonably foreseeable for registrants in those industries based on the emissions in their value chain. For example, some registrants may need to allocate capital to invest in lower emissions equipment. Investors thus need and use information about the full GHG emissions footprint and intensity of a registrant to determine and compare how exposed a registrant is to the financial risks associated with any transition to lower-emission products.

For example, in the automobile industry, the vast majority of car manufacturers' GHG emissions footprint comes from tailpipe emissions of cars driven by customers, as compared to the emissions from manufacturing the cars.[450] There is already a transition underway to reduce tailpipe emissions through the adoption of stricter fuel efficiency regulations [451] and by governmental initiatives that encourage the manufacture and demand for electric vehicles.[452] Demand for electric vehicles is increasing in the United States and globally,[453] and leading automobile manufacturers have announced plans to increase the manufacture of electric vehicles, with many setting commitments to manufacture all-electric fleets or achieve net-zero emissions.[454] This transition raises financial risks for automobile manufacturers, which can be gauged, in part, by their Scope 3 emissions. Investors can use Scope 3 emissions data concerning a car manufacturer's suppliers and the use of its sold products to assess whether a particular manufacturer is taking steps to mitigate or adapt to the risks posed by a transition to lower emission vehicles.

Changes in requirements by financial institutions and institutional investors can present similar financial risks for companies. As many financial institutions and investors begin to set their own GHG emissions reduction goals, they may consider the total GHG emissions footprint of companies that they finance or invest in to build portfolios to meet their goals.[455] Financial institutions and investors may focus on Scopes 1 and 2 emissions for companies in some industries, particularly for industries in which Scopes 1 and 2 represent the majority of companies' total GHG emissions footprint. For other industries, however, Scope 3 emissions represent a relatively significant portion of companies' total GHG footprint, and therefore may reflect a more complete picture of companies' exposure to transition risks than Scopes 1 and 2 emissions alone. For oil and gas product manufacturers, for example, Scope 3 emissions are likely to be material and thus necessary to an

[443] *See* proposed 17 CFR 229.1504(c)(1). As explained below, we are also proposing a safe harbor for Scope 3 disclosures. *See infra* Section II.G.3.

[444] *See infra* note 461 and accompanying text.

[445] *See supra* note 209.

[446] *TSC Industries, Inc. v Northway,* 426 U.S. at 448.

[447] *See, e.g.,* letters from Apple; and WK Associates.

[448] *See, e.g.,* letter from Wellington Management Co.

[449] *See* Eric Rosenbaum, *Climate experts are worried about the toughest carbon emissions for companies to capture* (Aug. 18, 2021) (''Scope 3 carbon emissions, or those not part of operations or under direct control, represent the majority of the carbon footprint for most companies, in some cases as high as 85% to 95%''), *available at https://www.cnbc.com/2021/08/18/apple-amazon-exxon-and-the-toughest-carbon-emissions-to-capture.html#:~:text=Scope%203%20carbon%20emissions%2C%20or,as%2085%25%to%2095%25. See also* MSCI, *Emissions: Seeing the Full Picture* (Sept. 17, 2020) (''For some companies and industries, Scope 3 emissions dominate the overall carbon footprint. For example, the Scope 3 emissions of the integrated oil and gas industry . . . are more than six times the level of its Scope 1 and 2 emissions.''), *available at https://www.msci.com/www/blog-posts/scope-3-carbon-emissions-seeing/02092372761;* letter from WK Associates, Inc. (June 14, 2021) (stating that Scope 3 emissions account for approximately 70–90% of lifecycle emissions from oil products and 60–85% of those from natural gas, according to the International Energy Agency).

[450] *See, e.g.,* TCFD, *Guidance on Metrics, Targets, and Transition Plans* (Oct. 2021), Appendix 1, Figure A1–1 (*Importance of Scope 3 GHG Emissions in Certain Sectors*) (showing that, for the automobiles and components sector, the majority of GHG emissions result from downstream product use), available at *https://assets.bbhub.io/company/sites/60/2021/07/2021-Metrics_Targets_Guidance-1.pdf.*

[451] *See, e.g.,* Coral Davenport, *E.P.A. Announces Tightest-Ever Auto Pollution Rules,* N.Y. Times, Dec. 20, 2021, available at *https://www.nytimes.com/2021/12/20/climate/tailpipe-rules-climate-biden.html?searchResultPosition=25* (reporting that the EPA announced strengthened limits on pollution from automobile tailpipes). In addition, more than a dozen states have adopted low emission vehicle standards. *See* California Air Resources Board, *States that have Adopted California's Vehicle Standards under Section 177 of the Federal Clean Air Act,* available at *https://ww2.arb.ca.gov/resources/documents/states-have-adopted-californias-vehicle-standards-under-section-177-federal.*

[452] *See, e.g.,* Catherine Lucey and Andrew Duehren, *Biden Touts Build Back Better in Meeting With CEOs,* Wall Street Journal, Jan. 26, 2022, available at *https://www.wsj.com/articles/biden-touts-build-back-better-in-meeting-with-ceos-11643227677?mod=Searchresults_pos1&page=* (reporting efforts to obtain Federal tax incentives to promote the use of electric and hydrogen-power vehicles).

[453] *See* Jack Ewing, *Sales of Electric Vehicles Surpass Diesel in Europe, a First,* N.Y. Times, Jan. 17, 2022 (stating that sales of battery-powered cars soared in Europe, the United States, and China in 2021), available at *https://www.nytimes.com/2022/01/17/business/electric-vehicles-europe.html?searchResultPosition=1.*

[454] *See, e.g.,* Tom Krisher and Aamer Madhani, *US automakers pledge huge increase in electric vehicles,* AP News, Aug. 5, 2021, available at *https://apnews.com/article/technology-joe-biden-business-environment-and-nature-economy-88fe6ca8e333f3d00f6d2e98c6652cea* (reporting that General Motors aspires to sell only electric passenger vehicles by 2035 and Ford and Stellantis (formerly Fiat Chrysler) each expect that 40% of global sales to be electric vehicles by 2030); *see also https://www.caranddriver.com/news/g35562831/ev-plans-automakers-timeline/*; and Jim Motavalli, *Every Automaker's EV Plans Through 2035 And Beyond,* Forbes, Oct. 4, 2021, available at *https://www.forbes.com/wheels/news/automaker-ev-plans/.*

[455] *See supra* Section I.C.1.

understanding of a registrant's climate-related risks.

When assessing the materiality of Scope 3 emissions, registrants should consider whether Scope 3 emissions make up a relatively significant portion of their overall GHG emissions. While we are not proposing a quantitative threshold for determining materiality, we note that some companies rely on, or support reliance on, a quantitative threshold such as 40 percent when assessing the materiality of Scope 3 emissions.[456] However, even when Scope 3 emissions do not represent a relatively significant portion of overall GHG emissions, a quantitative analysis alone would not suffice for purposes of determining whether Scope 3 emissions are material. Consistent with the concept of materiality in the securities laws, this determination would ultimately need to take into account the total mix of information available to investors, including an assessment of qualitative factors. Accordingly, Scope 3 emissions may make up a relatively small portion of a registrant's overall GHG emissions but still be material where Scope 3 represents a significant risk, is subject to significant regulatory focus, or ''if there is a substantial likelihood that a reasonable [investor] would consider it important.'' [457] Moreover, if a materiality analysis requires a determination of future impacts, *i.e.,* a transition risk yet to be realized, then both the probability of an event occurring and its magnitude should be considered. Even if the probability of an adverse consequence is relatively low, if the magnitude of loss or liability is high, then the information in question may still be material.

If a registrant determines that its Scope 3 emissions are not material, and therefore not subject to disclosure, it may be useful to investors to understand the basis for that determination. Further, if a registrant determines that certain categories of Scope 3 emissions are material, registrants should consider disclosing why other categories are not material. If, however, Scope 3 emissions are material, then understanding the extent of a registrant's exposure to Scope 3 emissions, and the choices it makes regarding them, would be important for investors when making investment or voting decisions.

Several commenters stated that disclosure of a registrant's Scope 3 emissions is essential to making an informed investment decision because Scope 3 emissions can indicate a registrant's exposure to climate-related transition risks.[458] For example, if policy changes lead to mandatory emissions reductions or carbon pricing, a registrant with high Scope 3 emissions could experience higher costs in sourcing key inputs. Similarly, if consumer preferences change to favor products that are less carbon intensive, a registrant could see a significant change in demand for its products. Registrants that do not account for these risks, or make suboptimal choices regarding them, could become less profitable in the future than registrants that acknowledge these risks and successfully mitigate them.[459] Thus, Scope 3 emissions disclosure could help convey to investors the potential financial risks facing a company related to any transition to a lower carbon economy. With Scope 3 information disclosed, investors would be able to assess, in conjunction with reported financial information, how GHG emissions impact the registrant's operations as well as its overall business strategy so that they can make more informed investment or voting decisions.[460]

Disclosure of Scope 3 emissions could also highlight instances where a registrant attempts to reduce its total Scopes 1 and 2 emissions by outsourcing carbon intensive activities. For example, a registrant could contract out certain high-emissions production activities so that its own Scope 1 or 2 emissions are lower than a similar company that has retained direct ownership and control over more of its production activities. Thus, Scope 3 emissions reporting could provide greater transparency and help preclude any efforts by registrants to obscure for investors the full magnitude of the climate-related risks associated with their GHG emissions.

The proposed rules would also require a registrant to disclose its Scope 3 emissions if it has set a GHG emissions reduction target or goal that includes Scope 3 emissions.[461] This disclosure requirement would enable investors to understand the scale and scope of actions the registrant may need to take to fulfill its commitment to reduce its Scope 3 emissions and the potential financial impact of that commitment on the registrant. It would also enable an investor to assess the registrant's strategy for meeting its Scope 3 emissions target or goal and its progress towards that target or goal, which may affect the registrant's business.

Scope 3 emissions disclosures would help investors to understand and assess the registrant's strategy. For example, Scope 3 emissions disclosures would allow an investor to better understand how feasible it would be for the registrant to achieve its targets through its current strategy, to track the registrant's progress over time, and to understand changes the registrant may make to its strategy, targets, or goals. Scope 3 emissions disclosures would thus be important to evaluating the financial effects of the registrant's target or goal. In addition, this disclosure could help prevent instances of greenwashing or other misleading claims concerning the potential impact of Scope 3 emissions on a registrant's business because investors, and the market would have access to a quantifiable, trackable metric.

A registrant's Scope 3 emissions disclosure, together with the proposed financial statement metrics, would also enable an investor to assess the efficiency and efficacy of the registrant's actions to achieve its target or goal (*e.g.,* by comparing the registrant's expenditures or other investments in lower carbon transition activities from year to year with any corresponding reduction in its Scope 3 emissions). If a registrant has a relatively ambitious Scope 3 emissions target, but discloses little investment in transition activities in its financial statements and little or no reduction in Scope 3 emissions from year to year, these disclosures could indicate to investors that the registrant may need to make a large expenditure or significant change to its business operations as it gets closer to its target date, or risk missing its target. Both potential outcomes could have financial ramifications for the registrant and, accordingly, investors.

The proposed disclosure requirement should also give investors the ability to evaluate whether a registrant's target or goal and its plan for achieving that target or goal could have an adverse impact on the registrant. For example, an investor might conclude that the financial costs of a registrant's plan would outweigh any benefits to the

[456] *See, e.g.,* letter from Uber Technologies; *see also* TCFD, *Guidance on Metrics, Targets, and Transition Plans,* at note 40, citing SBTi, *SBTi Criteria and Recommendations* (Oct. 2021), available at *https://sciencebasedtargets.org/resources/files/SBTi-criteria.pdf.*

[457] *TSC Industries* v. *Northway,* 426 U.S. at 449.

[458] *See, e.g.,* letters from Confluence Philanthropy; Forum for Sustainable and Responsible Investment; Mirova US LLC; NY City Comptroller; and Wellington Management Co.

[459] *See id.*

[460] For example, registrants that choose to mitigate climate-related risks by undertaking research and development activities to source inputs involving less GHG emissions might incur expenses in the short-term but could achieve potential long-term cost savings by implementing more energy-efficient production processes and avoiding potential penalties imposed by regulation.

[461] *See* proposed 17 CFR 229.1504(c)(1).

business, and factor that into how the registrant's securities fit into the investor's own investment portfolio given the investor's risk tolerance and other investment goals. Thus, the objective of this disclosure is not to drive targets, goals, plans, or conduct, but to provide investors with the tools to assess the implications of any targets, goals, or plans on the registrant in making investment or voting decisions.

This disclosure requirement could also enable investors to better compare firms. For example, two registrants may have the same total GHG emissions and have made the same commitments to reduce total GHG emissions from Scopes 1, 2, and 3 emissions combined. However, if the registrants have different proportions of emissions from Scope 1 and 2 versus Scope 3, investors might determine that there would be different costs and effects for these registrants from their disclosed plans to reduce their overall emissions.

Scope 3 emissions disclosures could also enable investors to better compare registrants' plans to achieve their Scope 3 emissions targets or goals. For example, registrants in the retail industry may have a relatively large portion of their Scope 3 emissions derived from customer travel to the registrant's stores and shipping products or goods to customers or stores. If a registrant in this industry has set Scope 3 emissions targets or goals, in order to meet those targets or goals it may choose to relocate its stores to be closer to public transportation. Another similarly situated registrant may elect to switch to using electric vehicles for shipping. A third similarly situated registrant might elect to take neither action, but instead assume Scope 3 emissions reductions based on customers' change in behavior. Investors could assess the likelihood of each of these three registrants meeting their Scope 3 emissions target or goal—as well as the likely financial and operational impact—which could depend on the amount and type of their Scope 3 emissions. Investors could also compare the potential impacts of these plans on the three different registrants. Without disclosures of the amount and type of Scope 3 emissions, investors would face difficulty assessing the likely impacts of a target or goal that includes Scope 3 emissions on registrants and comparing the relative impacts across registrants.

If required to disclose Scope 3 emissions, a registrant would be required to identify the categories of upstream and downstream activities that have been included in the calculation of its Scope 3 emissions. Consistent with the GHG Protocol,[462] the proposed rules identify several categories of activities that can give rise to Scope 3 emissions. Upstream activities from which Scope 3 emissions might result include:

- A registrant's purchased goods and services;
- A registrant's capital goods;
- A registrant's fuel and energy related activities not included in Scope 1 or Scope 2 emissions;
- Transportation and distribution of purchased goods, raw materials, and other inputs;
- Waste generated in a registrant's operations;
- Business travel by a registrant's employees;
- Employee commuting by a registrant's employees; and
- A registrant's leased assets related principally to purchased or acquired goods or services.[463]

Downstream activities from which Scope 3 emissions might result include:

- Transportation and distribution of a registrant's sold products, goods or other outputs;
- Processing by a third party of a registrant's sold products;
- Use by a third party of a registrant's sold products;
- End-of-life treatment by a third party of a registrant's sold products;
- A registrant's leased assets related principally to the sale or disposition of goods or services;
- A registrant's franchises; and
- Investments by a registrant.[464]

The list of upstream and downstream activities set forth in proposed Item 1500(r) is non-exclusive. If any upstream or downstream activities were significant to the registrant when calculating its Scope 3 emissions, the proposed rules would require it to identify such categories and separately disclose Scope 3 emissions data for each of those categories together with a total of all Scope 3 emissions.[465] For example, an energy company that produces oil and gas products may find that a significant category of activity resulting in Scope 3 emissions relates to the end use of its sold products. A manufacturer might find that a significant category of activities resulting in Scope 3 emissions relate to the emissions of its suppliers in the production of purchased goods or services, the processing of its sold products, or by the fuel consumed by its third-party transporters and distributors of those goods and services and of its sold products. In some cases, the category in which an emissions source belongs may be unclear, or the source might fit within more than one category. In those cases, registrants would need to use their best judgment as to the description of the emissions source and provide sufficient transparency as to the reasoning and methodology to facilitate investor understanding of the emissions category and source.

If required to disclose Scope 3 emissions, a registrant would also be required to describe the data sources used to calculate those emissions, including the use of any of the following:

- Emissions reported by parties in the registrant's value chain, and whether such reports were verified by the registrant or a third party, or unverified;
- Data concerning specific activities,[466] as reported by parties in the registrant's value chain; and
- Data derived from economic studies, published databases, government statistics, industry associations, or other third-party sources outside of a registrant's value chain, including industry averages of emissions, activities, or economic data.[467]

This information is intended to assist investors in assessing the reliability and accuracy of the registrant's Scope 3 emissions disclosure. For example, an investor might find emissions data related to the downstream transportation and distribution of a registrant's sold products more reliable if based on specific distances traveled by the registrant's transportation and distribution partners and company-specific emissions factors rather than estimates of distances traveled based on industry-average data and using national average emission factors. Although we recognize that a registrant may sometimes need to use industry- and national-average data when calculating its Scope 3 emissions, information about the data sources for its Scope 3 emissions would help

[462] See WBCSD and World Resources Institute, Greenhouse Gas Protocol Corporate Value Chain (Scope 3) Accounting and Reporting Standard (Sept. 2011).

[463] *See* proposed 17 CFR 229.1500(r).

[464] *See id.* The ''investments'' category would capture what are commonly referred to as ''financed emissions.''

[465] *See* proposed 17 CFR 229.1504(c)(1).

[466] Activity data refers to a quantitative measure of a level of activity that results in GHG emissions. Depending on the activity, such data could be expressed, for example, as: Liters of fuel consumed; kilowatt-hours of electricity consumed; kilograms of material consumed; kilometers of distance traveled; hours of time operated; square meters of area occupied; kilograms of waste generated; kilograms of product sold; or quantity of money spent. *See* GHG Protocol, *Corporate Value Chain (Scope 3) Accounting and Reporting Standard,* Chapter 7.

[467] *See* proposed 17 CFR 229.1504(c)(2).

investors better understand the risk exposure posed by the registrant's value chain in comparison with other registrants and make more informed investment decisions.

We acknowledge that a registrant's material Scope 3 emissions is a relatively new type of metric, based largely on third-party data, that we have not previously required. We are proposing the disclosure of this metric because we believe capital markets have begun to assign financial value to this type of metric, such that it can be material information for investors about financial risks facing a company. Scope 3 emissions disclosure is an integral part of both the TCFD [468] framework and the GHG Protocol,[469] which are widely accepted. It also has been widely recognized that, for some companies, disclosure of just Scopes 1 and 2 emissions could convey an incomplete, and potentially misleading, picture.[470] We have attempted to calibrate our proposal to balance investors' demand for this information with the current limitations of the Scope 3 emissions data.

We also recognize, as discussed below, that the reporting of Scope 3 emissions may present more challenges than the reporting of Scopes 1 and 2 emissions. But in light of the fact that a GHG emissions reporting regime may be incomplete without the reporting of Scope 3 emissions, we are proposing to include them, with an appropriate transition period and safe harbor, at the outset. Although we have not proposed to exclude specific upstream or downstream activities from the scope of the proposed Scope 3 disclosure requirement, we have limited the proposed disclosure requirement to those value chain emissions that overall are material. We also have not proposed a bright-line quantitative threshold for the materiality determination as suggested by some commenters [471] because whether Scope 3 emissions are material would depend on the particular facts and circumstances, making it difficult to establish a ''one size fits all'' standard.

[468] See, *e.g.,* TCFD, Guidance on Metrics, Targets, and Transition Plans (Oct. 2021), Appendix 1.

[469] *See, e.g.,* GHG Protocol, *Corporate Value Chain (Scope 3) Accounting and Reporting Standard.*

[470] *See, e.g.,* TCFD, *Guidance on Metrics, Targets, and Transition Plans* (Oct. 2021), Appendix 1; and letters from Apple; NY City Comptroller; and Wellington Investment Co.

[471] *See, e.g.,* letter from Catavento Consultancy (stating that Scope 3 emissions disclosure should be mandatory for larger companies and for those in which Scope 3 emissions account for more than 40% of total emissions).

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93. How would investors use GHG emissions disclosures to inform their investment and voting decisions? How would such disclosures provide insight into a registrant's financial condition, changes in financial condition, and results of operations? How would such disclosures help investors evaluate an issuer's climate risk-related exposure? Would such disclosures enable investors to better assess physical risks associated with climate-related events, transition risks, or both types of risks?

94. Should we require a registrant to disclose its GHG emissions both in the aggregate, per scope, and on a disaggregated basis for each type of greenhouse gas that is included in the Commission's proposed definition of ''greenhouse gases,'' as proposed? Should we instead require that a registrant disclose on a disaggregated basis only certain greenhouse gases, such as methane (CH_4) or hydrofluorocarbons (HFCs), or only those greenhouse gases that are the most significant to the registrant? Should we require disaggregated disclosure of one or more constituent greenhouse gases only if a registrant is obligated to separately report the individual gases pursuant to another reporting regime, such as the EPA's greenhouse gas reporting regime or any foreign reporting regime? If so, should we specify the reporting regime that would trigger this disclosure?

95. We have proposed defining ''greenhouse gases'' as a list of specific gases that aligns with the GHG Protocol and the list used by the EPA and other organizations. Should other gases be included in the definition? Should we expand the definition to include any other gases to the extent scientific data establishes a similar impact on climate change with reasonable certainty? Should we require a different standard to be met for other greenhouse gases to be included in the definition?

96. Should we require a registrant to express its emissions data in CO_2e, as proposed? If not, is there another common unit of measurement that we should use? Is it important to designate a common unit of measurement for GHG emissions data, as proposed, or should we permit registrants to select and disclose their own unit of measurement?

97. Should we require a registrant to disclose its total Scope 1 emissions and total Scope 2 emissions separately for its most recently completed fiscal year, as proposed? Are there other approaches that we should consider?

98. Should we require a registrant to disclose its Scope 3 emissions for the fiscal year if material, as proposed? Should we instead require the disclosure of Scope 3 emissions for all registrants, regardless of materiality? Should we use a quantitative threshold, such as a percentage of total GHG emissions (*e.g.,* 25%, 40%, 50%) to require the disclosure of Scope 3 emissions? If so, is there any data supporting the use of a particular percentage threshold? Should we require registrants in particular industries, for which Scope 3 emissions are a high percentage of total GHG emissions, to disclose Scope 3 emissions?

99. Should we require a registrant that has made a GHG emissions reduction commitment that includes Scope 3 emissions to disclose its Scope 3 emissions, as proposed? Should we instead require registrants that have made any GHG emissions reduction commitments, even if those commitments do not extend to Scope 3, to disclose their Scope 3 emissions? Should we only require Scope 3 emissions disclosure if a registrant has made a GHG emissions reduction commitment that includes Scope 3 emissions?

100. Should Scope 3 emissions disclosure be voluntary? Should we require Scope 3 emissions disclosure in stages, *e.g.,* requiring qualitative disclosure of a registrant's significant categories of upstream and downstream activities that generate Scope 3 emissions upon effectiveness of the proposed rules, and requiring quantitative disclosure of a registrant's Scope 3 emissions at a later date? If so, when should we require quantitative disclosure of a registrant's Scope 3 emissions?

101. Should we require a registrant to exclude any use of purchased or generated offsets when disclosing its Scope 1, Scope 2, and Scope 3 emissions, as proposed? Should we require a registrant to disclose both a total amount with, and a total amount without, the use of offsets for each scope of emissions?

102. Should we require a registrant to disclose its Scope 3 emissions for each separate significant category of upstream and downstream emissions as well as a total amount of Scope 3 emissions for the fiscal year, as proposed? Should we only require the disclosure of the total amount of Scope 3 emissions for the fiscal year? Should we require the separate disclosure of Scope 3 emissions only for certain categories of emissions and, if so, for which categories?

103. Should the proposed rules include a different standard for

requiring identification of the categories of upstream and downstream emissions, such as if those categories of emissions are significant to total GHG emissions or total Scope 3 emissions? Are there any other categories of, or ways to categorize, upstream or downstream emissions that a registrant should consider as a source of Scope 3 emissions? For example, should we require a registrant to disclose Scope 3 emissions only for categories of upstream or downstream activities over which it has influence or indirect control, or for which it can quantify emissions with reasonable reliability? Are there any proposed categories of upstream or downstream emissions that we should exclude as sources of Scope 3 emissions?

104. Should we, as proposed, allow a registrant to provide their own categories of upstream or downstream activities? Are there additional categories, other than the examples we have identified, that may be significant to a registrant's Scope 3 emissions and that should be listed in the proposed rule? Are there any categories that we should preclude, *e.g.,* because of lack of accepted methodologies or availability of data? Would it be useful to allow registrants to add categories that are particularly significant to them or their industry, such as Scope 3 emissions from land use change, which is not currently included in the Greenhouse Gas Protocol's Scope 3 categories? Should we specifically add an upstream emissions disclosure category for land use?

105. Should we require the calculation of a registrant's Scope 1, Scope 2, and/or Scope 3 emissions to be as of its fiscal year end, as proposed? Should we instead allow a registrant to provide its GHG emissions disclosures according to a different timeline than the timeline for its Exchange Act annual report? If so, what should that timeline be? For example, should we allow a registrant to calculate its Scope 1, Scope 2, and/or Scope 3 emissions for a 12-month period ending on the latest practicable date in its fiscal year that is no earlier than three months or, alternatively, six months prior to the end of its fiscal year? Would allowing for an earlier calculation date alleviate burdens on a registrant without compromising the value of the disclosure? Should we allow such an earlier calculation date only for a registrant's Scope 3 emissions? Would the fiscal year end calculations required for a registrant to determine if Scope 3 emissions are material eliminate the benefits of an earlier calculation date? Should we instead require a registrant to provide its GHG emissions disclosures for its most recently completed fiscal year one, two, or three months after the due date for its Exchange Act annual report in an amendment to that report?

106. Should we require a registrant that is required to disclose its Scope 3 emissions to describe the data sources used to calculate the Scope 3 emissions, as proposed? Should we require the proposed description to include the use of: (i) Emissions reported by parties in the registrant's value chain, and whether such reports were verified or unverified; (ii) data concerning specific activities, as reported by parties in the registrant's value chain; and (iii) data derived from economic studies, published databases, government statistics, industry associations, or other third-party sources outside of a registrant's value chain, including industry averages of emissions, activities, or economic data, as proposed? Are there other sources of data for Scope 3 emissions the use of which we should specifically require to be disclosed? For purposes of our disclosure requirement, should we exclude or prohibit the use of any of the proposed specified data sources when calculating Scope 3 emissions and, if so, which ones?

107. Should we require a registrant to provide location data for its disclosed sources of Scope 1, Scope 2, and Scope 3 emissions if feasible? If so, should the feasibility of providing location data depend on whether it is known or reasonably available pursuant to the Commission's existing rules (Securities Act Rule 409 and Exchange Act Rule 12b–21)? Would requiring location data, to the extent feasible, assist investors in understanding climate-related risks, and in particular, likely physical risks, associated with a registrant's emissions' sources? Would a requirement to disclose such location data be duplicative of any of the other disclosure requirements that we are proposing?

108. If we require a registrant to provide location data for its GHG emissions, how should that data be presented? Should the emissions data be grouped by zip code separately for each scope? Should the disclosure be presented in a cartographic data display, such as what is commonly known as a ''heat map''? If we require a registrant to provide location data for its GHG emissions, should we also require additional disclosure about the source of the emissions?

c. GHG Intensity

In addition to requiring the disclosure of its GHG emissions in gross terms, the proposed rules would also require a registrant to disclose the sum of its Scopes 1 and 2 emissions in terms of GHG intensity.[472] If required to disclose Scope 3 emissions, a registrant would also be required to separately disclose its Scope 3 emissions in terms of GHG intensity.[473] GHG intensity disclosure should provide context to a registrant's emissions in relation to its business scale (*e.g.,* emissions per economic output). For example, car manufacturer A may generate more emissions in terms of CO_2e than car manufacturer B; however, when analyzing an intensity metric (emissions per unit of production), it becomes apparent that car manufacturer A actually has a lower emission rate per car produced than car manufacturer B, which indicates a registrant's emission efficiency. Because emission efficiency can be a potential indicator of the likelihood of the registrant being impacted by transition risks, such GHG intensity disclosure could provide decision-useful information to investors. In addition, the proposed GHG intensity disclosure would provide a standardized method for presenting such measure of efficiency across registrants, which should facilitate comparability of the registrant's emissions efficiency over time.

The proposed rules would define ''GHG intensity'' (or ''carbon intensity'') to mean a ratio that expresses the impact of GHG emissions per unit of economic value (*e.g.,* metric tons of CO_2e per unit of total revenues, using the registrant's reporting currency) or per unit of production (*e.g.,* metric tons of CO_2e per unit of product produced).[474] For purposes of standardizing the disclosure and facilitating its comparability, we are proposing to require the disclosure of GHG intensity in terms of metric tons of CO_2e per unit of total revenue and per unit of production for the fiscal year.[475] Total revenue is one of the most commonly used and understood financial metrics when investors analyze a registrant's financial results and applies to most registrants (depending on the nature and maturity of the business) and therefore would be a good common denominator for the

[472] *See* proposed 17 CFR 229.1504(d)(1).

[473] *See* proposed 17 CFR 229.1504(d)(2). The proposed safe harbor for Scope 3 emissions disclosure would apply to this proposed GHG intensity metric for Scope 3 emissions. *See infra* Section II.C.3.

[474] *See* proposed 17 CFR 229.1500(i). We derived this proposed definition from the GHG Protocol. *See* GHG Protocol, *A Corporate Accounting and Reporting Standard,* Chapter 9.

[475] *See* proposed 17 CFR 229.1504(d)(1).

intensity calculation. The selected unit of production should be relevant to the registrant's industry to facilitate investor comparison of the GHG intensity of companies within an industry without regard to registrant size. Investors may find such a comparison to be useful to making informed investment decisions to the extent that a registrant within a particular industry that has a lower GHG intensity relative to its peers that face fewer climate-related risks.

If the registrant has no revenue for a fiscal year, it would be required to calculate its GHG intensity with another financial measure (*e.g.,* total assets), with an explanation of why the particular measure was used. Similarly, if the registrant does not have a unit of production, it would be required to calculate its GHG intensity with another measure of economic output, depending on the nature of its business (*e.g.,* data processing capacity, volume of products sold, or number of occupied rooms) with an explanation of why the particular measure was used.[476]

A registrant could also voluntarily disclose other additional measures of GHG intensity, including non-financial measures such as economic output, provided it includes an explanation of the reasons why those particular GHG intensity measures were used and why the registrant believes such measures provide useful information to investors.[477] In all cases, the registrant would be required to disclose the methodology and other information required pursuant to the proposed GHG emissions metrics instructions.[478]

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109. Should we require a registrant to disclose the intensity of its GHG emissions for the fiscal year, with separate calculations for (i) the sum of Scope 1 and Scope 2 emissions and, if applicable (ii) its Scope 3 emissions (separately from Scopes 1 and 2), as proposed? Should we define GHG intensity, as proposed? Is there a different definition we should use for this purpose?

110. Should we require the disclosed GHG intensity to be expressed in terms of metric tons of CO_2e per unit of total revenue, as proposed? Should we require a different financial measure of GHG intensity and, if so, which measure? For example, should GHG intensity be expressed in terms of metric tons of CO_2e per unit of total assets?

111. Should we require the disclosed GHG intensity to be expressed in terms of metric tons of CO_2e per unit of production, as proposed? Would such a requirement facilitate the comparability of the disclosure? Should we require a different economic output measure of GHG intensity and, if so, which measure? For example, should GHG intensity be expressed in terms of metric tons of CO_2e per number of employees? Should we require the GHG intensity to be expressed per unit of production relevant to the registrant's business (rather than its industry)? Is further guidance needed on how to comply with the proposed requirement? Would requiring GHG intensity to be expressed in terms of metrics tons of CO_2e per unit of production require disclosure of commercially sensitive or competitively harmful information?

112. Should we require a registrant with no revenue or unit of production for a fiscal year to disclose its GHG intensity based on, respectively, another financial measure or measure of economic output, as proposed? Should we require such a registrant to use a particular financial measure, such as total assets, or a particular measure of economic output, such as total number of employees? For registrants who may have minimal revenue, would the proposed calculation result in intensity disclosure that is confusing or not material? Should additional guidance be provided with respect to such instances?

113. Should we permit a registrant to disclose other measures of GHG intensity, in addition to the required measures, as long as the registrant explains why it uses the particular measure of GHG intensity and discloses the corresponding calculation methodology used, as proposed?

d. GHG Emissions Data for Historical Periods

The proposed rules would require disclosure to be provided for the registrant's most recently completed fiscal year and for the historical fiscal years included in the registrant's consolidated financial statements in the applicable filing, to the extent such historical GHG emissions data is reasonably available.[479] Requiring historical GHG emissions data, to the extent available, would provide useful information for investors by enabling investors to track over time the registrant's exposure to climate-related impacts represented by the yearly emissions data, and to assess how it is managing the climate-related risks associated with those impacts. Requiring GHG emissions disclosure for current and, when reasonably available, historical periods should enable investors to analyze trends in the impacts of material climate-related risks and to evaluate the narrative disclosure provided pursuant to proposed Item 1502.[480] Historical GHG emissions data also could be particularly useful when a registrant has announced a target or goal for reducing GHG emissions by a certain date by helping investors assess its progress in meeting that target or goal and the related impacts on the registrant.

Linking the required number of years of historical GHG emissions data to the historical periods required in the consolidated financial statements should benefit investors by requiring emissions data that is consistent with the financial statement metrics in the filing. This should help investors connect GHG emissions with the financial performance of a registrant in the same period, including the proposed financial statement metrics. Moreover, although we are not proposing to require the GHG emissions data to be included in the registrant's consolidated financial statements, we nevertheless believe that the GHG emissions data is relevant to, and would be read in conjunction with, information included in the consolidated financial statements. Just as data about a registrant's revenues and expenses on its income statement reflect its activities in financial terms for a given year, a registrant's emissions data reflect its carbon footprint activities for that year. For this reason, we have proposed requiring a registrant to provide its GHG emissions data for the same number of years as it is required to provide data on its income statement and cash flow statement, to the extent such emissions data is reasonably available. For example, a registrant that is required to include income statements and cash flow statements at the end of its three most recent fiscal years would be required to disclose three years of its Scope 1, Scope 2 and, if material to the registrant or if it has set a GHG emissions target or goal that includes its Scope 3 emissions, its Scope 3 emissions, expressed both in absolute terms and in terms of intensity.[481] If the registrant is a SRC,

[476] *See* proposed 17 CFR 229.1504(d)(3).

[477] *See* proposed 17 CFR 229.1504(d)(4).

[478] *See* proposed 17 CFR 229.1504(e)(1) and *infra* Section II.G.2 for the proposed disclosure requirements pertaining to GHG emissions methodology.

[479] *See* proposed 17 CFR 229.1504(a).

[480] *See supra* Section II.C for a discussion of proposed 17 CFR 229.1502.

[481] Alternatively, if a registrant has no revenue, and it decides to calculate GHG intensity using total assets, we believe it would be appropriate for that registrant to provide its GHG intensity for the same number of years as are required on its balance sheets (*i.e.,* two years if not a SRC).

only two years of Scopes 1 and 2 emissions metrics would be required.[482]

A registrant, however, would not otherwise be required to provide a corresponding GHG emissions metric for a fiscal year preceding its current reporting fiscal year if, for example, it was not required to and has not previously presented such metric for such fiscal year and the historical information necessary to calculate or estimate such metric is not reasonably available to the registrant without unreasonable effort or expense.[483]

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114. Should we require GHG emissions disclosure for the registrant's most recently completed fiscal year and for the appropriate, corresponding historical fiscal years included in the registrant's consolidated financial statements in the filing, to the extent such historical GHG emissions data is reasonably available, as proposed? Should we instead only require GHG emissions metrics for the most recently completed fiscal year presented in the relevant filing? Would requiring historical GHG emissions metrics provide important or material information to investors, such as information allowing them to analyze trends?

2. GHG Emissions Methodology and Related Instructions

The proposed rules would require a registrant to describe the methodology, significant inputs, and significant assumptions used to calculate its GHG emissions metrics.[484] As proposed, the description of the registrant's methodology must include the registrant's organizational boundaries, operational boundaries, calculation approach, and any calculation tools used to calculate the registrant's GHG emissions.[485] Organizational boundaries would be defined to mean the boundaries that determine the operations owned or controlled by a registrant for the purpose of calculating its GHG emissions.[486] Operational boundaries would be defined to mean the boundaries that determine the direct and indirect emissions associated with the business operations owned or controlled by a registrant.[487] This information should help investors understand the scope of a registrant's operations included in its GHG emissions metrics and how those metrics were measured. With this information, investors could more knowledgeably compare a registrant's GHG emissions metrics with the GHG emissions metrics of other registrants and make more informed investment decisions.

a. The Setting and Disclosure of Organizational Boundaries

The proposed rules would require a registrant to disclose its Scope 1 emissions and its Scope 2 emissions separately after calculating them from all sources that are included in the registrant's organizational and operational boundaries.[488] An initial step for many registrants may be to set their organizational boundaries.[489] Those boundaries determine the business operations owned or controlled by a registrant to be included in the calculation of its GHG emissions.[490] Because both Scope 1 and Scope 2 emissions relate to the operations owned or controlled by a registrant, setting a registrant's organizational boundaries is an important part of determining its Scopes 1 and 2 emissions.

Several commenters stated that the GHG Protocol's standards and guidance would provide an appropriate framework for reporting GHG emissions if the Commission required disclosure of GHG emissions.[491] A company following the GHG Protocol would base its organizational boundaries on either an equity share approach or a control approach.[492] Our proposed approach, however, would require a registrant to set the organizational boundaries for its GHG emissions disclosure using the same scope of entities, operations, assets, and other holdings within its business organization as those included in, and based upon the same set of accounting principles applicable to, its consolidated financial statements.[493]

For similar reasons to those noted above regarding the proposed time periods required for GHG emissions disclosure, we propose requiring the scope of consolidation and reporting to be consistent for financial data and GHG emissions data. This would be accomplished by applying existing GAAP.[494] Requiring a consistent approach should help avoid potential investor confusion about the reporting scope used in determining a registrant's GHG emissions and the reporting scope used for the financial statement metrics, which are included in the financial statements. Applying existing GAAP could help limit the compliance burden for registrants as they would be able to use familiar concepts from financial reporting when preparing their required GHG emissions disclosures. Requiring registrants to follow the scope of reporting used in their financial statements should also enhance comparability across registrants when compared with the multiple options available under the GHG Protocol.

Thus, as proposed, the scope of reporting for a registrant's GHG emissions metrics would be consistent with the scope of reporting for the proposed financial statement metrics and other financial data included in its consolidated financial statements in order to provide investors a consistent view of the registrant's business across its financial and GHG emissions disclosures. For example, a registrant that prepares its financial statements pursuant to U.S. GAAP would apply relevant guidance from U.S. GAAP (*e.g.,* FASB ASC Topic 810 *Consolidation* and FASB ASC Topic 323 *Investments—Equity Method and Joint Ventures*) when determining which entities would be subject to consolidation or which investments qualify for equity method accounting or proportionate consolidation.[495] Therefore, under the proposed rules a registrant would be required to include all of the emissions from an entity that it consolidates.[496] For an equity method investee or an

[482] We are proposing to exempt SRCs from Scope 3 disclosures. *See infra* Section II.G.3.

[483] *See* Securities Act Rule 409 and Exchange Act Rule 12b–21.

[484] *See* proposed 17 CFR 229.1504(e)(1).

[485] *See id.*

[486] *See* proposed 17 CFR 229.1500(m).

[487] *See* proposed 17 CFR 229.1500(l).

[488] *See* proposed 17 CFR 229.1504(b)(1).

[489] See GHG Protocol, Corporate Accounting and Reporting Standard, Chapter 3.

[490] *See* proposed 17 CFR 229.1500(m).

[491] *See supra* note 111.

[492] Under the GHG Protocol's equity share approach, a company accounts for GHG emissions from operations according to its share of equity in the operation. Under the GHG Protocol's control approach, a company accounts for 100% of the GHG emissions from operations over which it has control. A company can choose to define control either in financial or operational terms. *See GHG Protocol, Corporate Accounting and Reporting Standard,* Chapter 3.

[493] *See* proposed 17 CFR 229.1504(e)(2).

[494] Foreign private issuers that file consolidated financial statements under IFRS as issued by the IASB would apply IFRS under the proposed rules as the basis for setting its organizational boundaries for the purpose of providing the proposed GHG emissions disclosure.

[495] Issuers that are permitted to, and do, apply IFRS issued by the International Accounting Standards Board would apply the IASB's equivalent standards. *See, e.g.,* IFRS 10 *Consolidated Financial Statements,* IFRS 11 *Joint Arrangements* and International Accounting Standards (''IAS'') 28 *Investments in Associates and Joint Ventures. See supra* note 319, which states that foreign private issuers that file consolidated financial statements under home country GAAP and reconcile to U.S. GAAP, would be required to use U.S. GAAP as the basis for calculating and disclosing the proposed climate-related financial statement metrics. The same requirement would apply for the purpose of determining the proposed GHG emissions metrics.

[496] *See* proposed 17 CFR 229.1504(e)(2).

operation that is proportionally consolidated, the registrant would be required to include its share of emissions based on its percentage ownership of such investee or operation.[497] For a registrant that applies the equity method to an investee, the percentage of ownership interest used to record its share of earnings or losses in the investee must be the same for measuring its share of GHG emissions by the equity method investee.[498] The proposed rules would permit a registrant to exclude emissions from investments that are not consolidated, are not proportionately consolidated, or that do not qualify for the equity method of accounting in the registrant's consolidated financial statements.[499]

For example, a registrant might own or control several plants but have only a minority ownership in another plant over which it has no control. For the plants that are owned or controlled by the registrant, all of those plants' direct and indirect emissions should be included in its Scopes 1 and 2 emissions disclosure (regardless of ownership percentage that resulted in consolidation for financial statement purposes).[500] If the registrant's proportional interest in the latter plant is reflected in its consolidated financial statements (*e.g.,* the investment qualifies for the equity method or a proportionate consolidation approach), when calculating its Scopes 1 and 2 emissions the registrant should include such proportional share (based on ownership interest) of that plant's emissions in the total of each of its Scopes 1 and 2 emissions.[501]

A related provision under the proposed rules would require a registrant to use the same organizational boundaries when calculating its Scope 1 emissions and Scope 2 emissions [502] since both sets of emissions relate to operations that a registrant owns or controls. If required to disclose its Scope 3 emissions, a registrant would also be required to apply the same organizational boundaries used when determining its Scopes 1 and 2 emissions as an initial step in identifying the sources of indirect emissions from activities in its value chain over which it lacks ownership and control and which must be included in the calculation of its Scope 3 emissions.[503] Requiring a registrant to use the same organizational boundaries when calculating its Scopes 1, 2 and 3 emissions should help limit investor confusion over those operations or activities over which it has ownership or control (sources of its Scopes 1 and 2 emissions) and those activities in its value chain over which it lacks ownership or control (sources of its Scope 3 emissions). The proposed provision also would provide that, once a registrant has determined its organizational (and operational) boundaries, it must consistently use those boundaries when calculating its GHG emissions.[504] This proposed provision should help investors track and compare a registrant's GHG emissions over time.

b. The Setting and Disclosure of Operational Boundaries

When describing the methodology, significant inputs, and significant assumptions used to calculate its GHG emissions metrics, a registrant is required to describe its operational boundaries.[505] This would involve identifying emissions sources within its plants, offices, and other operational facilities that fall within its organizational boundaries, and then categorizing the emissions as either direct or indirect emissions. For example, a registrant might have direct emissions from one or more of the following sources that it owns or controls:

- Stationary equipment (from the combustion of fuels in boilers, furnaces, burners, turbines, heaters, and incinerators);
- Transportation (from the combustion of fuels in automobiles, trucks, buses, trains, airplanes, boats, ships, and other vessels);
- Manufacturing processes (from physical or chemical processes, such as CO_2 from the calcination process in cement manufacturing or from catalytic cracking in petrochemical processing, and PFC emissions from aluminum smelting); and
- Fugitive emission sources (equipment leaks from joints, seals, packing, gaskets, coal piles, wastewater treatment, pits, cooling towers, and gas processing facilities, and other unintentional releases).[506]

Most registrants would likely have emission sources from stationary equipment and transportation devices. Registrants in certain industrial sectors, such as cement, aluminum, and other manufacturers, or oil and gas production and refining, are likely also to produce emissions from physical or chemical processes. Some registrants would likely have emissions from all four types of sources, particularly if they have their own power generation or waste treatment facilities.[507]

The proposed rules would require a registrant to include its approach to categorizing its emissions and emissions sources when describing its methodology to determine its operational boundaries.[508] A registrant could use the above non-exclusive list of emissions sources or other categories of emissions sources as long as it describes how it determined the emissions to include as direct emissions, for the purpose of calculating its Scope 1 emissions, and indirect emissions, for the purpose of calculating its Scope 2 emissions.[509] For most registrants, purchased electricity would likely constitute a large percentage of their Scope 2 emissions. Although Scope 2 emissions are generated from a source external to a registrant, the electricity (or steam, heat, or cooling) is consumed by the registrant's operations that it owns or controls.

c. The Selection and Disclosure of a GHG Emissions Calculation Approach, Including Emission Factors

In addition to setting its organizational and operational boundaries, a registrant would need to select a GHG emissions calculation approach. While the direct measurement of GHG emissions from a source by monitoring concentration and flow rate is likely to yield the most accurate calculations, due to the expense of the direct monitoring of emissions, an acceptable and common method for calculating emissions involves the application of published emission factors to the total amount of purchased fuel consumed by a particular source.[510] The proposed rules would define ''emission factor'' as a multiplication factor allowing actual GHG emissions to be calculated from available activity data or, if no activity data is available, economic data, to

[497] *See id.*

[498] *See id.*

[499] *See* proposed 17 CFR 229.1504(b)(2).

[500] *See* proposed 17 CFR 229.1500(m) (defining organizational boundaries as the boundaries that determine the operations owned or controlled by a registrant) and 17 CFR 229.1504(b)(1) (requiring the disclosure of Scopes 1 and 2 emissions separately after calculating them from all sources included in a registrant's organizational and operational boundaries).

[501] *See* proposed 17 CFR 229.1504(e)(2).

[502] *See* proposed 17 CFR 229.1504(e)(3).

[503] *See id.*

[504] *See id.*

[505] *See* proposed Item 1504(e)(1).

[506] This non-exclusive list of possible emissions sources is based on categories of emissions sources provided in the GHG Protocol. *See* GHG Protocol, *Corporate Accounting and Reporting Standard,* Chapter 6.

[507] *See id.*

[508] *See* proposed 17 CFR 229.1504(e)(1).

[509] *See id.*

[510] *See, e.g.,* GHG Protocol, Corporate Accounting and Reporting Standard, Chapter 6.

derive absolute GHG emissions.[511] Emission factors are ratios that typically relate GHG emissions to a proxy measure of activity at an emissions source. Examples of activity data reflected in emission factors include kilowatt-hours of electricity used, quantity of fuel used, output of a process, hours of operation of equipment, distance travelled, and floor area of a building.[512] If no activity data is available, a registrant may use an emission factor based on economic data.[513] For example, when calculating Scope 3 emissions from purchased goods or services, a registrant could determine the economic value of the goods or services purchased and multiply it by an industry average emission factor (expressed as average emissions per monetary value of goods or services).[514]

The EPA has published a set of emission factors based on the particular type of source (*e.g.,* stationary combustion, mobile combustion, refrigerants, and electrical grid, among others) and type of fuel consumed (*e.g.,* natural gas, coal or coke, crude oil, and kerosene, among many others).[515] The GHG Protocol's own set of GHG emission calculation tools are based in part on the EPA's emission factors.[516] Whatever set of emission factors a registrant chooses to use, it must identify the emission factors and its source.[517]

After a registrant has selected a calculation approach (*i.e.,* direct measurement or application of emissions factors), the registrant would determine what data must be collected and how to conduct the relevant calculations, including whether to use any publicly-available calculation tools. In this regard, we note that there are a number of publicly-available calculation tools a registrant may elect to utilize in determining its GHG emissions.[518]

Finally, a registrant would gather and report GHG emissions up to the corporate level.

For example, when determining its Scope 1 emissions for a particular plant, a registrant might add up the amount of natural gas consumed by furnaces and other stationary equipment during its most recently completed fiscal year and then apply the CO_2 emission factor for natural gas to that total amount to derive the amount of GHG emissions expressed in CO_2e. The registrant would repeat this process for each type of fuel consumed and for each type of source. If a registrant owns a fleet of trucks, it might total the amount of diesel fuel or other type of gasoline consumed for the fiscal year and apply the appropriate CO_2 emission factor for that vehicle and type of fuel. A registrant that uses refrigerants also might apply the appropriate emission factor for the particular type of refrigerant to the total amount of that refrigerant used during the fiscal year. As part of the roll-up process for a registrant with multiple entities and emission sources, once it has determined the amount of CO_2e for each type of direct emissions source and for each facility within its organizational and operational boundaries, the registrant would then add them together to derive the total amount of Scope 1 emissions for the fiscal year.[519]

A registrant would undergo a similar process when calculating its Scope 2 emissions for its most recently completed fiscal year. There are two common methods for calculating Scope 2 emissions for purchased electricity: The market-based method and the location-based method.[520] Pursuant to the market-based method, a registrant would calculate its Scope 2 emissions based on emission factors and other data provided by the generator of electricity from which the registrant has contracted to purchase the electricity and which are included in the contractual instruments. Pursuant to the location-based method, a registrant would calculate its Scope 2 emissions based on average energy generation emission factors for grids located in defined geographic locations, including local, subnational, or national boundaries.[521] A registrant could use either of these methods, both methods, a combination, or another method as long as it identifies the method used and its source.[522] For example, if using the location-based method, the registrant would apply an appropriate emission factor for the electricity grid in its region to the total amount of electricity purchased from that grid during its fiscal year.[523] The registrant would then calculate the amount of CO_2e from purchased steam/heat, if any, by applying the appropriate emission factor for that type of energy source to the total amount consumed.[524] The registrant would report the sum of its CO_2e from purchased electricity and steam/heat as its total Scope 2 emissions for the fiscal year.

As noted above, in all instances a registrant would be required to describe its methodology, including its organizational and operational boundaries, calculation approach (including any emission factors used and the source of the emission factors), and any calculation tools used to calculate the GHG emissions.[525] Requiring a registrant to describe its methodology for determining its GHG emissions should provide investors with important information to assist them in evaluating the registrant's GHG emissions disclosure as part of its overall business and financial disclosure. Such disclosure should enable investors to evaluate the reasonableness and accuracy of the emission disclosures, and should promote consistency and comparability over time. For example, an investor

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[511] *See* proposed 17 CFR 229.1500(e).

[512] *See id.*

[513] *See id.*

[514] *See, e.g.,* Greenhouse Gas Protocol, *Corporate Value Chain (Scope 3) Accounting and Reporting Standard, Supplement to the GHG Protocol Corporate Accounting and Reporting Standard,* Chapter 1 (describing the ''spend-based method'' for calculating emissions from purchased goods or services).

[515] *See* EPA, Emission Factors for Greenhouse Gas Inventories (Apr. 2021), available at *https://www.epa.gov/sites/default/files/2021-04/documents/emission-factors_apr2021.pdf.*

[516] *See, e.g.,* The Greenhouse Gas Protocol, *GHG Emission Calculation Tool* (Mar. 2021), *available at https://ghgprotocol.org/calculation-tools.*

[517] *See* proposed 17 CFR 229.1504(e)(1).

[518] *See, e.g.,* GHG Protocol, *Corporate Accounting and Reporting Standard, Chapter* 6 (providing an overview of calculation tools by type of source (*e.g.,* for stationary combustion, mobile combustion, and air conditioning and refrigeration use) and by sector (*e.g.,* for aluminum production, iron and steel production, cement manufacturing, and pulp and paper production), which are available on the GHG Protocol website at *https://ghgprotocol.org/.* The EPA also has published a Simplified GHG Emissions Calculator that is designed as a simplified calculation tool to help small businesses and low emitter organizations estimate and inventory their annual GHG emissions. *See* EPA, Simplified GHG Emissions Calculator (2021), available at *https://www.epa.gov/climateleadership/simplified-ghg-emissions-calculator.*

[519] As noted earlier, a registrant that is required to report its direct emissions to the EPA may be able to use the EPA-provided data, together with data for any direct emissions not reported to the EPA, to help fulfill the Commission's proposed Scope 1 emission disclosure requirement.

[520] *See* World Resources Institute, *GHG Protocol Scope 2 Guidance* (2015), Chapter 4, available at *https://ghgprotocol.org/sites/default/files/standards/Scope%202%20Guidance_Final_Sept26.pdf.*

[521] *See id.*

[522] We note that, pursuant to the GHG Protocol, and as referenced by the EPA, a company that determines its Scope 2 emissions using a market-based approach would also calculate those emissions using the location-based method to provide a more complete picture of the company's Scope 2 emissions. *See* World Resources Institute, *GHG Protocol Scope 2 Guidance,* Chapter 7; and EPA Center for Corporate Climate Leadership, *Scope 1 and Scope 2 Inventory Guidance.*

[523] *See, e.g.,* EPA, *Emission Factors for Greenhouse Gas Inventories,* Table 6, which provides emission factors for regional electrical grids.

[524] *See, e.g.,* EPA, *Emission Factors for Greenhouse Gas Inventories,* Table 7, which provides emission factors for steam and heat.

[525] *See* proposed 17 CFR 229.1504(e)(1).

would be able to evaluate both if the registrant's selection of an emission factor is reasonable given the registrant's industry sector and whether changes in reported emissions reflect changes in actual emissions in accordance with its strategy or simply a change in calculation methodology.

Like registrants in other sectors, registrants in the financial sector would be required to disclose their Scope 3 emissions if those emissions are material and to describe the methodology used to calculate those emissions. A financial registrant's Scope 3 emissions disclosures would likely include the emissions from companies that the registrant provides debt or equity financing to (''financed emissions''). While financial registrants may use any appropriate methodology to calculate its Scope 3 emissions, the Partnership for Carbon Accounting Financials' Global GHG Accounting & Reporting Standard (the ''PCAF Standard'') provides one methodology that complements the GHG Protocol and assists financial institutions in calculating their financed emissions.[526] The PCAF Standard was developed to work with the calculation of Scope 3 emissions for the ''investment'' category of downstream emissions and was endorsed by the drafters of the GHG Protocol.[527] The PCAF Standard covers six asset classes: Listed equity and corporate bonds; business loans and unlisted equity; project finance; commercial real estate; mortgages; and motor vehicle loans.[528]

At this time, we are not proposing to require a particular methodology for the financial sector in order to provide a financial sector registrant the flexibility to choose the methodology that best suits its particular portfolio and financing activities. We believe the proposed requirement to disclose the methodology used (*e.g.,* the PCAF Standard or another standard) would provide sufficient information to an investor.

d. Additional Rules Related to Methodology Disclosure

We are proposing additional rules related to the methodology for calculating GHG emissions. Some of these rules would apply generally to the determination of GHG emissions while some would apply specifically to the calculation of Scope 3 emissions. For example, one proposed rule would provide that a registrant may use reasonable estimates when disclosing its GHG emissions as long as it also describes the assumptions underlying, and its reasons for using, the estimates.[529] While we encourage registrants to provide as accurate a measurement of its GHG emissions as is reasonably possible, we recognize that, in many instances, direct measurement of GHG emissions at the source, which would provide the most accurate measurement, may not be possible.

Several commenters indicated that a registrant may find it difficult to complete its GHG emissions calculations for its most recently completed fiscal year in time to meet its disclosure obligations for that year's Exchange Act annual report.[530] The proposed rules would permit a registrant to use a reasonable estimate of its GHG emissions for its fourth fiscal quarter if no actual reported data is reasonably available, together with actual, determined GHG emissions data for its first three fiscal quarters when disclosing its GHG emissions for its most recently completed fiscal year, as long as the registrant promptly discloses in a subsequent filing any material difference between the estimate used and the actual, determined GHG emissions data for the fourth fiscal quarter.[531] We believe that this proposed provision would help address the concerns of commenters about the timely completion of both the work required to disclose a registrant's GHG emissions as of its fiscal year-end and to meet its other Exchange Act annual reporting obligations.[532]

Another proposed provision would require a registrant to disclose, to the extent material and as applicable, any use of third-party data when calculating its GHG emissions, regardless of the particular scope of emissions.[533] While this proposed provision would be most relevant to the disclosure of Scope 3 emissions, where the use of third-party data is common, it would apply in other instances when third-party data is material to the GHG emissions determination, such as when determining Scope 2 emissions using contractual, supplier-provided emission factors for purchased electricity. When disclosing the use of third-party data, a registrant would be required to identify the source of the data and the process the registrant undertook to obtain and assess such data.[534] This information would help investors better understand the basis for, and assess the reasonableness of, the GHG emissions determinations and, accordingly, evaluate the GHG disclosures as part of a registrant's business and financial information.

One proposed provision would require a registrant to disclose any material change to the methodology or assumptions underlying its GHG emissions disclosure from the previous fiscal year.[535] For example, if a registrant uses a different set of emission factors, or develops a more direct method of measuring GHG emissions, which results in a material change to the GHG emissions produced from the previous year under (or assuming) the same organizational and operational boundaries, it would be required to report that change. This should help investors more knowledgeably compare the emissions data from year to year and better understand the nature and significance of a material change in emissions (*i.e.,* was the change primarily due to an implementation of strategy or a change in methodology).

Another proposed provision would require a registrant to disclose, to the extent material and as applicable, any gaps in the data required to calculate its GHG emissions.[536] This proposed provision would be particularly relevant to a registrant's Scope 3 emissions. While a registrant's GHG emissions disclosure should provide investors with a reasonably complete understanding of the registrant's GHG emissions in each scope of emissions, as previously noted, we recognize that a

[526] *See* PCAF, *Global GHG Accounting & Reporting Standard for the Financial Industry* (2020), available at *https://carbonaccountingfinancials.com/files/downloads/PCAF-Global-GHG-Standard.pdf.*

[527] *See id. See also* GHG Protocol Press Release, *New Standard Developed to Help Financial Industry Measure and Report Emissions* (Mar. 2021), *available at https://ghgprotocol.org/blog/new-standard-developed-help-financial-industry-measure-and-report-emissions.*

[528] While the guidance provided by the PCAF Standard for each asset class differs in certain respects, the PCAF Standard applies a common set of principles across the various asset classes. A key principle is that the GHG emissions from a client's activities financed by loans or investments attributable to the reporting financial institution should be allocated to that institution based on its proportional share of lending or investment in the borrower or investee through the application of an ''attribution factor.'' *See* PCAF, *Global GHG Accounting & Reporting Standard for the Financial Industry* (2020), Sections 4.2 and 5.

[529] *See* proposed 17 CFR 229.1504(e)(4).

[530] *See, e.g.,* letters from Cisco; Dow; Energy Infrastructure Council; National Mining Association; Newmont Corporation; and United Airlines Holdings, Inc.

[531] *See* proposed 17 CFR 229.1504(e)(4)(i). One commenter made a similar recommendation when stating that a registrant should be required to follow the same timeline for disclosure of its GHG emissions as for its Exchange Act annual reporting obligations. *See* letter from Pricewaterhouse Coopers.

[532] *See supra* note 530.

[533] *See* proposed 17 CFR 229.1504(e)(5).

[534] *See id.*

[535] *See* proposed 17 CFR 229.1504(e)(6).

[536] *See* proposed 17 CFR 229.1504(e)(7).

registrant may encounter data gaps, particularly when calculating its Scope 3 emissions. The proposed provision would require the registrant to disclose the data gaps and discuss whether it used proxy data or another method to address such gaps. A registrant would also be required to discuss how its accounting for any data gaps has affected the accuracy or completeness of its GHG emissions disclosure.[537] This information should help investors understand certain underlying uncertainties and limitations, and evaluate the corresponding reliability, of a registrant's GHG emissions disclosure, particularly for its Scope 3 emissions, as part of their assessment of the registrant's business and financial information.

One proposed provision would provide that, when determining whether its Scope 3 emissions are material, and when disclosing those emissions, in addition to emissions from activities in its value chain, a registrant must include GHG emissions from outsourced activities that it previously conducted as part of its own operations, as reflected in the financial statements for the periods covered in the filing.[538] This proposed approach, which is consistent with the GHG Protocol,[539] would help ensure that investors receive a complete picture of a registrant's carbon footprint by precluding the registrant from excluding emissions from activities that are typically conducted as part of operations over which it has ownership or control but that are outsourced in order to reduce its Scopes 1 or 2 emissions.

Another proposed provision would provide that, if a registrant is required to disclose Scope 3 emissions, and if there was any significant overlap in the categories of activities producing the Scope 3 emissions, the registrant must describe the overlap, how it accounted for the overlap, and its disclosed total Scope 3 emissions.[540] For example, a mining registrant may mine and process iron ore for conversion into steel products. Because the processing of iron ore and steelmaking both require the use of coal, GHG emissions would arise both from the downstream activities involving the processing of sold products and the use of sold products (*i.e.,* the use of iron ore in the production of steel). If the registrant has allocated GHG emissions to both categories (*i.e.,* processing of sold products and use of sold products), it would be required to describe the overlap in emissions between the two categories of downstream activities, how it accounted for the overlap, and the effect on its disclosed total Scope 3 emissions. For example, if the total reported Scope 3 emissions involved some double-counting because of the overlap, a registrant would be required to report this effect. This information could help investors better understand the true extent of a registrant's disclosed Scope 3 emissions and, thus, the climate-related risks faced by the registrant.

Finally, a proposed provision would provide that a registrant may present its estimated Scope 3 emissions in terms of a range as long as it discloses its reasons for using the range and the underlying assumptions.[541] This proposed provision reflects our understanding that, because a registrant may encounter more difficulties obtaining all of the data required for determining its Scope 3 emissions compared to determining its Scopes 1 and 2 emissions, presenting its Scope 3 emissions in terms of a range may be a reasonable means of estimating these emissions when faced with such gaps in the data.

Request for Comment

115. Should we require a registrant to disclose the methodology, significant inputs, and significant assumptions used to calculate its GHG emissions metrics, as proposed? Should we require a registrant to use a particular methodology for determining its GHG emission metrics? If so, should the required methodology be pursuant to the GHG Protocol's Corporate Accounting and Reporting Standard and related standards and guidance? Is there another methodology that we should require a registrant to follow when determining its GHG emissions? Should we base our climate disclosure rules on certain concepts developed by the GHG Protocol without requiring a registrant to follow the GHG Protocol in all respects, as proposed? Would this provide flexibility for registrants to choose certain methods and approaches in connection with GHG emissions determination that meet the particular circumstances of their industry or business or that emerge along with developments in GHG emissions methodology as long as they are transparent about the methods and underlying assumptions used? Are there adjustments that should be made to the proposed methodology disclosure requirements that would provide flexibility for registrants while providing sufficient comparability for investors?

116. Should we require a registrant to disclose the organizational boundaries used to calculate its GHG emissions, as proposed? Should we require a registrant to determine its organizational boundaries using the same scope of entities, operations, assets, and other holdings within its business organization as that used in its consolidated financial statements, as proposed? Would prescribing this method of determining organizational boundaries avoid potential investor confusion about the reporting scope used in determining a registrant's GHG emissions and the reporting scope used for the financial statement metrics, which are included in the financial statements? Would prescribing this method of determining organizational boundaries result in more robust guidance for registrants and enhanced comparability for investors? If, as proposed, the organizational boundaries must be consistent with the scope of the registrant's consolidated financial statements, would requiring separate disclosure of the organizational boundaries be redundant or otherwise unnecessary?

117. Except for calculating Scope 3 emissions, the proposed rules would not require a registrant to disclose the emissions from investments that are not consolidated, proportionately consolidated, or that do not qualify for the equity method of accounting. Should we require such disclosures for Scopes 1 and 2 emissions, and if so, how?

118. Could situations arise where it is impracticable for a registrant to align the scope of its organizational boundaries for GHG emission data with the scope of the consolidation for the rest of its financial statements? If so, should we allow a registrant to take a different approach to determining the organizational boundaries of its GHG emissions and provide related disclosure, including an estimation of the resulting difference in emissions disclosure (in addition to disclosure about methodology and other matters that would be required by the proposed GHG emissions disclosure rules)?

119. Alternatively, should we require registrants to use the organizational boundary approaches recommended by the GHG Protocol (*e.g.,* financial control, operational control, or equity share)? Do those approaches provide a clear enough framework for complying with the proposed rules? Would such an

[537] *See id.*

[538] *See* proposed 17 CFR 229.1504(e)(8).

[539] *See* Greenhouse Gas Protocol, *Corporate Value Chain (Scope 3) Accounting and Reporting Standard, Supplement to the GHG Protocol Corporate Accounting and Reporting Standard,* Chapter 6.

[540] *See* proposed 17 CFR 229.1504(e)(9).

[541] *See* proposed 17 CFR 229.1504(e)(4)(ii).

approach cause confusion when analyzing information in the context of the consolidated financial statements or diminish comparability? If we permit a registrant to choose one of the three organizational boundary approaches recommended by the GHG Protocol, should we require a reconciliation with the scope of the rest of the registrant's financial reporting to make the disclosure more comparable?

120. Should we require a registrant to disclose its operational boundaries, as proposed? Should we require a registrant to discuss its approach towards the categorization of emissions (*e.g.,* as direct or indirect emissions) and emissions sources (*e.g.,* stationary or mobile) when describing its operational boundaries, as proposed?

121. The proposed operational boundaries disclosure is based largely on concepts developed by the GHG Protocol. Would requiring a registrant to determine its organizational boundaries pursuant to the GAAP applicable to the financial statement metrics included in the financial statements but its operational boundaries largely pursuant to concepts developed by the GHG Protocol cause confusion? Should we require a registrant to apply the GAAP applicable to its financial statements when determining whether it ''controls'' a particular source pursuant to the definition of Scope 1 emissions, or particular operations pursuant to the definition of Scope 2 emissions, as proposed? If not, how should ''control'' be determined and would applying a definition of control that differs from applicable GAAP result in confusion for investors?

122. Should we require a registrant to use the same organizational boundaries when calculating its Scopes 1 and 2 emissions, as proposed? Are there any circumstances when a registrant's organizational boundaries for determining its Scope 2 emissions should differ from those required for determining its Scope 1 emissions? Should we also require a registrant to apply the same organizational boundaries used when determining its Scopes 1 and 2 emissions as an initial step in identifying the sources of indirect emissions from activities in its value chain over which it lacks ownership and control and which must be included in the calculation of its Scope 3 emissions, as proposed? Are there any circumstances where using a different organizational boundary for purposes of Scope 3 emissions disclosure would be appropriate?

123. Should we require a registrant to be consistent in its use of its organizational and operational boundaries once it has set those boundaries, as proposed? Would the proposed requirement help investors to track and compare the registrant's GHG emissions over time?

124. Should we require a registrant to disclose the methodology for calculating the GHG emissions, including any emission factors used and the source of the emission factors, as proposed? Should we require a registrant to use a particular set of emission factors, such as those provided by the EPA or the GHG Protocol?

125. Should we permit a registrant to use reasonable estimates when disclosing its GHG emissions as long as it also describes the assumptions underlying, and its reasons for using, the estimates, as proposed? Should we permit the use of estimates for only certain GHG emissions, such as Scope 3 emissions? Should we permit a registrant to use a reasonable estimate of its GHG emissions for its fourth fiscal quarter if no actual reported data is reasonably available, together with actual, determined GHG emissions data for its first three fiscal quarters when disclosing its GHG emissions for its most recently completed fiscal year, as long as the registrant promptly discloses in a subsequent filing any material difference between the estimate used and the actual, determined GHG emissions data for the fourth fiscal quarter, as proposed? If so, should we require a registrant to report any such material difference in its next Form 10–Q if domestic, or in a Form 6–K, if a foreign private issuer? Should we permit a domestic registrant to report any such material difference in a Form 8–K if such form is filed (rather than furnished) with the Commission? Should any such reasonable estimate be subject to conditions to help ensure accuracy and comparability? If so, what conditions should apply?

126. Should we require a registrant to disclose, to the extent material, any use of third-party data when calculating its GHG emissions, regardless of the particular scope of emissions, as proposed? Should we require the disclosure of the use of third-party data only for certain GHG emissions, such as Scope 3 emissions? Should we require the disclosure of the use of third-party data for Scope 3 emissions, regardless of its materiality to the determination of those emissions? If a registrant discloses the use of third-party data, should it also be required to identify the source of such data and the process the registrant undertook to obtain and assess the data, as proposed?

127. Should we require a registrant to disclose any material change to the methodology or assumptions underlying its GHG emissions disclosure from the previous year, as proposed? If so, should we require a registrant to restate its GHG emissions data for the previous year, or for the number of years for which GHG emissions data has been provided in the filing, using the changed methodology or assumptions? If a registrant's organizational or operational boundaries, in addition to methodology or assumptions, change, to what extent should we require such disclosures of the material change, restatements or reconciliations? In these cases, should we require a registrant to apply certain accounting standards or principles, such as FASB ASC Topic 250, as guidance regarding when retrospective disclosure should be required?

128. Should we require a registrant to disclose, to the extent material, any gaps in the data required to calculate its GHG emissions, as proposed? Should we require the disclosure of data gaps only for certain GHG emissions, such as Scope 3 emissions? If a registrant discloses any data gaps encountered when calculating its Scope 3 emissions or other type of GHG emissions, should it be required to discuss whether it used proxy data or another method to address such gaps, and how its management of any data gaps has affected the accuracy or completeness of its GHG emissions disclosure, as proposed? Are there other disclosure requirements or conditions we should adopt to help investors obtain a reasonably complete understanding of a registrant's exposure to the GHG emissions sourced by each scope of emissions?

129. When determining the materiality of its Scope 3 emissions, or when disclosing those emissions, should a registrant be required to include GHG emissions from outsourced activities that it previously conducted as part of its own operations, as reflected in the financial statements for the periods covered in the filing, in addition to emissions from activities in its value chain, as proposed? Would this requirement help ensure that investors receive a complete picture of a registrant's carbon footprint by precluding the registrant from excluding emissions from activities that are typically conducted as part of operations over which it has ownership or control but that are outsourced in order to reduce its Scopes 1 or 2 emissions? Should a requirement to include outsourced activities be subject to certain conditions or exceptions and, if so, what conditions or exceptions?

130. Should we require a registrant that must disclose its Scope 3 emissions to discuss whether there was any

significant overlap in the categories of activities that produced the Scope 3 emissions? If so, should a registrant be required to describe any overlap, how it accounted for the overlap, and its effect on the total Scope 3 emissions, as proposed? Would this requirement help investors assess the accuracy and reliability of the Scope 3 emissions disclosure?

131. Should we permit a registrant to present its Scope 3 emissions in terms of a range as long as it discloses its reasons for using the range and the underlying assumptions, as proposed? Should we place limits or other parameters regarding the use of a range and, if so, what should those limits or parameters be? For example, should we require a range to be no larger than a certain size? What other conditions or guidance should we provide to help ensure that a range, if used, is not overly broad and is otherwise reasonable?

132. Should we require a registrant to follow a certain set of published standards for calculating Scope 3 emissions that have been developed for a registrant's industry or that are otherwise broadly accepted? For example, should we require a registrant in the financial industry to follow PCAF's Global GHG Accounting & Reporting Standard for the Financial Industry when calculating its financed emissions within the ''Investments'' category of Scope 3 emissions? Are there other industry-specific standards that we should require for Scope 3 emissions disclosure? Should we require a registrant to follow the GHG Protocol's Corporate Value Chain (Scope 3) Accounting and Reporting Standard if an industry-specific standard is not available for Scope 3 emissions disclosure? If we should require the use of a third-party standard for Scope 3 emissions reporting, or any other scope of emissions, how should we implement this requirement?

3. The Scope 3 Emissions Disclosure Safe Harbor and Other Accommodations

We recognize that the calculation and disclosure of Scope 3 emissions may pose difficulties compared to Scopes 1 and 2 emissions, which has caused concern for some commenters.[542] It may be difficult to obtain activity data from suppliers and other third parties in a registrant's value chain, or to verify the accuracy of that information. It may also be necessary to rely heavily on estimates and assumptions to generate Scope 3 emissions data. For example, registrants may need to rely on assumptions about how customers will use their products in order to calculate Scope 3 emissions from the use of sold products.

Depending on the size and complexity of a company and its value chain, the task of calculating Scope 3 emissions could be challenging.[543] We expect that some of these challenges may recede over time. For example, as more companies make their Scope 1 and 2 emissions data publicly available, these data can serve as the input for other companies' Scope 3 calculations. In addition, large companies that are voluntarily disclosing Scope 3 emissions information currently are also working with suppliers to increase access to emissions data and improve its reliability,[544] which could have positive spillover effects for other companies that use the same suppliers. Furthermore, within certain industries, there is work underway to improve methodologies and share best practices to make Scope 3 calculations less burdensome and more reliable.[545] Notwithstanding these anticipated developments, calculating and disclosing Scope 3 emissions could represent a challenge for certain registrants, in particular those that do not currently report such information on a voluntary basis.

To balance concerns about reporting Scope 3 emissions with the need for decision-useful emissions disclosure, we are proposing the following accommodations for Scope 3 emissions disclosure:

- A safe harbor for Scope 3 emissions disclosure from certain forms of liability under the Federal securities laws; [546]
- An exemption for smaller reporting companies (''SRCs'') from the Scope 3 emissions disclosure provision; [547] and
- A delayed compliance date for Scope 3 emissions disclosure.[548]

We are proposing a safe harbor for Scope 3 emissions disclosure to alleviate concerns that registrants may have about liability for information that would be derived largely from third parties in a registrant's value chain. Many commenters recommended that the Commission adopt a safe harbor for climate-related disclosures.[549] These commenters asserted that a safe harbor would encourage registrants to provide meaningful, quantitative metrics and analysis. Other commenters focused their recommendation for a safe harbor on certain types of climate-related disclosures, such as those pertaining to scenario analysis, third-party derived data (such as Scope 3 emissions),[550] or forward-looking statements generally.[551] With respect to Scope 3 emissions specifically, commenters recommended that the Commission provide a safe harbor due to the reliance on estimates and data needed for Scope 3 emissions reporting that are outside of the registrant's control.[552]

While we are not proposing a broad safe harbor for all climate-related disclosures, many of which are similar

[542] *See, e.g.,* letter from Dimensional Fund Advisors; *see also supra* note 422.

[543] While there may be less challenging approaches, such as using industry averages or proxies for activity data (such as economic data), the result may be less accurate and could obscure the impact of choices that companies may make to reduce their Scope 3 emissions. For example, if a company uses industry averages to calculate Scope 3 emissions from shipping its products, it may have difficulty communicating to investors how its selection of a shipping company that runs on lower emissions fuel or picks more efficient routes has lowered its Scope 3 emissions.

[544] *See, e.g.,* Apple, *Environmental Social Governance Report* (2021), available at *https://s2.q4cdn.com/470004039/files/doc_downloads/2021/08/2021_Apple_ESG_Report.pdf* (stating that Apple works with its suppliers to help address Apple's environmental commitments, such as becoming carbon neutral by 2030 across its entire product footprint).

[545] *See, e.g.,* PCAF, *The Global GHG Accounting and Reporting Standard for the Financial Industry.* In addition, the American Petroleum Institute has developed an overview of Scope 3 methodologies to inform oil and gas companies about Scope 3 estimation approaches. *See* API and IPIECA, *Estimating petroleum industry value chain (Scope 3) greenhouse gas emissions,* available at *https://www.api.org/~/media/Files/EHS/climate-change/Scope-3-emissions-reporting-guidance-2016.pdf.* Finally, an initiative launched by food and beverage companies, Danone and Mars, together with the Science Based Targets Initiative, aims to provide Scope 3 guidance to companies in difference industries, starting with the food and beverage industry. *See* SB, *Serious About Scope 3: Pioneering Companies Embracing Complexity, Reaping the Benefits,* available at *https://sustainablebrands.com/read/supply-chain/serious-about-scope-3-pioneering-companies-embracing-complexity-reaping-the-benefits.*

[546] *See* 17 CFR 229.1504(f).

[547] *See* proposed 17 CFR 229.1504(c)(3).

[548] *See infra* Section II.M.

[549] *See, e.g.,* letters from ACCO Brands Corp.; American Bankers Association; American Petroleum Institute; American Property Casualty Insurance Association; Associated General Contractors of America; Bank of America Corporation; Biotechnology Innovation Organization; ConocoPhillips; Delta Airlines, Inc. (June 16, 2021); Deutsches Bank AG; Dow; Enbridge Inc.; Energy Infrastructure Council; Etsy, Inc.; Freeport-McMoran; KPMG LLP; Managed Funds Association; Nacco Industries; National Investor Relations Institute; National Ocean Industries Association; Neuberger Berman; NIRI Los Angeles; Oshkosh Corporation; Salesforce.com; SASB; SIFMA (June 10, 2021); Society for Corporate Governance; United Airlines Holdings, Inc. (June 11, 2021); and Wachtell Rosen Lipton & Katz.

[550] *See, e.g.,* letters from Business Council for Sustainable Energy; Dimensional Fund Advisors; and Independent Community Bankers of America.

[551] *See, e.g.,* letters from AICPA; BlackRock; Center for Climate and Energy Solutions; Crowe LLP; Energy Strategy Coalition; Institute of Management Accountants; Japanese Bankers Association; Nareit; National Mining Association; and Newmont Corporation.

[552] *See, e.g.,* letters from Dimensional Fund Advisors; and International Capital Markets Association (June 15, 2021).

to other business and financial information required by Commission rules, we are proposing a targeted safe harbor for Scope 3 emissions data in light of the unique challenges associated with this information. The proposed safe harbor would provide that disclosure of Scope 3 emissions by or on behalf of the registrant would be deemed not to be a fraudulent statement unless it is shown that such statement was made or reaffirmed without a reasonable basis or was disclosed other than in good faith.[553] The safe harbor would extend to any statement regarding Scope 3 emissions that is disclosed pursuant to proposed subpart 1500 of Regulation S–K and made in a document filed with the Commission.[554] For purposes of the proposed safe harbor, the term ''fraudulent statement'' would be defined to mean a statement that is an untrue statement of material fact, a statement false or misleading with respect to any material fact, an omission to state a material fact necessary to make a statement not misleading, or that constitutes the employment of a manipulative, deceptive, or fraudulent device, contrivance, scheme, transaction, act, practice, course of business, or an artifice to defraud as those terms are used in the Securities Act or the Exchange Act or the rules or regulations promulgated thereunder.[555] The proposed safe harbor is intended to mitigate potential liability concerns associated with providing emissions disclosure based on third-party information by making clear that registrants would only be liable for such disclosure if it was made without a reasonable basis or was disclosed other than in good faith. It also may encourage more robust Scope 3 emissions information, to the extent registrants feel reassured about relying on actual third-party data as opposed to national or industry averages for their emissions estimates.

Several commenters expressed concern that the Commission would impose a ''one size fits all'' approach, which could disproportionately impact smaller registrants, when adopting climate-related disclosure rules.[556] Several commenters recommended that the Commission phase-in or scale down the climate-related disclosure requirements for smaller registrants.[557]

Although we are not proposing to exempt SRCs from the full scope of the proposed climate-related disclosure rules, we are proposing to exempt SRCs from the proposed Scope 3 emissions disclosure requirement.[558] We believe that exempting SRCs from the proposed Scope 3 emissions disclosure requirement would be appropriate in light of the proportionately higher costs they could incur, compared to non-SRCs, to engage in the data gathering, verification, and other actions associated with Scope 3 emissions reporting, many of which may have fixed cost components.

To further ease the burden of complying with the proposed Scope 3 disclosure requirement, we are also proposing a delayed compliance date for this requirement. As explained in greater detail below, all registrants, regardless of their size, would have an additional year to comply initially with the Scope 3 disclosure requirement beyond the compliance date for the other proposed rules. Moreover, because a registrant's Scope 3 emissions consist of the Scopes 1 and 2 emissions of its suppliers, distributors, and other third parties in the registrant's value chain, to the extent those parties become subject to the proposed rules, the increased availability of Scopes 1 and 2 emissions data following the rules' effectiveness should help ease the burden of complying with the Scope 3 emissions disclosure requirement.

Finally, we note that Securities Act Rule 409 and Exchange Act Rule 12b–21, which provide accommodations for information that is unknown and not reasonably available, would be available for the proposed Scope 3 emissions disclosures.[559] These rules allow for the conditional omission of required information when such information is unknown and not reasonably available to the registrant, either because obtaining the information would involve unreasonable effort or expense, or because the information rests peculiarly within the knowledge of another person not affiliated with the registrant.[560]

Request for Comment

133. Should we provide a safe harbor for Scope 3 emissions disclosure, as proposed? Is the scope of the proposed safe harbor clear and appropriate? For example, should the safe harbor apply to any registrant that provides Scope 3 disclosure pursuant to the proposed rules, as proposed? Should we limit the use of the safe harbor to certain classes of registrants or to registrants meeting certain conditions and, if so, which classes or conditions? For example, should we require the use of a particular methodology for calculating and reporting Scope 3 emissions, such as the PCAF Standard if the registrant is a financial institution, or the GHG Protocol Scope 3 Accounting and Reporting Standard for other types of registrants? Should we clarify the scope of persons covered by the language ''by or on behalf of a registrant'' by including language about outside reviewers retained by the registrant or others? Should we define a ''fraudulent statement,'' as proposed? Is the level of diligence required for the proposed safe harbor (*i.e.,* that the statement was made or reaffirmed with a reasonable basis and disclosed in good faith) the appropriate standard? Should the safe harbor apply to other climate-related disclosures, such as Scopes 1 and 2 emissions disclosures, any targets and goals disclosures in response to proposed Item 1505 (discussed below), or the financial statement metrics disclosures required pursuant to Proposed Article 14 of Regulation S–X? Should the safe harbor apply indefinitely, or should we include a sunset provision that would eliminate the safe harbor some number of years, (*e.g.,* five years) after the effective date or applicable compliance date of the rules? Should the safe harbor sunset after certain conditions are satisfied? If so, what types of conditions should we consider? What other approaches should we consider?

134. Should we provide an exemption from Scope 3 emissions disclosure for SRCs, as proposed? Should the exemption not apply to a SRC that has set a target or goal or otherwise made a commitment to reduce its Scope 3 emissions? Are there other classes of registrants we should exempt from the

[553] *See* proposed 17 CFR 229.1504(f)(1).

[554] *See* proposed 17 CFR 229.1504(f)(2).

[555] *See* proposed 17 CFR 229.1504(f)(3). This definition is based on the definition of fraudulent statement in 17 CFR 230.175.

[556] *See, e.g.,* letters from Elisha Doerr (May 24, 2021); Freedomworks Foundation (June 14, 2021); Roger Hawkins (May 24, 2021); and Jonathan Skee (May 26, 2021).

[557] *See, e.g.,* letters from American Bankers Association (June 11, 2021); Biotechnology Innovation Organization (June 15, 2021); BNP Paribas; Cardano Risk Management Ltd.; Catavento Consultancy; Chamber of Commerce (June 11, 2021); Credit Roundtable (June 11, 2021); Douglas Hileman Consulting; Environmental Bankers Association (June 9, 2021); Grant Thornton; Virginia Harper Ho; Manulife Investment Management; Mirova US; Morrison & Foerster; NEI Investments (June 11, 2021); New York State Society of Certified Public Accountants; PIMCO; and SIFMA.

[558] *See* proposed 17 CFR 229.1504(c)(3). We also are proposing a later compliance date for SRCs. *See infra* Section II.M.

[559] *See* 17 CFR 230.409 and 17 CFR 240.12b–21.

[560] *See id.* We expect, however, that a registrant that requires emissions data from another registrant in its value chain would be able to obtain that data without unreasonable effort or expense because of the increased availability of Scopes 1 and 2 emissions data for registrants following the effectiveness of the proposed rules.

Scope 3 emissions disclosure requirement? For example, should we exempt EGCs, foreign private issuers, or a registrant that is filing or has filed a registration statement for its initial public offering during its most recently completed fiscal year from the Scope 3 disclosure requirement? Instead of an exemption, should we provide a longer phase in for the Scope 3 disclosure requirements for SRCs than for other registrants?

H. Attestation of Scope 1 and Scope 2 Emissions Disclosure

1. Overview

The proposed rules would require a registrant, including a foreign private issuer, that is an accelerated filer or large accelerated filer to include in the relevant filing an attestation report covering the disclosure of its Scope 1 and Scope 2 emissions [561] and to provide certain related disclosures about the service provider.[562] As proposed, the attestation engagement must, at a minimum, be at the following assurance level for the indicated fiscal year for the required GHG emissions disclosure:[563]

Limited assurance	Reasonable assurance
Fiscal Years 2 and 3 after Scopes 1 and 2 emissions disclosure compliance date.	Fiscal Years 4 and beyond after Scopes 1 and 2 emissions disclosure compliance date.

To provide additional clarity, the following table illustrates the application of the transition periods assuming that the proposed rules will be adopted with an effective date in December 2022 and that the accelerated filer or large accelerated filer has a December 31st fiscal year-end:

Filer type	Scopes 1 and 2 GHG disclosure compliance date *	Limited assurance	Reasonable assurance
Accelerated Filer	Fiscal year 2024 (filed in 2025)	Fiscal year 2025 (filed in 2026)	Fiscal year 2027 (filed in 2028).
Large Accelerated Filer	Fiscal year 2023 (filed in 2024)	Fiscal year 2024 (filed in 2025)	Fiscal year 2026 (filed in 2027).

* *See infra* Section II.M for a discussion of the proposed disclosure compliance dates for Scopes 1 and 2 GHG emissions disclosure. If the accelerated filer or the large accelerated filer has a non-calendar-year fiscal year-end date that results in its 2024 or 2023 fiscal year, respectively, commencing before the compliance dates of the rules, it would not be required to comply with proposed GHG emissions disclosure requirements until the following fiscal year (as discussed below in Section II.M). Accordingly, for such filers, the time period for compliance with the corresponding attestation requirements under proposed Item 1505 would be one year later than illustrated above.

During the transition period when limited assurance is required, the proposed rules would permit an accelerated filer or a large accelerated filer, at its option, to obtain reasonable assurance of its Scope 1 and 2 emissions disclosure.[564] For example, an accelerated filer or a large accelerated filer may choose to obtain reasonable assurance such that its GHG emissions disclosure receives the same level of assurance as its financial statements.[565]

At its option, an accelerated filer or a large accelerated filer would be able to obtain any level of assurance over its climate-related disclosures that are not required to be assured pursuant to proposed Item 1505(a). For example, an accelerated filer or a large accelerated filer could voluntarily include an attestation report at the limited assurance level for its GHG intensity metrics or its Scope 3 emissions disclosure. To avoid potential confusion, however, the voluntary assurance obtained by such filer would be required to follow the requirements of proposed Item 1505(b)–(d), including using the same attestation standard as the required assurance over Scope 1 and Scope 2.[566] For filings made by accelerated filers and large accelerated filers after the compliance date for the GHG emissions disclosure requirements but before proposed Item 1505(a) requires limited assurance, the filer would only be required to provide the disclosure called for by proposed Item 1505(e). As discussed below in Section II.H.5, a registrant that is not an accelerated filer or a large accelerated filer that obtains voluntary assurance would be required to comply only with proposed Item 1505(e).

Many commenters recommended that we require climate-related disclosures to be subject to some level of assurance to enhance the reliability of the disclosures.[567] Commenters noted that companies are increasingly seeking some type of third-party assurance or

[561] *See* proposed 17 CFR 229.1505(a). In order to attest to the Scopes 1 and 2 emissions disclosure, we believe a GHG emissions attestation provider would need to include in its evaluation relevant contextual information. In particular, the attestation provider would be required to evaluate the registrant's compliance with (i) proposed Item 1504(a), which includes presentation requirements (*e.g.,* disaggregation by each constituent greenhouse gas), (ii) the calculation instructions included in proposed Item 1504(b), and (iii) the disclosure requirements in proposed Item 1504(e) regarding methodology, organizational boundary, and operational boundary. *See infra* Section II.H.3 for further discussion of the criteria against which the Scopes 1 and 2 emissions disclosure are measured or evaluated.

[562] *See* proposed 17 CFR 229.1505(d).

[563] *See* proposed 17 CFR 229.1505(a)(1).

[564] Reasonable assurance is equivalent to the level of assurance provided in an audit of a registrant's consolidated financial statements included in a Form 10–K. Limited assurance is equivalent to the level of assurance (commonly referred to as a ''review'') provided over a registrant's interim financial statements included in a Form 10–Q.

[565] We refer to ''assurance'' broadly when describing the level and scope of assurance to which climate-related disclosures should be subject. Our proposed approach to assurance has been guided by ''attestation'' standards published by organizations including the PCAOB, AICPA, and the International Auditing and Assurance Standards Board (''IAASB''). Such attestation standards apply to engagements other than audit and review of historical financial statements and have been widely used in the current voluntary ESG and GHG assurance market for a number of years.

[566] *See* proposed 17 CFR 229.1505(a)(2). If the accelerated filer or large accelerated filer was required to obtain reasonable assurance over its Scope 1 and Scope 2 emissions disclosures and the attestation provider chose to follow, for example, the AICPA attestation standards, the accelerated filer or large accelerated filer could voluntarily obtain limited assurance over its GHG intensity metric or Scope 3 emissions disclosures, and the attestation provider would be required to follow the AICPA's attestation standard for providing limited assurance.

[567] *See, e.g.,* letters from AICPA; Americans for Financial Reform Education Fund *et al;* Andrew Behar; Baillie Gifford; Carbon Tracker Initiative; Cardano Risk Management Ltd.; CDP; Center for American Progress; Center for Audit Quality; Ceres et al.; Climate Disclosure Standards Board; Climate Governance Initiative; Emmanuelle Haack; Eni SpA; ERM CVS (recommending limited assurance); George Serafeim; Regenerative Crisis Response Committee; Friends of the Earth, Amazon Watch, and Rainforest Action Network; Hermes Equity Ownership Limited; Impax Asset Management; Institutional Shareholder Services; Interfaith Center on Corporate Responsibility (recommending reasonable assurance); International Corporate Governance Institute; International Organization for Standardization; Morningstar, Inc.; Natural Resources Defense Council; NY City Comptroller; NY State Comptroller; Oxfam America; PRI ; Pricewaterhouse Coopers; Revolving Door Project; TotalEnergies (recommending limited assurance); Value Balancing Alliance; WBCSD; William and Flora Hewlett Foundation; and World Benchmarking Alliance.

verification over ESG and climate-related disclosures. For example, according to one commenter, 80 percent of S&P 100 companies currently subject certain items of their ESG information, including climate-related disclosures such as greenhouse gas emissions, to some type of third-party assurance or verification.[568] Several commenters recommended that we require climate-related disclosures to be subject to limited assurance,[569] which provides a lower level of assurance than reasonable assurance, but is less costly, and is the most common form of assurance provided for ESG, including climate-related disclosures, in the current voluntary reporting landscape.[570]

One commenter recommended that, at a minimum, we require a registrant to obtain a limited assurance report for its Scopes 1 and 2 emissions disclosure while encouraging optional verification for other ESG metrics.[571] Another commenter indicated that a limited assurance requirement for climate-related disclosures would be similar to the EU's Corporate Sustainability Reporting Directive proposal that, if adopted, would initially require companies in the European Union to obtain limited assurance on reported sustainability information with an option to move towards reasonable assurance in the future.[572] One commenter stated the view that, while the professional capacity of audit firms might, at this point, be insufficient to provide reasonable assurance of ESG data, it supported a mandatory limited assurance requirement for climate risk reporting.[573] Other commenters recommended that we require climate-related disclosures to be audited at the reasonable assurance level.[574]

Some commenters, however, opposed any third-party assurance requirement for climate-related disclosures because of the significant cost that these commenters asserted it could impose on public companies, and because, in their view, application of assurance standards to data that is different from traditional financial reporting disclosures, such as GHG emissions, would be a relatively new and evolving field.[575] Some of these commenters indicated that, as a first step, registrants should develop their internal controls and disclosure controls and procedures (''DCP'') to include climate-related disclosures, and defer mandated third-party assurance requirements to a later time.[576]

We recognize that requiring GHG emissions disclosure in Commission filings should enhance the consistency, comparability, and reliability of such disclosures due to the application of DCP and the proposed inclusion of certain prescriptive elements that may help improve standardization of GHG emissions calculations. Nevertheless, the evolving and unique nature of GHG emissions reporting involves and, in some cases, warrants varying methodologies, differing assumptions, and a substantial amount of estimation. Certain aspects of GHG emissions disclosure also involve reliance on third-party data. As such, requiring a third party's attestation over these disclosures would provide investors with an additional degree of reliability regarding not only the figures that are disclosed, but also the key assumptions, methodologies, and data sources the registrant used to arrive at those figures. In other contexts, such as mineral resources and oil and gas reserves, the Commission has recognized the value that third parties with specialized expertise in audit and engineering can bring to company disclosures of physical resources or risks.[577]

Our rules typically do not require registrants to obtain assurance over disclosure provided outside of the financial statements, including quantitative disclosure. We believe, however, that there are important distinctions between existing quantitative disclosure required to be provided outside of the financial statements and the proposed GHG emissions disclosure. In contrast to GHG emissions disclosure, quantitative disclosure outside of the financial statements typically is derived, at least in part, from the same books and records that are used to generate a registrant's audited financial statements and accompanying notes and that are subject to ICFR. Accordingly, such quantitative disclosure has been subject to audit procedures as part of the audit of the financial statements in the same filing. Further, the auditor's read and consider obligation requires an evaluation of this quantitative information based on the information obtained through the audit of the financial statements.[578] Unlike other quantitative information that is provided outside of the financial statements, GHG emissions disclosure would generally not be developed from information that is included in the registrant's books and records and, therefore, would not be subjected to audit procedures.[579] In addition, although not an assurance engagement, we have adopted rules requiring an expert to review and provide conclusions on other specialized, quantitative data that is provided outside of the financial statements.[580] Accordingly, to enhance its reliability, we believe it is appropriate to require that GHG emissions disclosure be subject to third-party attestation.

For similar reasons, we also considered proposing to require that management assess and disclose the effectiveness of controls over GHG

[568] *See* letter from CAQ; *see also* CAQ, *S&P 500 and ESG Reporting* (Aug. 9, 2021), available at *https://www.thecaq.org/sp-500-and-esg-reporting/* (stating that more than half of S&P 500 companies had some form of assurance or verification over ESG metrics, including GHG emissions metrics).

[569] *See, e.g.,* letters from Credit Suisse; ERM CVS; PayPal Holdings, Inc.; TotalEnergies; and Walmart.

[570] *See* letter from Energy Infrastructure Council; *see also* CAQ, *S&P 500 and ESG Reporting* (Aug. 9, 2021).

[571] *See* letter from PayPal Holdings, Inc.

[572] *See* letter from CAQ.

[573] *See* letter from Credit Suisse.

[574] *See, e.g.,* letters from Ceres *et al.;* and Interfaith Center on Corporate Responsibility.

[575] *See, e.g.,* letters from American Petroleum Institute; Investment Company Institute; and National Association of Manufacturers.

[576] *See, e.g.,* letters from American Petroleum Institute; and Investment Company Institute. We agree that registrants should develop their DCP to include their GHG emissions disclosures. When the proposed GHG emissions disclosures are included in Form 10–K and Form 20–F annual reports, our rules governing DCP would apply to those disclosures. *See* 17 CFR 240.13a–15 and 240.15d–15.

[577] *See* 17 CFR 229.1302 (requiring a registrant's disclosure of exploration results, mineral resources, or mineral reserves to be based on and accurately reflect information and supporting documentation prepared by a qualified person, which, pursuant to 17 CFR 229.1300, is defined to mean a mineral industry professional with at least five years of relevant experience in the type of mineralization and type of deposit under consideration who meets certain additional criteria); and 17 CFR 229.1202(a)(7) (requiring a registrant to disclose the qualifications of the technical person primarily responsible for overseeing the preparation of the oil and gas reserves estimates or reserves audit).

[578] *See* PCAOB AS 2710 *Other Information in Documents Containing Audited Financial Statements* (requiring an auditor to read the other information (included in an annual report with the audited financial statements) and consider whether such information, or the manner of its presentation, is materially inconsistent with information, or the manner of its presentation, appearing in the financial statements). For example, disclosure pursuant to 17 CFR 229.303 (Item 303 of Regulation S–K—MD&A) is derived in part from the same books and records that are subject to ICFR and used to generate a registrant's audited financial statements and accompanying notes (*e.g.,* the liquidity and capital resources disclosures are anchored to the audited cash flows information disclosed in the financial statements).

[579] Although GHG emission disclosure would generally not be directly derived from the same books and records that are used to generate a registrant's audited financial statements and accompanying notes and that are subject to ICFR, GHG emission disclosure, as proposed, would be required to use the same organizational and operational boundaries as the registrant's financial statement disclosures. *See* proposed 17 CFR 229.1504(e)(2).

[580] *See Modernization of Property Disclosures for Mining Registrants,* Release No. 33–10570 (Oct. 31, 2018), [83 FR 66344 (Dec. 26, 2018)].

emissions disclosure (apart from the existing requirements with respect to the assessment and effectiveness of DCP). More specifically, in addition to the requirement to assess such controls, we considered whether to require management to include a statement in their annual report regarding their responsibility for the design and evaluation of controls over GHG emissions disclosures, as well as to disclose their conclusion regarding the effectiveness of such controls. We also considered proposing to require a GHG emissions attestation provider's attestation of the effectiveness of controls over GHG emissions disclosure in addition to the proposed attestation over the Scopes 1 and 2 GHG emissions disclosure. Although both such requirements could further enhance the reliability of the related Scopes 1 and 2 GHG emissions disclosure, we are not currently proposing them at this time. We are, however, continuing to consider these alternatives, including: (i) the need to develop guidance for management on conducting such an assessment and (ii) whether appropriate attestation standards exist. Accordingly, we request comment on these and related issues below.

The Commission has long recognized the important role played by an independent audit in contributing to the reliability of financial reporting.[581] Relatedly, studies suggest that investors have greater confidence in information that has been assured, particularly when it is assured at the reasonable assurance level.[582] Although a limited assurance engagement provides a lower level of assurance than a reasonable assurance engagement,[583] studies of ESG-related assurance, which is typically provided at a limited assurance level, have found benefits such as credibility enhancement, lower cost of equity capital, and lower analyst forecast errors and dispersion.[584] Therefore, proposing to require Scope 1 and Scope 2 emissions disclosure by accelerated filers and large accelerated filers be subject to limited assurance initially, with an eventual scaling up to reasonable assurance, could potentially improve both the actual reliability of disclosure and investor confidence in such disclosure.[585]

Increasing investor demand for consistent, comparable, and reliable climate-related financial information appears to have led a growing number of companies to voluntarily obtain third-party assurance over their climate-related disclosures both within the U.S. and globally. For example, according to one study, 53% of the S&P 500 companies had some form of assurance or verification over climate-related metrics, along with other metrics.[586] Another survey of sustainability reporting trends from 5,200 companies across 52 countries (including the United States) stated that, of the top 100 companies (by revenue), 80% have reporting on ESG (including climate), with up to 61% of those companies also obtaining assurance.[587] The prevalence of major companies obtaining assurance in connection with their voluntary sustainability reports suggests that both the companies and their investors are focused on the reliability of such disclosures.

Although many registrants have voluntarily obtained some level of assurance for their climate-related disclosures, current voluntary ESG assurance practices have been varied with respect to the levels of assurance provided (*e.g.,* limited versus reasonable), the assurance standards used, the types of service providers, and the scope of disclosures covered by the assurance. This fragmentation has diminished the comparability of the assurance provided and may require investors to become familiar with many different assurance standards and the varying benefits of different levels of assurance. The consequences of such fragmentation has also been highlighted by certain international organizations,[588] including IOSCO, which stated that the ''perceived lack of clarity and consistency around the purpose and scope of [voluntary] assurance . . . potentially lead[s] to market confusion, including misleading investors and exacerbating the expectations gap.'' [589] For example, investors may see that a service provider has produced an assurance report for a registrant's GHG emissions disclosure and have an expectation that such assurance will enhance the reliability of that disclosure without always understanding the service provider's qualifications for producing the report, what level of assurance (*e.g.,* limited versus reasonable) is being provided, what scope of assurance (*e.g.,* the disclosures covered by the assurance) is being provided with respect to the registrant's GHG emissions disclosure, and the methodologies and procedures that the attestation provider used. While some experienced assurance providers may be proficient in applying attestation standards to GHG emissions disclosures, other assurance providers may lack GHG emissions expertise. Similarly, some service providers providing assurance may have expertise in GHG emissions but have minimal assurance experience. Moreover, some service providers may use standards that are

[581] *See Qualifications of Accountants,* Release No. 33–10876 (Oct. 16, 2020) [85 FR 80508 (Dec. 11, 2020)], at 80508. *See also* Statement of Paul Munter, Acting Chief Accountant, *The Importance of High Quality Independent Audits and Effective Audit Committee Oversight to High Quality Financial Reporting to Investors* (Oct. 26, 2021), available at *https://www.sec.gov/news/statement/munter-audit-2021/10/26.*

[582] *See, e.g.,* Carol Callaway Dee, et al., *Client Stock Market Reaction to PCAOB Sanctions against a Big Four Auditor,* 28 Contemp. Acct. Res. 263 (Spring 2011) (''Audits are valued by investors because they assure the reliability of and reduce the uncertainty associated with financial statements.''); Center for Audit Quality, *2019 Main Street Investor Survey* (''[I]nvestors continue to register high degrees of confidence in the ability of public company auditors to fulfill their investor-protection roles. Eighty-three percent of US retail investors view auditors as effective in their investor-protection role within the US capital markets, up from 81% in 2018); and CFA Institute, *CFA Institute Member Survey Report—Audit Value, Quality, and Priorities* (2018).

[583] *See infra* note 604 for a discussion of the key differences between limited and reasonable assurance engagements.

[584] *See, e.g.,* Ryan J. Casey, et al., *Understanding and Contributing to the Enigma of Corporate Social Responsibility (CSR) Assurance in the United States,* 34 Auditing: A Journal of Practice and Theory 97, 122 (Feb. 2015) (finding that corporate social responsibility (''CSR'') assurance results in lower cost-of-capital along with lower analyst forecast errors and dispersion, and that financial analysts find related CSR reports to be more credible when independently assured). *See also infra* note 592 for statistics illustrating that limited assurance is more commonly obtained voluntarily in the current market than reasonable assurance over ESG-related information.

[585] *See, e.g.,* letter from Institute for Policy Integrity, Environmental Defense Fund, Initiative on Climate Risk & Resilience Law (''Voluntary frameworks typically lack independent auditing requirements, which is one reason many investors perceive current disclosures to be unreliable or uneven.''). *See also* EVORA Global and SIERA, *Investor Survey 2021: Part 2 ESG Data Challenge* (2021), 7, available at *https://evoraglobal.com/wp-content/uploads/2021/12/ESG-Data-Challenge-Investor-Survey-Part-2.pdf* (''Investors are integrating ESG across the investment lifecycle, for the purposes of strategy, reporting, peer benchmarking, etc., however the majority (86%) are not sure of their ESG data quality. About 52% of the investors consider that their ESG data is partially investment-grade.''); State Street Global Advisors, *The ESG Data Challenge* (Mar. 2019), available at *https://www.ssga.com/investment-topics/environmental-social-governance/2019/03/esg-data-challenge.pdf.*

[586] *See* CAQ, *S&P 500 and ESG Reporting* (Aug. 9, 2021).

[587] *See* KPMG, *The KPMG Survey of Sustainability Reporting 2020,* available at https://home.kpmg/xx/en/home/insights/2020/11/the-time-has-come-survey-of-sustainability-reporting.html.

[588] International Federation of Accountants, *The State of Play in Sustainability Assurance* (June 23, 2021), available at *https://www.ifac.org/knowledge-gateway/contributing-global-economy/discussion/state-play-sustainability-assurance;* Lawrence Heim, International Federation of Accountants, *IFAC: Poor ESG Assurance an* ''*Emerging Financial Stability Risk*'' (July 1, 2021), available at *https://practicalesg.com/2021/07/ifac-poor-esg-assurance-an-emerging-financial-stability-risk/.*

[589] IOSCO, *Report on Sustainability-related Issuer Disclosures* (June 2021).

developed by accreditation bodies with notice and public comment and other robust due process procedures [590] for standard setting, while other service providers may use privately developed ''verification'' standards.[591]

To improve accuracy, comparability, and consistency with respect to the proposed GHG emissions disclosure, we are proposing to require a minimum level of attestation services for accelerated filers and large accelerated filers including: (1) Limited assurance for Scopes 1 and 2 emissions disclosure that scales up to reasonable assurance after a specified transition period; (2) minimum qualifications and independence requirements for the attestation service provider; and (3) minimum requirements for the accompanying attestation report. These proposed requirements would be minimum standards that the GHG emissions attestation provider engaged by accelerated filers and large accelerated filers must meet, but, as mentioned above, would not prevent a registrant from obtaining a heightened level of assurance over its climate-related disclosures (prior to the transition to reasonable assurance) or to obtain assurance over climate-related disclosures other than Scope 1 and Scope 2 emissions.

By specifying minimum standards for the attestation provided with respect to GHG emissions disclosure by accelerated filers and large accelerated filers, the proposed rules should improve accuracy and consistency in the reporting of this information, while also providing investors with an enhanced level of reliability against which to evaluate the disclosure. In addition to the proposed minimum standards for attestation services, the proposed additional disclosure requirements for registrants, described below, should further assist investors in understanding the qualifications and suitability of the GHG emissions attestation provider selected by the registrant, particularly in light of the broad spectrum of attestation providers that would be permitted to provide attestation services under the proposed rules.

Although we are proposing certain minimum standards for attestation services, this proposal does not aim to create or adopt a specific attestation standard for assuring GHG emissions, just as this proposal does not define a single methodology for calculating GHG emissions. This is because both the reporting and attestation landscapes are currently evolving and it would be premature to adopt one approach and potentially curtail future innovations in these two areas. The evolving nature of GHG emissions calculations and attestation standards could suggest that it may also be premature to require assurance. We are soliciting comment on the feasibility of our proposal and will consider any public feedback received, but we have preliminarily determined that the phased-in approach that we are proposing, along with an extended period for disclosure compliance for accelerated filers, balances the benefits of third-party review with the costs of seeking assurance in this evolving space.

The proposed minimum standards for attestation services and the proposed additional disclosure requirements would not eliminate fragmentation with respect to assurance or obviate the need for investors to assess and compare multiple attestation standards. Nevertheless, we believe some flexibility in our approach is warranted at this time given the unique and evolving nature of third-party assurance for climate-related disclosures. We believe the proposed minimum standards and additional disclosure requirements would enable investors to better understand the assurance that has been provided.

We are cognizant of the fact that the calculation and disclosure of GHG emissions would be new for many registrants, as would be the application of assurance standards to GHG emissions disclosure. For these reasons and the reasons discussed in greater detail below, we are proposing to require assurance (1) only for accelerated filers and large accelerated filers, (2) only with respect to Scope 1 and Scope 2 emissions, and (3) with an initial transition period for limited assurance and a subsequent transition period for reasonable assurance.

Although we have considered the challenges that mandatory assurance of GHG emissions disclosure could present, accelerated filers and large accelerated filers should have the necessary resources to devote to complying with such requirements over the proposed implementation timetable. For the many large accelerated filers that are already voluntarily obtaining some form of assurance over their GHG emissions, any cost increases associated with complying with the proposed rules would be mitigated.[592] Furthermore, larger issuers generally bear proportionately lower compliance costs than smaller issuers due to the fixed cost components of such compliance.[593]

The proposed transition periods would also provide existing accelerated filers and large accelerated filers one fiscal year to transition to limited assurance [594] and two additional fiscal years to transition to reasonable assurance.[595] For existing accelerated filers, this transition period would be in addition to the one additional year they will have to comply with the Scopes 1 and 2 emission disclosure requirements (compared to large accelerated filers). As such, these filers would have significant time to develop processes to support their GHG emissions disclosure requirements and the relevant DCP, as well as to adjust to the incremental costs and efforts associated with escalating levels of assurance. During this transition period, GHG emissions attestation providers would also have time to prepare themselves for providing such services in connection with Commission filings.

In addition to the challenges posed by the newness of calculating and disclosing GHG emissions, we believe that only requiring assurance over Scope 1 and Scope 2 emissions would be appropriate because the emissions result directly or indirectly from

[590] *See infra* Section II.H.3.

[591] *See, e.g.*, CAQ, *S&P 500 and ESG Reporting* (Aug. 9, 2021) (pointing to the use of assurance methodologies developed by individual service providers, which in some cases were based on IAASB International Standard on Assurance Engagements (ISAE) 3000 with modifications).

[592] *See, e.g.,* CAQ, *S&P 500 and ESG Reporting* (Aug. 9, 2021) (providing statistics on limited assurance versus reasonable assurance obtained voluntarily in the current market (*e.g.,* at least 26 of 31 companies that obtained assurance from public company auditors obtained limited assurance; at least 174 of 235 companies that obtained assurance or verification from other service providers (non-public company auditors) obtained limited assurance)). For similar information on the S&P 100, see CAQ, *S&P 100 and ESG Reporting* (Apr. 29, 2021), available at *https://www.thecaq.org/sp-100-and-esg-reporting/*. Based on an analysis by Commission staff on Mar. 3, 2022, a substantial number of the S&P 500 companies (460+) are large accelerated filers and therefore would be subject to the proposed assurance requirements.

[593] *See infra* note 955 in Section IV.C of the Economic Analysis for further discussion on proportionate costs between different types of filers.

[594] *See infra* note 604 for a discussion of the key differences between limited and reasonable assurance engagements.

[595] By limiting the assurance requirements to accelerated filers and large accelerated filers, a new registrant would not be required to provide assurance until it has been subject to the requirements of Section 13(a) or 15(d) of the Exchange Act for a period of at least twelve calendar months and it has filed at least one annual report pursuant to Section 13(a) or 15(d) of the Exchange Act. *See* 17 CFR 240.12b–2. Therefore, no registrant would be required to provide assurance covering its GHG emissions disclosure during an initial public offering. However, any registrant that voluntarily includes an attestation report for GHG emissions disclosure would be required to comply with proposed Item 1505(e).

facilities owned or activities controlled by a registrant, which makes it relatively more accessible and easier to subject to the registrant's DCP compared to Scope 3 data. Further, as discussed earlier, many registrants already voluntarily seek assurance over their GHG emissions disclosure (predominately Scope 1 and Scope 2 disclosures),[596] which further supports the feasibility and readiness of Scope 1 and Scope 2 emissions disclosure for mandatory assurance. In contrast, we are not proposing to require assurance of Scope 3 emissions disclosure at this time because the preparation of such disclosure presents unique challenges.[597] Depending on the size and complexity of a company and its value chain, the task of calculating Scope 3 emissions could be relatively more burdensome and expensive than calculating Scope 1 and Scope 2 emissions. In particular, it may be difficult to obtain activity data from suppliers, customers, and other third parties in a registrant's value chain, or to verify the accuracy of that information compared to disclosures of Scope 1 and Scope 2 emissions data, which are more readily available to a registrant.

We are proposing to require accelerated filers and large accelerated filers to obtain limited assurance, with an eventual scaling up to reasonable assurance. The objective of a limited assurance engagement is for the service provider to express a conclusion about whether it is aware of any material modifications that should be made to the subject matter (*e.g.,* the Scopes 1 and 2 emissions disclosure) in order for it to be fairly stated or in accordance with the relevant criteria (*e.g.,* the methodology and other disclosure requirements specified in proposed 17 CFR 229.1504 (Item 1504 of Regulation S–K).[598] In such engagements, the conclusion is expressed in the form of negative assurance regarding whether any material misstatements have been identified.[599] In contrast, the objective of a reasonable assurance engagement, which is the same level of assurance provided in an audit of a registrant's consolidated financial statements, is to express an opinion on whether the subject matter is in accordance with the relevant criteria, in all material respects. A reasonable assurance opinion provides positive assurance that the subject matter is free from material misstatement.[600]

Reasonable assurance is feasible whenever limited assurance can be provided on a subject,[601] and as noted above the voluntary attestation obtained by some registrants has been at the reasonable assurance level.[602] We understand, however, that a limited assurance engagement is less extensive and is currently the level of assurance most commonly provided[603] in the voluntary assurance market for climate-related disclosure.[604] Therefore, prior to the transition to reasonable assurance, the additional compliance efforts required to comply with the proposed assurance requirement should be limited for the many registrants that—according to commenters and others—are already obtaining limited assurance for their climate-related disclosures.[605] Furthermore, although reasonable assurance provides a significantly higher level of assurance than limited assurance, we believe limited assurance would benefit investors during the initial transition period by enhancing the reliability of a registrant's Scopes 1 and 2 emissions disclosure, in light of the benefits that assurance provides, as discussed above. Moreover, under the proposed rules, accelerated filers and large accelerated filers would not be prevented from obtaining reasonable assurance for their climate disclosures earlier than required. After the transition to mandatory reasonable assurance, investors would have the benefits of a higher level of assurance with smaller incremental costs to accelerated filers and large accelerated filers than moving directly to a reasonable assurance requirement.

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135. Should we require accelerated filers and large accelerated filers to obtain an attestation report covering their Scope 1 and Scope 2 emissions disclosure, as proposed? Should we require accelerated filers and large accelerated filers to obtain an attestation report covering other aspects of their climate-related disclosures beyond Scope 1 and 2 emissions? For example, should we also require the attestation of GHG intensity metrics, or of Scope 3

[596] For specific examples, *see, e.g.,* Etsy, Inc. FY 2021 Form 10–K, available at *https://s22.q4cdn.com/941741262/files/doc_financials/2021/q4/ETSY-12.31.2021-10K.pdf* (external third-party attestation report available at *https://s22.q4cdn.com/941741262/files/doc_financials/2021/q4/PwC/Limited-Assurance-Report-Assertion-Etsy-FY21_2.24.22_final-signed_final.pdf*); Johnson Controls International plc 2021 Sustainability Report, available at *https://www.johnsoncontrols.com/2021sustainability* (external third-party verification report available at *https://www.johnsoncontrols.com/-/media/jci/corporate-sustainability/reporting-and-policies/gri/2020/ghg-jci-fy-2020-verification-statement.pdf*); Norfolk Southern Corporation 2021 GHG Emissions Report, available at *http://www.nscorp.com/content/dam/nscorp/get-to-know-ns/about-ns/environment/2020-GHG-Emissions-Report.pdf;* Koninklijke Philips NV (Royal Philips) Annual Report 2021, at 269, available at *https://www.results.philips.com/publications/ar21/downloads/pdf/en/Philips/English.pdf?v=20220225104533;* Starbucks Coffee Company FY 2020 GHG emissions inventory assurance report, at 2, available at *https://stories.starbucks.com/uploads/2021/04/StaFY20/Third-Party-Independent-Verification-and-Assurance-Reports.pdf;* and Vornado Realty Trust FY 2020 ESG report, available at *https://books.vno.com/books/idpn/#p=1. See also supra* note 592 for S&P 100 and S&P 500 related statistics.

[597] *See supra* Section II.G.3 for further discussion of the unique challenges presented by the disclosure of Scope 3 emissions.

[598] *See, e.g.,* AICPA's Statement on Standards for Attestation Engagements (SSAE) No.22, AT–C Section 210.

[599] *See infra* Section II.H.3 for further discussion of the attestation report requirements, including the difference between a conclusion and an opinion.

[600] *See, e.g.,* AICPA SSAE No. 21, AT–C Sections 205 and 206.

[601] Under commonly used attestation standards, both a reasonable assurance engagement and a limited assurance engagement have the same requirement that the subject matter (*e.g.,* Scope 1 and Scope 2 emissions) of the engagement be appropriate as a precondition for providing assurance. Thus, if the subject matter is appropriate for a limited assurance engagement, it is also appropriate for a reasonable assurance engagement. *See* AICPA SSAE No. 18 (Apr. 2016); and IAASB ISAE 3000 (Revised) (Dec. 2013).

[602] For example, some registrants have voluntarily sought reasonable assurance over certain information, including Scopes 1, 2, and 3 emissions, for which others have voluntarily sought limited assurance. *See, e.g.,* Apple, Inc. Environmental Progress Report (Mar. 2021), at 88–90, available at *https://www.apple.com/environment/pdf/Apple_Environmental_Progress_Report_2021.pdf;* United Parcel Service, Inc. (UPS) FY 2020 GRI Content Index, at 72, available at *https://about.ups.com/content/dam/upsstories/assets/reporting/sustainability-2021/2020_UPS_GRI_Content_Index_081921v2.pdf;* and Guess?, Inc. FY2020–2021 Sustainability Report, at 91, available at *https://static1.squarespace.com/static/609c10ed49db5202181d673f/t/6faf8af82418f5da4778f6f/1627060411937/GUESS+FY20-21+Sustainability+Report.pdf.*

[603] *See supra* note 592 (providing statistics on limited assurance obtained voluntarily in the current market).

[604] The scope of work in a limited assurance engagement is substantially less than a reasonable assurance engagement. The primary difference between the two levels of assurance relates to the nature, timing, and extent of procedures required to obtain sufficient, appropriate evidence to support the limited assurance conclusion or reasonable assurance opinion. Limited assurance engagements primarily include procedures such as inquiries and analytical procedures and do not necessarily include a consideration of whether internal controls have been effectively designed, whereas reasonable assurance engagements require the assurance service provider to consider and obtain an understanding of internal controls. More extensive testing procedures beyond inquiries and analytical procedures, including recalculation and verification of data inputs, are also required in reasonable assurance engagements, such as inspecting source documents that support transactions selected on a sample basis. Driven by these differences, the cost of limited assurance is generally lower than that of reasonable assurance.

[605] *See* letters from CAQ and Energy Infrastructure Council; *supra* note 592 (providing statistics on voluntary assurance obtained by S&P 100 and S&P 500 companies).

emissions, if disclosed? Conversely, should we require accelerated filers and large accelerated filers to obtain assurance covering only Scope 1 emissions disclosure? Should any voluntary assurance obtained by these filers after limited assurance is required be required to follow the same attestation requirements of Item 1505(b)–(d), as proposed?

136. If we required accelerated filers and large accelerated filers to obtain an attestation report covering Scope 3 emissions disclosure, should the requirement be phased-in over time? If so, what time frame? Should we require all Scope 3 emissions disclosure to be subject to assurance or only certain categories of Scope 3 emissions? Would it be possible for accelerated filers and large accelerated filers to obtain an attestation report covering the process or methodology for calculating Scope 3 emissions rather than obtaining an attestation report covering the calculations of Scope 3 emissions? Alternatively, is there another form of verification over Scope 3 disclosure that would be more appropriate than obtaining an attestation report?

137. Should the attestation requirement be limited to accelerated filers and large accelerated filers, as proposed? Alternatively, should the attestation requirement be limited to a subset of accelerated filers and large accelerated filers? If so, what conditions should apply? Should the attestation requirement only apply to well-known seasoned issuers?[606] Should the attestation requirement also apply to other types of registrants? Should we create a new test for determining whether the attestation requirements apply to a registrant that would take into account the resources of the registrant and also apply to initial public offerings? For example, should we create a test similar to the SRC definition,[607] which includes a separate determination for initial registration statements, but using higher public float and annual revenue amounts?

138. Instead of requiring only accelerated filers and large accelerated filers to include an attestation report for Scope 1 and Scope 2 emissions, should the proposed attestation requirements also apply to registrants other than accelerated filers and large accelerated filers? If so, should the requirement apply only after a specified transition period? Should such registrants be required to provide assurance at the same level as accelerated filers and large accelerated filers and over the same scope of GHG emissions disclosure, or should we impose lesser requirements (*e.g.,* only limited assurance and/or assurance over Scope 1 emissions disclosure only)?

139. Should we require accelerated filers and large accelerated filers to initially include attestation reports reflecting attestation engagements at a limited assurance level, eventually increasing to a reasonable assurance level, as proposed? What level of assurance should apply to the proposed GHG emissions disclosure, if any, and when should that level apply? Should we provide a one fiscal year transition period between the GHG emissions disclosure compliance date and when limited assurance would be required for accelerated filers and large accelerated filers, as proposed? Should we provide an additional two fiscal year transition period between when limited assurance is first required and when reasonable assurance is required for accelerated filers and large accelerated filers, as proposed?

140. Should we provide the same transition periods (from the Scopes 1 and 2 emissions disclosure compliance date) for accelerated filers and large accelerated filers, as proposed? Instead, should different transition periods apply to accelerated filers and large accelerated filers? Should we provide transition periods with different lengths than those proposed? Should we require the attestation to be at a reasonable assurance level without having a transition period where only limited assurance is required? Should we instead impose assurance requirements to coincide with reporting compliance periods?

141. Under prevailing attestation standards, ''limited assurance'' and ''reasonable assurance'' are defined terms that we believe are generally understood in the marketplace, both by those seeking and those engaged to provide such assurance. As a result, we have not proposed definitions of those terms. Should we define ''limited assurance'' and ''reasonable assurance'' and, if so, how should we define them? Would providing definitions in this context cause confusion in other attestation engagements not covered by the proposed rules? Are the differences between these types of attestation engagements sufficiently clear without providing definitions?

142. As proposed, there would be no requirement for a registrant to either provide a separate assessment and disclosure of the effectiveness of controls over GHG emissions disclosure by management or obtain an attestation report from a GHG emissions attestation provider specifically covering the effectiveness of controls over GHG emissions disclosure. Should we require accelerated filers and large accelerated filers to provide a separate management assessment and disclosure of the effectiveness of controls over GHG emissions disclosure (separate from the existing requirements with respect to the assessment and effectiveness of DCP)? Should we require management to provide a statement in their annual report on their responsibility for the design and evaluation of controls over GHG emissions disclosure and to disclose their conclusion regarding the effectiveness of such controls? Instead of, or in addition to, such management assessment and statement, should we require the registrant to obtain an attestation report from a GHG emissions attestation provider that covers the effectiveness of such GHG emissions controls as of the date when the accelerated filer or large accelerated filer is required to comply with the reasonable assurance requirement under proposed Item 1505(a)? If so:

(i) Would it be confusing to apply either such requirement in light of the existing DCP requirements that would apply to the proposed GHG emissions disclosure?

(ii) Would a separate management assessment and statement on the effectiveness of controls over GHG emissions provide meaningful disclosure to investors beyond the existing requirement for DCP?

(iii) Should we specify that the separate management assessment and statement must be provided by the accelerated filer's or large accelerated filer's principal executive and principal financial officers, or persons performing similar functions? Should we clarify which members of the accelerated filer or large accelerated filer's management should be involved in performing the underlying assessment?

(iv) What controls framework(s) would the effectiveness of the registrant's controls over GHG emissions disclosure be evaluated against, if any?

(v) For the GHG emissions attestation provider, what requirements should be applied to such GHG emissions disclosure controls attestation requirement? For example, what attestation standards should apply? Should other service provider(s) in addition to or in lieu of the GHG emissions attestation provider be permitted to provide such attestation over the effectiveness of the GHG controls?

(vi) Should we limit such a requirement to accelerated filers and

[606] *See* 17 CFR 230.405 (defining ''well-known seasoned issuer'').

[607] *See, e.g.,* 17 CFR 240.12b–2.

large accelerated filers only or should it apply to other registrants as well?

(vii) What would be the potential benefits and costs of either approach?

(viii) Should we require a certification on the design and evaluation of controls over GHG emissions disclosures by officers serving in the principal executive and principal financial officer roles or persons performing similar functions for an accelerated filer or large accelerated filer? Would a certification requirement have any additional benefits or impose any additional costs when compared to a requirement for management to assess and disclose in a statement in the annual report the effectiveness of controls over GHG emissions?

143. We considered whether to require registrants to include the GHG emissions metrics in the notes or a separate schedule to their financial statements, by amending Regulation S–X instead of Regulation S–K.

(i) Would there be benefits to including this information in a registrant's financial statements? For example, would requiring the GHG emissions disclosure to be included in the financial statements improve the consistency, comparability, reliability, and decision-usefulness of the information for investors? Would it facilitate the integration of GHG metrics and targets into the registrant's financial analysis? Would such placement cause registrants to incur significantly more expense in obtaining an audit of the disclosure? If so, please quantify those additional expenses where possible.

(ii) Should we require a registrant to include the GHG emissions disclosure in its audited financial statements so that the disclosure would be subject to the existing requirements for an independent audit and ICFR? If so, we seek comment on the following aspects of this alternative:

(a) If GHG emissions disclosure is subject to ICFR, or an internal control framework similar to ICFR, would GHG emissions disclosure be more reliable compared to what is currently proposed? What are the benefits or costs?

(b) Should the GHG emissions disclosure be included in a note to the registrant's financial statements (*e.g.,* in the note where the proposed financial statement metrics as discussed above in Section II.F would be included) or in a schedule, or somewhere else? If the GHG emissions disclosure was required in the financial statements, should it be subject to a reasonable assurance audit like the other information in the financial statements? If in a schedule, should the GHG emissions disclosure be disclosed in a schedule similar to those required under Article 12 of Regulation S–X, which would subject the disclosure to audit and ICFR requirements? Should we instead require the metrics to be disclosed as supplemental financial information, similar to the disclosure requirements under FASB ASC Topic 932–235–50–2 for registrants that have significant oil- and gas-producing activities? If so, should such supplemental schedule be subject to ICFR requirements? Instead of requiring the GHG emissions disclosure to be included in a note to the registrant's audited financial statements, should we require a new financial statement for such metrics?

(c) PCAOB auditing standards apply to the audit of a registrant's financial statements. If GHG emissions disclosure is included in a supplemental schedule to the financial statements, should we allow other auditing standards to be applied? If so, which ones? What, if any, additional guidance or revisions to such standards would be needed in order to apply them to the audit of GHG emissions disclosure?

(d) What are the costs and benefits of employing registered public accounting firms to perform audits of GHG emissions disclosure and related attestation of internal controls? Are there potential cost savings in employing registered public accountants that currently perform audits of financial statements and attestation of ICFR to review GHG emissions disclosure and any related internal controls? If we require GHG emissions disclosure to be presented in the financial statements, should we permit entities other than registered public accounting firms to provide assurance of this information, as proposed for the current attestation requirements under Regulation S–K? If not limited to registered public accounting firms, who should be permitted to provide assurance of GHG emissions disclosure? Should we permit environmental consultants, engineering firms, or other types of specialists to provide assurance? What are the costs and benefits of such approach? Would the reliability of the audits and therefore the information disclosed be affected if assurance providers other than registered public accounting firms are permitted to conduct these audits? Please provide supporting data where possible. If we should allow for assurance providers that are not registered public accounting firms, what qualifications and oversight should they have, and what requirements should we impose on them? Should we direct the PCAOB to develop a separate registration process for service providers that are not otherwise registered? What expertise, independence and quality control standards should apply?

(e) What would be the other potential benefits and costs of such an approach?

2. GHG Emissions Attestation Provider Requirements

The proposed rules would require the GHG emissions attestation report required by proposed Item 1505(a) for accelerated filers and large accelerated filers to be prepared and signed by a GHG emissions attestation provider.[608] The proposed rules would define a GHG emissions attestation provider to mean a person or a firm that has all of the following characteristics:

- Is an expert in GHG emissions by virtue of having significant experience in measuring, analyzing, reporting, or attesting to GHG emissions. Significant experience means having sufficient competence and capabilities necessary to:

  o perform engagements in accordance with professional standards and applicable legal and regulatory requirements; and

  o enable the service provider to issue reports that are appropriate under the circumstances.[609]

- Is independent with respect to the registrant, and any of its affiliates,[610] for whom it is providing the attestation report, during the attestation and professional engagement period.[611]

The proposed expertise requirement is intended to help ensure that the service provider preparing the attestation report has sufficient competence and capabilities necessary to execute the attestation engagement. In this regard, if the service provider is a firm, we would expect that it have policies and procedures designed to provide it with reasonable assurance that the personnel selected to conduct the GHG emissions attestation engagement have significant experience with respect to both attestation engagements and GHG disclosure. This would mean that the service provider has the qualifications necessary for fulfillment of the responsibilities that it would be called on to assume, including the appropriate engagement of

[608] *See* proposed 17 CFR 229.1505(b).

[609] *See* proposed 17 CFR 229.1505(b)(1).

[610] ''Affiliates,'' for purposes of proposed 17 CFR 229.1505 has the meaning provided in 17 CFR 210.2–01, except references to ''audit'' are deemed to be references to the attestation services provided pursuant to this section. *See* proposed 17 CFR 229.1505(b)(2)(iii).

[611] *See* proposed 17 CFR 229.1505(b)(2) and 229.1505(b)(2)(iv) (defining the term ''attestation and professional engagement period'').

specialists, if needed.[612] The proposed expertise requirement would apply to the person or the firm signing the GHG emissions attestation report.[613]

The second proposed requirement is modeled on the Commission's qualifications for accountants under 17 CFR 210.2–01 (Rule 2–01 of Regulation S–X), which are designed to ensure that auditors are independent of their audit clients. Similar to how assurance provided by independent public accountants improves the reliability of financial statements and disclosures and is a critical component of our capital markets, assurance of GHG emissions disclosure by independent service providers should also improve the reliability of such disclosure. Academic studies demonstrate that assurance provided by an independent auditor reduces the risk that an entity provides materially inaccurate information to external parties, including investors, by facilitating the dissemination of transparent and reliable financial information.[614] We expect that GHG emissions disclosure would similarly benefit if assured by an independent service provider. Moreover, the potential conflicts of interest, or even the appearance of such conflicts of interest, between the GHG emissions attestation provider and the registrant could raise doubts for investors about whether they can rely on the attestation service and its report.

Similar to Rule 2–01 of Regulation S–X,[615] the proposed rules would provide that a GHG emissions attestation provider is not independent if during the attestation and professional engagement period such attestation provider is not, or a reasonable investor with knowledge of all relevant facts and circumstances would conclude that such attestation provider is not, capable of exercising objective and impartial judgment on all issues encompassed within the attestation provider's engagement.[616] The proposed definition for the attestation and professional engagement period, which is modeled on Rule 2–01 of Regulation S–X, includes both (1) the period covered by the attestation report and (2) the period of the engagement to attest to the registrant's GHG emissions or to prepare a report filed with the Commission (the ''professional engagement period''). Under the proposed rules, the professional engagement period would begin when the GHG attestation service provider either signs an initial engagement letter (or other agreement to attest to a registrant's GHG emissions) or begins attest procedures, whichever is earlier.[617]

The proposed rules would further state that, in determining whether a GHG emissions attestation provider is independent, the Commission will consider:

- Whether a relationship or the provision of a service creates a mutual or conflicting interest between the attestation provider and the registrant (or any of its affiliates), places the attestation provider in the position of attesting to such attestation provider's own work, results in the attestation provider acting as management or an employee of the registrant (or any of its affiliates), or places the attestation provider in a position of being an advocate for the registrant (or any of its affiliates);[618] and
- all relevant circumstances, including all financial or other relationships between the attestation provider and the registrant (or any of its affiliates), and not just those relating to reports filed with the Commission.[619]

These proposed provisions are modeled on the factors used by the Commission in determining whether an accountant is independent.[620] Similar to Rule 2–01 of Regulation S–X, the proposed provisions should help protect investors by requiring the GHG emissions attestation provider to be independent both in fact and appearance from the registrant, including its affiliates.

Because the GHG emissions attestation provider would be a person whose profession gives authority to the statements made in the attestation report and who is named as having provided an attestation report that is part of the registration statement, the registrant would be required to obtain and include the written consent of the GHG emissions attestation provider pursuant to Securities Act Section 7,[621] the corresponding rule requiring the written consents of such experts,[622] and the Regulation S–K provision requiring the attachment of the written consent of an expert to a Securities Act registration statement or an Exchange Act report that incorporates by reference a written expert report attached to a previously filed Securities Act registration statement.[623] The GHG emissions attestation provider would also be subject to liability under the federal securities laws for the attestation conclusion or, when applicable, opinion provided. Such liability should encourage the attestation service provider to exercise due diligence with respect to its obligations under a limited or reasonable assurance engagement.

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144. Should we require a registrant to obtain a GHG emissions attestation report that is provided by a GHG emissions attestation provider that meets specified requirements, as proposed? Should one of the requirements be that the attestation provider is an expert in GHG emissions, with significant experience in measuring, analyzing, reporting, or attesting to GHG emissions, as proposed? Should we specify that significant experience means having sufficient competence and capabilities

[612] Independent auditors and accountants are already required to comply with similar quality control and management standards when providing audit and attest services under the PCAOB, AICPA, or IAASB standards. *See, e.g.,* PCAOB, Quality Control (QC) Standards Section 20 *System of Quality Control for a CPA Firm's Accounting and Auditing Practice* and Section 40 *The Personnel Management Element of a Firm's System of Quality Control—Competencies Required by a Practitioner-in-Charge of an Attest Engagement,* available at *https://pcaobus.org/oversight/standards/qc-standards;* AICPA, QC Section 10, *A Firm's System of Quality Control,* available at *https://us.aicpa.org/content/dam/aicpa/research/standards/auditattest//qc-00010.pdf;* and IAASB, International Standard on Quality Management 1, *Quality Management for Firms that Perform Audits or Reviews of Financial Statements, or Other Assurance or Related Services Engagements,* available at *https://www.ifac.org/system/files/publications/files/IAASB-Quality-Management-ISQM-1-Quality-Management-for-Firms.pdf.*

[613] We have adopted similar expertise requirements in the past to determine eligibility to prepare a mining technical report. Although also relating to technical, specialized disclosures, the mining technical report requirements differ in that such an engagement is not an assurance engagement. *See Modernization of Property Disclosures for Mining Registrants,* Release No. 33–10570 (Oct. 31, 2018), [83 FR 66344 (Dec. 26, 2018)].

[614] *See* Mark Defond & Jieying Zhang, *A Review of Archival Auditing Research,* 58 J. Acct. & Econ., 275 (2014); *Qualifications of Accountants,* Release No. 33–10876 (Oct. 16, 2020) [85 FR 80508 (Dec. 11, 2020)], at 80508 (''The Commission has long recognized that an audit by an objective, impartial, and skilled professional contributes to both investor protection and investor confidence''). *See also* Statement of Paul Munter, Acting Chief Accountant, *The Importance of High Quality Independent Audits and Effective Audit Committee Oversight to High Quality Financial Reporting to Investors* (Oct. 26, 2021).

[615] *See* 17 CFR 210.2–01(b).

[616] *See* proposed 17 CFR 229.1505(b)(2)(i).

[617] *See* proposed 17 CFR 229.1505(b)(2)(iv).

[618] *See* proposed 17 CFR 229.1505(b)(2)(ii)(A).

[619] *See* proposed 17 CFR 229.1505(b)(2)(ii)(B).

[620] *See* 17 CFR 210.2–01. For the avoidance of doubt, we note that if the independent accountant who audits the registrant's consolidated financial statements is also engaged to perform the GHG emissions attestation for the same filing, the fees associated with the GHG emissions attestation engagement would be considered ''Audit-Related Fees'' for purposes of Item 9(e) of 17 CFR 240.14a-101, Item 14 of Form 10–K, Item 16C of Form 20–F, or any similar requirements.

[621] 15 U.S.C. 77g.

[622] *See* 17 CFR 230.436.

[623] *See* 17 CFR 229.601(b)(23).

necessary to: (a) Perform engagements in accordance with professional standards and applicable legal and regulatory requirements and (b) enable the service provider to issue reports that are appropriate under the circumstances, as proposed? Should we instead require that the GHG emissions attestation provider have a specified number of years of the requisite type of experience, such as 1, 3, 5, or more years? Should we specify that a GHG emissions attestation provider meets the expertise requirements if it is a member in good standing of a specified accreditation body that provides oversight to service providers that apply attestation standards? If so, which accreditation body or bodies should we consider (*e.g.,* AICPA)? Are there any other requirements for the attestation provider that we should specify? Instead, should we require a GHG emissions attestation provider to be a PCAOB-registered audit firm?

145. Is additional guidance needed with respect to the proposed expertise requirement? Should we instead include prescriptive requirements related to the qualifications and characteristics of an expert under the proposed rules? For example, should we include a provision that requires a GHG emissions attestation provider that is a firm to have established policies and procedures designed to provide it with reasonable assurance that the personnel selected to provide the GHG attestation service have the qualifications necessary for fulfillment of the responsibilities that the GHG emissions attestation provider will be called on to assume, including the appropriate engagement of specialists, if needed?

146. Should we require the GHG emissions attestation provider to be independent with respect to the registrant, and any of its affiliates, for whom it is providing the attestation report, as proposed? Should we specify that a GHG emissions attestation provider is not independent if such attestation provider is not, or a reasonable investor with knowledge of all relevant facts and circumstances would conclude that such attestation provider is not, capable of exercising objective and impartial judgment on all issues encompassed within the attestation provider's engagement, as proposed? The proposed provision is based on a similar provision regarding the qualification of an accountant to be an independent auditor under Rule 2–01 of Regulation S–X. Is Rule 2–01 an appropriate model for determining the independence of a GHG emissions attestation provider? Is being independent from a registrant and its affiliates an appropriate qualification for a GHG emissions attestation provider?

147. Should we specify that the factors the Commission would consider in determining whether a GHG emissions attestation provider is independent include whether a relationship or the provision of a service creates a mutual or conflicting interest between the attestation provider and the registrant, including its affiliates, places the attestation provider in the position of attesting to such attestation provider's own work, results in the attestation provider acting as management or an employee of the registrant, including its affiliates, or places the attestation provider in a position of being an advocate for the registrant and its affiliates, as proposed? Should we specify that the Commission also will consider all relevant circumstances, including all financial and other relationships between the attestation provider and the registrant, including its affiliates, and not just those relating to reports filed with the Commission, as proposed?

148. Should we adopt all of the proposed factors for determining the independence of a GHG emissions attestation provider, or are there factors we should omit? Are there any additional factors that we should specify that the Commission will consider when determining the independence of a GHG emissions attestation provider? For example, should we include any non-exclusive specifications of circumstances that would be inconsistent with the independence requirements, similar to those provided in 17 CFR 210.2–01(c) (Rule 2–01(c) of Regulation S–X)?

149. Should the definition of ''affiliates'' be modeled on Rule 2–01, as proposed, or should we use a different definition? Would defining the term differently than proposed cause confusion because the rest of the proposed independence requirement is modeled on Rule 2–01? Many accountants are likely familiar with the proposed definition given their required compliance with Rule 2–01, would non-accountants understand how to comply with and apply this concept?

150. Should the term ''attestation and professional engagement period'' be defined in the proposed manner? If not, how should ''attestation and professional engagement period'' be defined? Alternatively, should the Commission specify a different time period during which an attestation provider must meet the proposed independence requirements?

151. Should we include disclosure requirements when there is a change in, or disagreement with, the registrant's GHG emissions attestation provider that are similar to the disclosure requirements in Item 4.01 of Form 8–K and 17 CFR 229.304 (Item 304 of Regulation S–K)?

152. Accountants are already required to comply with the relevant quality control and management standards when providing audit and attest services under the PCAOB, AICPA, or IAASB standards. These quality control and management standards would apply to accountants providing GHG attestation services pursuant to those standards as well. Should we require the GHG emissions attestation provider to comply with additional minimum quality control requirements (*e.g.,* acceptance and continuance of engagements, engagement performance, professional code of conduct, and ethical requirements) to provide greater consistency over the quality of service provided by GHG emissions attestation providers who do not (or cannot) use the PCAOB, AICPA, or IAASB attestation standards? If so, what should the minimum requirements be?

153. As proposed, the GHG emissions attestation provider would be a person whose profession gives authority to statements made in the attestation report and who is named as having provided an attestation report that is part of the registration statement, and therefore the registrant would be required to obtain and include the written consent of the GHG emissions provider pursuant to Securities Act Section 7 and related Commission rules. This would subject the GHG emissions attestation provider to potential liability under Section 11 of the Securities Act. Would the possibility of Section 11 liability deter qualified persons from serving as GHG emissions attestation providers? Should we include a provision similar to 17 CFR 230.436(c), or amend that rule, to provide that a report on GHG emissions at the limited assurance level by a GHG emissions attestation provider that has reviewed such information is not considered part of a registration statement prepared or certified by a person whose profession gives authority to a statement made by him or a report prepared or certified by such person within the meaning of Section 7 and 11 of the Act?

3. GHG Emissions Attestation Engagement and Report Requirements

The proposed rules would require the attestation report required by proposed Item 1505(a) for accelerated filers and large accelerated filers to be included in the separately-captioned ''Climate-Related Disclosure'' section in the

relevant filing and provided pursuant to standards that are publicly available at no cost and are established by a body or group that has followed due process procedures, including the broad distribution of the framework for public comment.[624] The requirement that the standards be established by a body or group that has followed due process procedures would be similar to the requirements for determining a suitable, recognized control framework for use in management's evaluation of an issuer's ICFR.[625] In both cases, a specific framework is not prescribed but minimum requirements for what constitutes a suitable framework are provided. This approach would help to ensure that the standards upon which the attestation engagement and report are based are the result of a transparent, public, and reasoned process. This requirement should also help to protect investors who may rely on the attestation report by limiting the standards to those that have been sufficiently developed. Rather than prescribe a particular attestation standard, the proposed approach recognizes that more than one suitable attestation standard exists and that others may develop in the future.

In our view, the attestation standards, for example, of the PCAOB,[626] AICPA,[627] and IAASB [628] would meet this due process requirement. In addition, all of these attestation standards are publicly available at no cost to investors who desire to review them. We believe that open access is an important consideration when determining the suitability of attestation standards for application to GHG emissions disclosure because it would enable investors to evaluate the report against the requirements of the selected attestation standard. By highlighting these standards, we do not mean to imply that other standards currently used in voluntary reporting would not be suitable for use under the proposed rules. Our proposal intends to set minimum standards while acknowledging the current voluntary practices of registrants. As noted below, we seek comment on whether other standards currently used in the voluntary climate-related assurance market or that are otherwise under development would meet the proposed due process requirement and also be suitable for application to GHG emissions under the Commission's proposed rules.

The proposed rules would not include any requirement for a registrant to obtain an attestation report covering the effectiveness of internal control over GHG emissions disclosure, and therefore such a report would not be required even when the GHG emissions attestation engagement is performed at a reasonable assurance level. Given the current evolving state of GHG emissions reporting and assurance, we believe that existing DCP obligations, and the proposed requirement that accelerated filers and large accelerated filers initially obtain at least limited assurance of such disclosure, are appropriate first steps toward enhancing the reliability of GHG emissions disclosure. We also note that, under prevailing attestation standards for limited assurance engagements, the testing of and attestation over internal controls are not required.[629] With respect to the eventual reasonable assurance engagements, while there are requirements under prevailing attestation standards to consider and obtain an understanding of internal controls, there is no required attestation of the effectiveness of internal controls such as that included in Section 404(b) of the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley Act).[630]

We recognize that the attestation standards that a GHG emissions attestation provider may use would have specific requirements for the form and content of attestation reports. The proposed rules would require a GHG emissions attestation provider to follow the specific requirements regarding form and content of the reports set forth by the attestation standard (or standards) used by such attestation provider.[631] Nevertheless, in order to provide some standardization and comparability of GHG emissions attestation reports, the proposed rules would impose minimum requirements for the GHG emissions attestation report.[632] In particular, such minimum report requirements would provide investors with consistent and comparable information about the GHG emissions attestation engagement and report obtained by the registrant when the engagement is conducted by a GHG emissions attestation provider using an attestation standard that may be less widely used or that has less robust report requirements than more prevalent standards.

The proposed minimum attestation engagement and report requirements are primarily derived from the AICPA's attestation standards (*e.g.,* SSAE No. 18), which are commonly used by accountants who currently provide GHG attestation engagement services as well as other non-GHG-related attestation engagement services, and are largely similar to the report requirements under PCAOB AT–101 and IAASB ISAE 3410. Many of the following proposed minimum attestation report requirements are also elements of an accountant's report when attesting to internal control over financial reporting, of an accountant's report on audited financial statements (which is conducted at a reasonable assurance level), or of a review report on interim financial statements (which is conducted at a limited assurance level). We explain below each of the proposed minimum components of a GHG emissions attestation report. These are all common elements of current assurance reports and are also similar to elements of other expert reports and legal opinions provided in Commission filings and other transactions.

As proposed, the GHG emissions attestation report would be required to include an identification or description of the subject matter or assertion on which the attestation provider is

[624] *See* proposed 17 CFR 229.1505(a)(2) and (c).

[625] *See* 17 CFR 240.13a–15(c) and 240.15d–15(c) (stating that the ''framework on which management's evaluation of the issuer's internal control over financial reporting is based must be a suitable, recognized control framework that is established by a body or group that has followed due-process procedures, including the broad distribution of the framework for public comment'').

[626] *See* PCAOB AT Section 101, Attest Engagements, available at *https://pcaobus.org/oversight/standards/attestation-standards/details/AT101.*

[627] *See* AICPA SSAE No. 18 (general attestation standard), available at *https://us.aicpa.org/content/dam/aicpa/research/standards/auditattest/downloadabledocuments/ssae-no-18.pdf;* SSAE No. 22, Review Engagements (limited assurance standard, effective for reports dated on or after June 15, 2022), available at *https://us.aicpa.org/content/dam/aicpa/research/standards/auditattest/downloadabledocuments/ssae-22.pdf;* and SSAE No. 21, Direct Examination Engagements (reasonable assurance standard, effective for reports dated on or after June 15, 2022 and will amend SSAE No. 18), available at *https://us.aicpa.org/content/dam/aicpa/research/standards/auditattest/downloadabledocuments/ssae-21.pdf.*

[628] *See* IAASB ISAE 3000 (Revised), Assurance Engagements Other than Audits or Reviews of Historical Financial Information, available at *https://www.ifac.org/system/files/publications/files/ISAE%203000%20Revised%20-%20for%20IAASB.pdf. See also* IAASB ISAE 3410, Assurance Engagements on Greenhouse Gas Statements, available at *https://www.ifac.org/system/files/publications/files/Basis%20for%20Conclusions%20-%20ISAE%203410%20Assurance%20Engagements%20on%20Greenhouse%20Gas%20Statements-final_0.pdf.*

[629] *See, e.g.,* AICPA SSAE No. 22, AT–C § 210.A16.

[630] *See* 15 U.S.C. 7262(b) (requiring a registered public accounting firm that prepares or issues an audit report for certain issuers to attest to, and report on, the assessment made by the management of the issuer with respect to internal controls).

[631] *See* proposed 17 CFR 229.1505(c).

[632] *See* proposed 17 CFR 229.1505(c)(1) through (13).

reporting.[633] For example, the attestation report would identify the subject matter as Scope 1 and Scope 2 emissions disclosure. If a registrant voluntarily sought attestation of additional items of disclosure, such as GHG intensity metrics or Scope 3 emissions, the attestation provider would be required to identify those additional items as well in the attestation report. If a registrant has made an assertion about the measurement or evaluation of the subject matter to the attestation provider,[634] the attestation report must include such assertion. For example, the attestation report might refer to the registrant's assertion that the Scope 1 and Scope 2 emissions disclosure included within the filing has been presented in accordance with Item 1504 of Regulation S–K. These proposed minimum requirements would elicit information that is fundamental to understanding the attestation report and would clarify the scope of the attestation report when the scope does not align with the scope of the registrant's GHG emissions disclosure (*e.g.,* when Scope 3 emissions disclosure is included in the filing but not covered by the attestation report).

The proposed rules would also require the GHG emissions attestation report to include the point in time or period of time to which the measurement or evaluation of the subject matter or assertion relates.[635] Therefore, the attestation provider would be required to identify the time period to which the Scopes 1 and 2 emissions disclosure (or other additional disclosure) relates, which would be the registrant's most recently completed fiscal year or some other 12-month period if permitted under the applicable climate-related disclosure rules [636] as well as any relevant historical period disclosure included within the filing. This proposed requirement seeks to avoid any confusion investors may have about which period or periods of the climate-related disclosures included within the filing are subject to the attestation.

The proposed rules would also require the attestation report to identify the criteria against which the subject matter was measured or evaluated.[637] For an attestation report solely covering Scopes 1 and 2 emissions disclosure, the identified criteria would include the requirements in proposed Item 1504 of Regulation S–K and, in particular, Item 1504(a), which includes presentation requirements such as disaggregation by each constituent greenhouse gas. The identified criteria would also include Item 1504(b) and the applicable instructions in Item 1504(e) regarding methodology, organizational boundary, and operational boundary. In other words, this minimum requirement would require an attestation provider to refer to the requirements with which the registrant must comply when making the disclosure that is subject to the attestation. Without the frame of reference provided by the identified criteria, the conclusion or opinion included in the report may be open to individual interpretation and misunderstanding by investors.

Prevailing attestation standards require the criteria against which the subject matter is measured or evaluated to be ''suitable.'' In the context of the proposed rules, suitable criteria would, when followed, result in reasonably consistent measurement or evaluation of the registrant's disclosure that is within the scope of the engagement. Characteristics of suitable criteria include relevance, objectivity, measurability, and completeness.[638] We believe that proposed Item 1504 of Regulation S–K would satisfy the suitable criteria requirements of the prevailing attestation standards because the proposed requirements set forth relevant, objective standards that call for measurable and complete disclosure of GHG emissions that would allow for a consistent evaluation of the registrant's disclosure.

The GHG emissions attestation report would further be required to include a statement that identifies the level of assurance provided and describes the nature of the attestation engagement.[639] For example, under the proposed rule, an attestation report providing limited assurance would need to include not only a statement that limited assurance is the provided level of assurance, but also would need to describe the scope of work performed in a limited assurance engagement, which typically would indicate that the procedures performed vary in nature, timing, and extent compared to a reasonable assurance engagement. This proposed minimum requirement would help investors understand the level of assurance provided.

The proposed rules would require the attestation report to include a statement that identifies the attestation standard (or standards) used.[640] As previously discussed, the standard used must be publicly available at no cost and have been established by a body or group that has followed due process procedures, including the broad distribution of the framework for public comment.[641] This minimum report requirement would allow investors to easily identify the attestation standard that the engagement is executed against, which is particularly important because the proposed rules do not prescribe a particular attestation standard. Understanding the attestation standard used would allow investors to better understand the attestation performed by evaluating the report against the attestation standard's requirements and would facilitate comparability across the attestation reports of different registrants.

The attestation report would also be required to include a statement that describes the registrant's responsibility to report on the subject matter or assertion being reported on in order to make it clear to investors who is ultimately responsible for the disclosure.[642] At a minimum, this proposed provision would require a statement that the registrant is responsible for the subject matter, or its assertion on the subject matter. This proposed requirement, like all of the minimum requirements, has corollaries outside of the GHG emissions context. For example, an independent auditor's audit report on a registrant's financial statements is required to include a statement that the registrant's management is responsible for the financial statements that are being audited.[643]

The proposed rules would further require the attestation report to include a statement that describes the attestation provider's responsibilities in connection with the preparation of the attestation report.[644] This is consistent with existing requirements in reports such as those issued by the independent auditor on the audited financial statements or a review report on the interim financial statements. For example, with respect to

[633] *See* proposed 17 CFR 229.1505(c)(1).

[634] *See, e.g.,* AICPA SSAE No. 22, AT–C § 210.45(c); AICPA SSAE No. 21, AT–C § 205.63(c).

[635] *See* proposed 17 CFR 229.1505(c)(1).

[636] As previously mentioned, we are soliciting comment regarding whether the GHG emissions should be reported as of fiscal year-end or some other 12-month period. *See supra* Section II.G.1.

[637] *See* proposed 17 CFR 229.1505(c)(2).

[638] *See, e.g.,* AICPA SSAE No. 18, AT–C § 105.A16 and .A42; AICPA SSAE No. 21, AT–C § 105.A16 and .A44. In addition to relevance and completeness, the characteristics of suitable criteria under ISAE 3000.A23 include reliability, neutrality and understandability. Despite the differences in the characteristics listed, the underlying concepts and objectives are consistent.

[639] *See* proposed 17 CFR 229.1505(c)(3).

[640] *See* proposed 17 CFR 229.1505(c)(4).

[641] *See* proposed 17 CFR 229.1505(a)(2).

[642] *See* proposed 17 CFR 229.1505(c)(5).

[643] *See, e.g.,* PCAOB AS 3101, par. 9(a).

[644] *See* proposed 17 CFR 229.1505(c)(6).

a limited assurance engagement, under prevailing attestation standards, the report would typically include a statement that the attestation provider's responsibilities include expressing a conclusion on the subject matter or the assertion based on the attestation provider's review.[645] Similarly, for a reasonable assurance engagement, the report would typically include a statement that the attestation provider's responsibilities include expressing an opinion on the subject matter or assertion, based on the attestation provider's examination.[646]

The proposed rules would also require the attestation report to include a statement that the attestation provider is independent, as required by proposed 17 CFR 229.1505(a).[647] Because independence from the registrant, including its affiliates, would be a necessary qualification for the GHG emissions attestation provider,[648] the attestation report would be required to include the attestation provider's confirmation of his or her compliance with the proposed independence requirement.

The proposed rules would further require the attestation report, for a limited assurance engagement, to include a description of the work performed as a basis for the attestation provider's conclusion.[649] This proposed provision is intended to enhance the transparency of the GHG emissions attestation report for investors by eliciting disclosure about the procedures undertaken by the attestation provider in its limited assurance engagement, such as inquiries and analytical procedures. This information would allow investors to assess and understand the extent of procedures performed to support the conclusion reached by the attestation provider, which could also facilitate an investor's comparison of different attestation reports provided under the same or different attestation standards.

The GHG emissions attestation report would also be required to include a statement that describes any significant inherent limitations associated with the measurement or evaluation of the subject matter (at a minimum, Scopes 1 and 2 emissions) against the criteria (*i.e.,* the applicable requirements in proposed Item 1504).[650] Such a statement is a common characteristic of attestation reports, including the independent auditor's report on internal control over financial reporting. This proposed provision is intended to elicit disclosure about the estimation uncertainties inherent in the quantification of GHG emissions, driven by reasons such as the state of the science, methodology, and assumptions used in the measurement and reporting processes. For example, an attestation provider might include in its report a statement about measurement uncertainty resulting from accuracy and precision of GHG emission conversion factors.

The proposed rules would require the GHG emissions attestation report to include the attestation provider's conclusion or opinion, as applicable, based on the attestation standard(s) used.[651] For a limited assurance engagement, under prevailing attestation standards, the conclusion would typically state whether the provider is aware of any material modifications that should be made to the subject matter in order for the disclosure to be in accordance with (or based on) the requirements specified in Item 1504, or for the registrant's assertion about such subject matter to be fairly stated.[652] For a reasonable assurance engagement, the attestation provider would typically provide an opinion on whether the subject matter is in accordance with (or based on) the requirements specified in Item 1504 in all material respects, or that the registrant's assertion about its subject matter is fairly stated, in all material respects.[653]

Finally, the proposed rules would require the GHG emissions attestation report to include the signature of the attestation provider (whether by an individual or a person signing on behalf of the attestation provider's firm),[654] the city and state where the attestation report has been issued,[655] and the date of the report.[656] These are all common elements of current assurance and expert reports, and each of these proposed provisions would help to identify and confirm the validity of the GHG emissions attestation provider.

Request for Comment

154. Should we require the attestation engagement and related attestation report to be provided pursuant to standards that are publicly available at no cost and are established by a body or group that has followed due process procedures, including the broad distribution of the framework for public comment, as proposed? Is the requirement of ''due process procedures, including the broad distribution of the framework for public comment'' sufficiently clear? Would the attestation standards of the PCAOB, AICPA, and IAASB meet this due process requirement? Are there other standards currently used in the voluntary climate-related assurance market or otherwise in development that would meet the due process and publicly availability requirements? For example, would verification standards commonly used by non-accountants currently, such as ISO 14064–3 and the AccountAbility's AA1000 Series of Standards, meet the proposed requirements? Are there standards currently used in the voluntary climate-related assurance market or otherwise under development that would be appropriate for use under the Commission's climate-related disclosure rules although they may not strictly meet the proposed public comment requirement? If so, please explain whether those standards have other characteristics that would serve to protect investors?

155. Should we require that the attestation standards used be publicly available at no cost to investors, as proposed? Should we permit the use of attestation standards, even if not publicly available at no cost, provided that registrants provide access to those standards at the request of their investors?

156. Should we require the GHG emissions attestation report to meet certain minimum requirements in addition to any form and content requirements set forth by the attestation standard or standards used by the GHG emissions attestation provider, as proposed? Should we instead require that the attestation report solely meet whatever requirements are established by the attestation standard or standards used?

157. Should we adopt each of the proposed minimum requirements? Are there any proposed requirements that we should omit or add to the proposed list of minimum GHG emissions attestation report requirements?

158. Regarding the proposed provision requiring the identification of the criteria against which the subject matter was measured or evaluated, would reference to proposed Item 1504(a), Item 1504(b), and Item 1504(e)'s instructions concerning the

[645] *See, e.g.,* AICPA SSAE No.22, AT–C sec. 210.45(f).

[646] *See, e.g.,* AICPA SSAE No. 21, AT–C sec. 205.63(f) and sec. 206.12(e)(ii).

[647] *See* proposed 17 CFR 229.1505(c)(7).

[648] *See supra* Section II.H.2.

[649] *See* proposed 17 CFR 229.1505(c)(8).

[650] *See* proposed 17 CFR 229.1505(c)(9).

[651] *See* proposed 17 CFR 229.1505(c)(10).

[652] *See, e.g.,* AICPA SSAE No. 22, AT–C sec. 210.45(l).

[653] *See, e.g.,* AICPA SSAE No. 21 AT–C sec. 205.63(k) and sec. 206.12(j).

[654] *See* proposed 17 CFR 229.1505(c)(11).

[655] *See* proposed 17 CFR 229.1505(c)(12).

[656] *See* proposed 17 CFR 229.1505(c)(13).

presentation, methodology, including underlying assumptions, and organizational and operational boundaries applicable to the determination of Scopes 1 and 2 emissions meet the ''suitable criteria'' requirement under prevailing attestation standards (*e.g.,* AICPA SSAE No. 18, AT–C 105.A16)?

159. If we require or permit a registrant to use the GHG Protocol as the methodology for determining GHG emissions, would the provisions of the GHG Protocol qualify as ''suitable criteria'' against which the Scope 1 and Scope 2 emissions disclosure should be evaluated?

4. Additional Disclosure by the Registrant

In addition to the minimum attestation report requirements described above, which reflect the contents of attestation reports under prevailing attestation standards, we are proposing to require disclosure by the registrant of certain additional matters related to the attestation of a registrant's GHG emissions.[657] These disclosures are not typically included in an attestation report, and would not be included in the GHG emissions attestation report under the proposed rules. Instead, the registrant would be required to provide these disclosures in the separately captioned ''Climate-Related Disclosure'' section, where the GHG emissions disclosure would be provided pursuant to the proposed rules.[658]

These proposed additional disclosures should assist investors in evaluating the qualifications of the GHG emissions attestation provider selected by the registrant, particularly in light of the broad spectrum of attestation providers that would be permitted to provide an attestation report under the proposed rules.[659]

We considered requiring the proposed disclosures to be provided in the attestation report but are not proposing to do so because we are concerned such an approach may create confusion by conflicting with prevalent attestation standards. Furthermore, in light of the variety of attestation service providers the registrant is permitted to engage, requiring the registrant to provide such disclosures may allow the registrant to better provide its investors with relevant information about the qualifications of the service provider that the registrant engaged for the GHG emissions attestation.

With respect to the Scope 1 and Scope 2 emissions attestation required pursuant to proposed Item 1505(a) for accelerated filers and large accelerated filers,[660] the registrant would be required to disclose in the filing, based on relevant information obtained from any GHG emissions attestation provider:

- Whether the attestation provider has a license from any licensing or accreditation body to provide assurance, and if so, the identity of the licensing or accreditation body, and whether the attestation provider is a member in good standing of that licensing or accreditation body;[661]
- Whether the GHG emissions attestation engagement is subject to any oversight inspection program, and if so, which program (or programs);[662] and
- Whether the attestation provider is subject to record-keeping requirements with respect to the work performed for the GHG emissions attestation engagement and, if so, identify the record-keeping requirements and the duration of those requirements.[663]

The first two above items of disclosure would help investors better understand the qualifications of the GHG emissions attestation provider, which in turn could help them assess the reliability of the attestation results. An example of a license from a licensing or accreditation body to provide assurance would be a Certified Public Accountant license issued by a state board of accountancy (*e.g.,* the California Board of Accountancy), while an example of oversight programs would include the AICPA peer review program, among others. The proposed disclosure requirement about any record-keeping requirements to which the attestation provider is subject would help enhance the transparency of the attestation process by providing investors with information about the business practices of the attestation provider that has been retained by the registrant.[664]

Request for Comment

160. Should we require certain items of disclosure related to the attestation of a registrant's GHG emissions to be provided by the registrant in its filing that includes the attestation report (where the GHG emissions and other climate-related disclosures are presented), based on relevant information obtained from the GHG emissions attestation provider, as proposed? Should these additional items of disclosure instead be included in the attestation report?

161. Should we require the registrant to disclose whether the attestation provider has a license from any licensing or accreditation body to provide assurance, and if so, the identity of the licensing or accreditation body, and whether the attestation provider is a member in good standing of that licensing or accreditation body, as proposed? In lieu of disclosure, should we require a GHG emissions attestation provider to be licensed to provide assurance by specified licensing or accreditation bodies? If so, which licensing or accreditation bodies should we specify?

162. Should we require a registrant to disclose whether the GHG emissions attestation engagement is subject to any oversight inspection program, and if so, which program (or programs), as proposed? Should we instead require the registrant to disclose whether the attestation engagement is subject to certain specified oversight programs? If so, which oversight programs should we specify?

163. Should we require a registrant to disclose whether the attestation provider is subject to record-keeping requirements with respect to the work performed for the GHG emissions attestation engagement and, if so, identify the record-keeping requirements and duration of those requirements, as proposed? In lieu of disclosure, should we specify that the record-keeping requirements of a GHG emissions attestation provider must be of a certain minimum duration, such as three, five, or seven years, or some other period? Should we specify that the record-keeping requirements must include certain reasonable procedures and, if so, what procedures?

5. Disclosure of Voluntary Attestation

Because GHG emissions reporting and assurance landscapes are both relatively new and evolving as described earlier, at this time, we are proposing to require a registrant, other than a large accelerated filer or an accelerated filer that is required to include a GHG emissions attestation report pursuant to proposed Item 1505(a), to disclose within the separately captioned ''Climate-Related Disclosure'' section in

[657] *See* proposed 17 CFR 229.1505(d).

[658] *See id.*

[659] *See supra* Section II.H.2.

[660] If an accelerated filer or a large accelerated filer voluntarily obtains assurance beyond what would be required by proposed Item 1505(a) and uses a different service provider for such assurance, it would also be required to provide the information required by proposed Item 1505(d) for such service provider.

[661] *See* proposed 17 CFR 229.1505(d)(1).

[662] *See* proposed 17 CFR 229.1505(d)(2).

[663] *See* proposed 17 CFR 229.1505(d)(3).

[664] For example, the AICPA imposes a minimum five-year documentation retention program for an audit. *See* AU–C 230.17. Although document retention is less prescriptive for attestation engagements, many attestation providers adhere to the five-year period in practice.

the filing the following information if the registrant's GHG emissions disclosures were subject to third-party attestation or verification:

(i) Identify the provider of such assurance or verification; [665]

(ii) Describe the assurance or verification standard used; [666]

(iii) Describe the level and scope of assurance or verification provided; [667]

(iv) Briefly describe the results of the assurance or verification; [668]

(v) Disclose whether the third-party service provider has any other business relationships with or has provided any other professional services to the registrant that may lead to an impairment of the service provider's independence with respect to the registrant; [669] and

(vi) Disclose any oversight inspection program to which the service provider is subject (*e.g.,* the AICPA's peer review program).[670]

Taken together, these proposed disclosure items should help investors understand the nature and reliability of the attestation or verification provided and help them assess whether the voluntary assurance or verification has enhanced the reliability of the GHG emissions disclosure. We are limiting the proposed assurance disclosure requirement to a registrant's GHG emissions disclosure because registrants are more likely to obtain assurance voluntarily for this disclosure item than for other climate-related disclosures.[671] The proposed approach should mitigate the compliance burden of the proposed GHG emissions disclosure rules, taking into consideration the proportionate compliance costs that may impact accelerated and large accelerated filers versus other types of filers, while providing transparency for investors about the level and reliability of the assurance or verification, if any, provided on the GHG emissions disclosures.

Request for Comment

164. Should we require a registrant that is not required to include a GHG emissions attestation report pursuant to proposed Item 1505(a) to disclose within the separately captioned ''Climate-Related Disclosure'' section in the filing the following information, if the registrant's GHG emissions disclosure was subject to third-party attestation or verification, as proposed:

(i) Identify the provider of such assurance or verification;

(ii) Disclose the assurance or verification standard used;

(iii) Describe the level and scope of assurance or verification provided;

(iv) Briefly describe the results of the assurance or verification;

(v) Disclose whether the third-party service provider has any other business relationships with or has provided any other professional services to the registrant that may lead to an impairment of the service provider's independence with respect to the registrant; and

(vi) Disclose any oversight inspection program to which the service provider is subject (*e.g.,* the AICPA's peer review program), each as proposed?

Are there other disclosure items that we should require if a registrant has obtained voluntary assurance or verification of the climate-related disclosures? Are there any of the proposed disclosure items that we should omit? Should we specify parameters or include guidance on when the services provided by a third-party would be considered ''assurance'' or ''verification'' and thus require disclosure pursuant to the proposed rules? Should a registrant be required to furnish a copy of or provide a link to the assurance or verification report so that it is readily accessible by an investor?

165. Instead of requiring a registrant to disclose whether the third-party service provider has any other business relationships with or has provided any other professional services to the registrant that may lead to an impairment of the service provider's independence with respect to the registrant as proposed, should we require the third-party service provider to be independent, according to the standard proposed under Item 1505(b) for accelerated filers and large accelerated filers that are required to include a GHG emissions attestation report pursuant to proposed Item 1505(a)? If not, should we provide guidance as to what constitutes an impairment of a service provider's independence with respect to the registrant? Would this result in decision-useful information to an investor? Should we instead require a registrant to disclose whether the third-party service provider would be considered independent under some other independence requirement?

166. As proposed, a registrant would be required to disclose any oversight inspection program to which the service provider is subject, such as the PCAOB's inspection program or the AICPA's peer review program. Are there other oversight programs that we should provide as examples? Would such disclosure provide decision-useful information to an investor? Is it clear what ''any oversight inspection program'' would include?

167. As proposed, a registrant would not be required to disclose the voluntary assurance or verification fees associated with the GHG disclosures. Should we require GHG disclosure assurance or verification fees to be disclosed? Would such disclosure be decision-useful to investors making voting or investment decisions?

I. Targets and Goals Disclosure

If a registrant has set any climate-related targets or goals, then the proposed rules would require the registrant to provide certain information about those targets or goals.[672] Those goals or targets might, for example, relate to the reduction of GHG emissions, or address energy usage,[673] water usage, conservation or ecosystem restoration. A registrant might also set goals with regard to revenues from low-carbon products in line with anticipated regulatory requirements, market constraints, or other goals established by a climate-related treaty, law, regulation, policy, or organization. The proposed disclosure requirements could help investors better understand the scope of a registrant's climate-related targets or goals, including those related to GHG emissions, and assist in assessing progress towards achieving those targets or goals.

Many commenters recommended that we require registrants to provide detailed information about their climate-related targets and goals, including action plans and timelines for achieving such targets as GHG emissions reductions and performance data measured against those targets.[674] This information could be important for investors in light of the fact that, according to one publication, two-thirds of S&P 500 companies had set a carbon

[665] *See* proposed 17 CFR 229.1505(e)(1).

[666] *See* proposed 17 CFR 229.1505(e)(2).

[667] *See* proposed 17 CFR 229.1505(e)(3).

[668] *See* proposed 17 CFR 229.1505(e)(4).

[669] *See* proposed 17 CFR 229.1505(e)(5).

[670] *See* proposed 17 CFR 229.1505(e)(6).

[671] *See, e.g.,* letters from BNP Paribas; Eni SpA; ERM CVS; and Walmart. *See also* CAQ, *S&P 500 and ESG Reporting.*

[672] *See* proposed 17 CFR 229.1506(a)(1).

[673] For example, numerous companies have pledged to achieve 100% of the electricity used in their global operations from renewable sources by 2050. *See* RE100, What are the requirements to become a RE100 member?, *available at https://www.there100.org/technical-guidance.*

[674] *See, e.g.,* letters from Americans for Financial Reform Education Fund and Public Citizen; Center for Law and Social Policy; Domini Impact Investments; Dynamhex, Inc.; FAIRR Initiative; Generation Investment Management; Hannon Armstrong; HP, Inc.; Interfaith Center on Corporate Responsibility; NYC Office of Comptroller; Pre-Distribution Initiative; Regenerative Crisis Response Committee; and WK Associates.

reduction target by the end of 2020.[675] Despite the numerous commitments to reduce GHG emissions, according to several sources, many companies do not provide their investors with sufficient information to understand how the companies intend to achieve those commitments or the progress made regarding them.[676] The proposed disclosure requirements are intended to elicit enhanced information about climate-related targets and goals so that investors can better evaluate these points.

If a registrant has set climate-related targets or goals, the proposed rules would require it to disclose them, including, as applicable, a description of:

- The scope of activities and emissions included in the target;
- The unit of measurement, including whether the target is absolute or intensity based;
- The defined time horizon by which the target is intended to be achieved, and whether the time horizon is consistent with one or more goals established by a climate-related treaty, law, regulation, policy, or organization;
- The defined baseline time period and baseline emissions against which progress will be tracked with a consistent base year set for multiple targets;
- Any interim targets set by the registrant; and
- How the registrant intends to meet its climate-related targets or goals.[677]

This information would help investors understand a registrant's particular target or goal and a particular timeline for that target or goal, how the target or goal is to be measured, and how progress against the target or goal is to be tracked. For example, a registrant might disclose that it plans to cut its Scopes 1 and 2 emissions by 50 percent by 2030.[678] The registrant might also disclose a target to reduce its Scope 3 emissions by 50 percent by 2035. In addition, the registrant might also set a goal of achieving net zero greenhouse gas emissions across its operations by 2050, in keeping with the goals of the Paris Agreement.

Under the proposed rules, the registrant would be required to disclose the baseline year for multiple targets.[679] Requiring disclosure of defined baseline time periods and baseline emissions against which progress will be tracked, with a consistent base year for multiple targets, could help investors compare the progress made towards each target. The registrant would also be required to disclose the unit of measurement, including whether the target is expressed in absolute terms or is intensity-based. If the registrant has set intervening targets (*e.g.,* reducing its Scope 3 emissions by 35 percent by 2030), the registrant would be required to disclose these targets.[680] Each of the proposed disclosure requirements is intended to provide investors with additional insight into the scope and specifics of a registrant's climate-related targets or goals.

The proposed rules would further require a registrant to discuss how it intends to meet its climate-related targets or goals.[681] This information should enable investors to better understand the potential impacts on a registrant associated with pursuing its climate-related targets or goals. For example, for a target or goal regarding net GHG emissions reduction, the discussion could include a strategy to increase energy efficiency, transition to lower carbon products, purchase carbon offsets or RECs, or engage in carbon removal and carbon storage.[682] For a registrant operating in a water-stressed area, with the goal of reducing its freshwater needs, the discussion could include a strategy to increase the water efficiency of its operations, such as by recycling wastewater or, if in agriculture, engaging in bioengineering techniques to make crops more resilient and less water dependent. Information about how a registrant intends to achieve its climate-related target or goal could provide investors with a better understanding of the potential costs to mitigate a potential climate-related risk, such as a manufacturer's reduction of GHG emissions through implementation of a relatively high cost solution such as carbon capture and storage technology.[683]

The proposed rules would also require a registrant to disclose relevant data to indicate whether it is making progress toward achieving the target or goal and how such progress has been achieved.[684] A registrant would be required to update this disclosure each fiscal year by describing the actions taken during the year to achieve its targets or goals.[685] This proposed disclosure could help investors assess how well a registrant is managing its identified climate-related risks.

Some companies might establish climate-related goals or targets without yet knowing how they will achieve those goals. They might plan to develop their strategies over time, particularly as new technologies become available that might facilitate their achievement of their goals. The fact that a company has set a goal or target does not mean that it has a specific plan for how it will achieve those goals. What is important is that investors be informed of a registrant's plans and progress wherever it is in the process of developing and implementing its plan.

If the registrant has used carbon offsets or RECs in its plan to achieve climate-related targets or goals, it would be required to disclose the amount of carbon reduction represented by the offsets or the amount of generated renewable energy represented by the RECS, the source of the offsets or RECs, a description and location of the underlying projects, any registries or other authentication of the offsets or RECs, and the cost of the offsets or RECs.[686] For example, a carbon offset might pertain to an underlying project to reduce GHG emissions, increase the storage of carbon, or enhance GHG removals from the atmosphere. Information regarding the source, value, underlying projects, and authentication of the offsets or RECs could help investors assess the offsets or RECs and the effectiveness of the registrant's plan to achieve its climate-related targets or goals. Such information could also help investors understand changes in the use or viability of the carbon offsets or RECs as part of achieving a registrant's climate-related targets or goals that are caused by changes in regulation or markets. A reasonable investor could well assess differently the effectiveness and value to a registrant of the use of carbon offsets where the underlying projects resulted in authenticated reductions in GHG emissions compared to the use of offsets where the underlying projects resulted in the avoidance, but not the reduction, in GHG emissions or otherwise lacked verification. As some commenters have indicated, mandated detailed disclosure about the nature of a purchased carbon

[675] *See supra* note 66 (referencing The Wall Street Journal (Nov. 5, 2021)).

[676] *See, e.g.,* Jocelyn Timperley, The Guardian, *The truth behind corporate climate pledges* (July 26, 2021); Peter Eavis and Clifford Krauss, The New York Times, *What's Really Behind Corporate Promises on Climate Change?* (May 12, 2021); and Alice C. Hill and Jennifer Nash, The Hill, *The truth behind companies' 'net zero' climate commitments* (Apr. 9, 2021).

[677] *See* proposed 17 CFR 229.1506(b)(1) through (6).

[678] *See* proposed 17 CFR 229.1506(b)(3).

[679] *See* proposed 17 CFR 229.1506(b)(4).

[680] *See* proposed 17 CFR 229.1506(b)(5).

[681] *See* proposed 17 CFR 229.1506(b)(6).

[682] *See* proposed 17 CFR 229.1506(b)(6).

[683] *See* proposed 17 CFR 229.1502.

[684] *See* proposed 17 CFR 229.1506(c).

[685] *See id.*

[686] *See* proposed 17 CFR 229.1506(d).

offset could also help to mitigate instances of greenwashing.[687]

Proposed 17 CFR 229.1505(a)(2) (Item 1505(a)(2)) would state that a registrant may provide the disclosures required by the section when discussing climate-related impacts on its strategy, business model, and outlook (in response to proposed Item 1502) or when discussing its transition plan as part of its risk management disclosure (in response to proposed Item 1503). If so, it need not repeat the disclosure in response to the proposed targets and goals section but should cross-refer to the section where the information has been provided.

A registrant's disclosure of its climate-related targets or goals should not be construed to be promises or guarantees. To the extent that information regarding a registrant's climate-related targets or goals would constitute forward-looking statements, which we would expect, for example, with respect to how a registrant intends to achieve its climate-related targets or goals and expected progress regarding those targets and goals, the PSLRA safe harbors would apply to such statements, assuming all other statutory requirements for those safe harbors are satisfied.

Request for Comment

168. Should we require a registrant to disclose whether it has set any targets related to the reduction of GHG emissions, as proposed? Should we also require a registrant to disclose whether it has set any other climate-related target or goal, *e.g.,* regarding energy usage, water usage, conservation or ecosystem restoration, or revenues from low-carbon products, in line with anticipated regulatory requirements, market constraints, or other goals, as proposed? Are there any other climate-related targets or goals that we should specify and, if so, which targets or goals? Is it clear when disclosure under this proposed item would be triggered, or do we need to provide additional guidance? Would our proposal discourage registrants from setting such targets or goals?

169. Should we require a registrant, when disclosing its targets or goals, to disclose:

- The scope of activities and emissions included in the target;
- The unit of measurement, including whether the target is absolute or intensity based;
- The defined time horizon by which the target is intended to be achieved, and whether the time horizon is consistent with one or more goals established by a climate-related treaty, law, regulation, or organization;
- The defined baseline time period and baseline emissions against which progress will be tracked with a consistent base year set for multiple targets;
- Any intervening targets set by the registrant; and
- How it intends to meet its targets or goals, each as proposed?

Are there any other items of information about a registrant's climate-related targets or goals that we should require to be disclosed, in addition to or instead of these proposed items? Are there any proposed items regarding such targets or goals that we should exclude from the required disclosure? If a registrant has set multiple targets or goals, should it be permitted to establish different base years for those targets or goals?

170. Should we require a registrant to discuss how it intends to meet its climate-related targets or goals, as proposed? Should we provide examples of potential items of discussion about a target or goal regarding GHG emissions reduction, such as a strategy to increase energy efficiency, a transition to lower carbon products, purchasing carbon offsets or RECs, or engaging in carbon removal and carbon storage, as proposed? Should we provide additional examples of items of discussion about climate-related targets or goals and, if so, what items should we add? Should we remove any of the proposed examples of items of discussion?

171. Should we require a registrant, when disclosing its targets or goals, to disclose any data that indicates whether the registrant is making progress towards meeting the target and how such progress has been achieved, as proposed?

172. Should we require that the disclosure be provided in any particular format, such as charts? Would certain formats help investors and others better assess these disclosures in the context of assessing the registrant's business and financial condition? What additional or other requirements would help in this regard?

173. If a registrant has used carbon offsets or RECs, should we require the registrant to disclose the amount of carbon reduction represented by the offsets or the amount of generated renewable energy represented by the RECS, the source of the offsets or RECs, the nature and location of the underlying projects, any registries or other authentication of the offsets or RECs, and the cost of the offsets or RECs, as proposed? Are there other items of information about carbon offsets or RECs that we should specifically require to be disclosed when a registrant describes its targets or goals and the related use of offsets or RECs? Are there proposed items of information that we should exclude from the required disclosure about offsets and RECs?

174. Should we apply the PSLRA statutory safe harbors as they currently exist to forward-looking statements involving climate-related targets and goals, or other climate-related forward-looking information? Should we instead create a separate safe harbor for forward-looking climate-related information, including targets and goals? Should we adopt an exception to the PSLRA statutory safe harbors that would extend the safe harbors to climate-related forward-looking disclosures made in an initial public offering registration statement?

J. Registrants Subject to the Climate-Related Disclosure Rules and Affected Forms

The proposed climate-related disclosure rules would apply to a registrant with Exchange Act reporting obligations pursuant to Exchange Act Section 13(a)[688] or Section 15(d)[689] and

[687] *See, e.g.,* letter from Dimensional Fund Advisors.

[688] 15 U.S.C. 78m(a).

[689] 15 U.S.C. 78o(d).

companies filing a Securities Act or Exchange Act registration statement. Specifically, we are proposing to require a registrant to include climate-related disclosure in Securities Act or Exchange Act registration statements (Securities Act Forms S–1, F–1, S–3, F–3, S–4, F–4, and S–11, and Exchange Act Forms 10 and 20–F)[690] and Exchange Act annual reports (Forms 10–K and 20–F), including the proposed financial statement metrics.[691] Similar to the treatment of other important business and financial information, the proposed rules would also require registrants to disclose any material change to the climate-related disclosure provided in a registration statement or annual report in its Form 10–Q (or, in certain circumstances, Form 6–K for a registrant that is a foreign private issuer that does not report on domestic forms).[692]

The proposed rules would amend Form 20–F and the Securities Act forms that a foreign private issuer may use to register the offer and sale of securities under the Securities Act to require the same climate-related disclosures as proposed for a domestic registrant.[693] Because climate-related risks potentially impact both domestic and foreign private issuers, regardless of the registrant's jurisdiction of origin or organization, requiring that foreign private issuers provide this disclosure would be important to achieving our goal of more consistent, reliable, and comparable information across registrants. Moreover, we note that Form 20–F imposes substantially similar disclosure requirements as those required for Form 10–K filers on matters, such as risk factors and MD&A, that are similar and relevant to the proposed climate-related disclosures.[694]

We are not proposing generally to exempt SRCs, EGCs,[695] or registrants that are foreign private issuers from the entire scope of the proposed climate-related disclosure rules because we agree with commenters who stated that, because of their broad impact across industries and jurisdictions, climate-related risks may pose a significant risk to the operations and financial condition of domestic and foreign issuers, both large and small.[696] While we are not proposing to exempt SRCs from the full scope of the proposed climate-related disclosure rules, we are proposing to exempt SRCs from the proposed Scope 3 emissions disclosure requirement.[697] We also are proposing to provide a longer transition period for SRCs to comply with the proposed rules than we are proposing for other registrants.[698] The proposed accommodations for Scope 3 emissions disclosures could mitigate the proposed rules' compliance burden for smaller registrants that, when compared to larger registrants with more resources, may be less able to afford the fixed costs associated with the reporting of GHG emissions. In addition, the extended compliance period would give SRCs additional time to allocate the resources necessary to compile and prepare their climate-related disclosures.

Request for Comment

175. Should the proposed climate-related disclosures be required in Exchange Act reports and registration statements, as proposed? Should we exempt SRCs from all of the proposed climate-related disclosure rules instead of exempting them solely from Scope 3 emissions disclosure requirements, as proposed? Should we exempt SRCs from certain other proposed climate-related disclosure requirements and, if so, which requirements? For example, in addition to the proposed exemption from Scope 3 emissions disclosure, should we exempt SRCs from the proposed requirement to disclose Scopes 1 and 2 emissions? Are there certain types of other registrants, such as EGCs or business development companies (''BDCs''),[699] that should be excluded from all or some of the proposed climate-related disclosure rules?

176. Should we require foreign private issuers that report on Form 20–

[690] Form 20–F is the Exchange Act form used by a foreign private issuer for its annual report or to register a class of securities under Section 12 of the Exchange Act. The proposed rules would amend Part I of Form 20–F to require a foreign private issuer to provide the climate-related disclosures pursuant to the proposed rules either when registering a class of securities under the Exchange Act or when filing its Exchange Act annual report. A foreign private issuer would also be required to comply with the proposed rules when filing a Securities Act registration statement on Form F–1. Because Form F–1 requires a registrant to include the disclosures required by Part I of Form 20–F, the proposed amendment to Form 20–F would render unnecessary a formal amendment to Form F–1. We are similarly not formally amending Forms S–3 and F–3 because the climate-related disclosure would be included in a registrant's Form 10–K or 20–F annual report that is incorporated by reference into those Securities Act registration statements.

[691] *See* Form 20–F, General Instruction B(d) (stating that Regulation S–X applies to the presentation of financial information in the form). Although Item 17 and 18 of Form 20–F, and the forms that refer to Form 20–F (including Forms F–1 and F–3) permit a foreign private issuer to file financial statements prepared in accordance with IFRS as issued by the IASB, the proposed Article 14 disclosure would nevertheless be required (similar to disclosure required by Article 12 of Regulation S–X). *See Acceptance from Foreign Private Issuers of Financial Statements Prepared in Accordance with International Financial Reporting Standards Without Reconciliation to U.S. GAAP,* Rel. No. 33–8879 (Dec. 21, 2007) [73 FR 986 (Jan. 4, 2008)], 999, n.136 (stating that ''Regulation S–X will continue to apply to the filings of all foreign private issuers, including those who file financial statements prepared using IFRS as issued by the IASB,'' but providing that such issuers ''will comply with IASB requirements for form and content within the financial statements, rather than with the specific presentation and disclosure provisions in Articles 4, 5, 6, 7, 9, and 10 of Regulation S–X'').

[692] Form 6–K is the form furnished by a foreign private issuer with an Exchange Act reporting obligation if the issuer: (i) Makes or is required to make the information public pursuant to the law of the jurisdiction of its domicile or in which it is incorporated or organized, or (ii) files or is required to file the information with a stock exchange on which its securities are traded and which was made public by that exchange, or (iii) distributes or is required to distribute the information to its security holders. *See* General Instruction B to Form 6–K. That instruction currently list certain types of information that are required to be furnished pursuant to subparagraphs (i), (ii), and (iii), above. While we are proposing to amend Form 6–K to add climate-related disclosure to the list of the types of information to be provided on Form 6–K, a foreign private issuer would not be required to provide the climate-related disclosure if such disclosure is not required to be furnished pursuant to subparagraphs (i), (ii), or (iii) of General Instruction B.

[693] *See* proposed Item 3.E to Form 20–F.

[694] For similar reasons, we believe that requiring the proposed climate disclosures on Forms F–1, F–3, and F–4 is appropriate because those forms either require the disclosure pursuant to certain parts of Form 20–F (Forms F–1 and F–4) and certain items, such as risk factors, under Regulation S–K, or permit the incorporation by reference of Form 20–F (Forms F–3 and F–4) and therefore require disclosure similar to the domestic forms.

[695] An emerging growth company (''EGC'') is a registrant that had total annual gross revenues of less than $1.07 billion during its most recently completed fiscal year and has not met the specified conditions for no longer being considered an EGC. *See* 17 CFR 230.405; 17 CFR 240.12b–2; 15 U.S.C. 77b(a)(19); 15 U.S.C. 78c(a)(80); and *Inflation Adjustments and Other Technical Amendments under Titles I and II of the JOBS Act,* Release No. 33–10332 (Mar. 31, 2017) [82 FR 17545 (Apr. 12, 2017)].

[696] *See, e.g.,* letters from Rob Bonta, California Attorney General *et al.;* Ceres *et al.;* and Natural Resources Defense Council.

[697] *See* proposed 17 CFR 229.1504(c)(3). In this regard we note that participants in the Commission-hosted 2021 Small Business Forum recommended that the Commission provide exemptions or scaled requirements for small and medium-sized companies in connection with any new ESG disclosure requirements adopted by the Commission. *See* Report on the 40th Annual Small Business Forum (May 2021), available at *https://www.sec.gov/files/2021_OASB_Annual_Forum_Report_FINAL_508.pdf. See also* Office of the Advocate for Small Business Capital Formation, *Annual Report for Fiscal Year 2021* (supporting ''efforts to continue tailoring the disclosure and reporting framework to the complexity and size of operations of companies, either by scaling obligations or delaying compliance for the smallest of the public companies, particularly as it pertains to potential new or expanded disclosure requirements'').

[698] *See infra* Section II.M.

[699] A BDC is a closed-end investment company that has a class of its equity securities registered under, or has filed a registration statement pursuant to, Section 12 of the Exchange Act, and elects to be regulated as a business development company. *See* Section 54 of the Investment Company Act, 15 U.S.C. 80a–53. Like other Section 12 registrants, BDCs are required to file Exchange Act annual reports.

F to provide the same climate-related disclosures as Form 10–K filers, as proposed? Should we require climate-related disclosures in the registration statements available for foreign private issuers, as proposed? If not, how should the climate-related disclosures provided by foreign private issuer registrants differ from the disclosures provided by domestic registrants?

177. Should we require a registrant to disclose any material changes to the climate-related disclosure provided in its registration statement or annual report in its Form 10–Q or Form 6–K, as proposed? Are there any changes that should be required to be reported on Form 8–K?

178. Should we require the climate-related disclosure in the forms specified above? Is the application of the proposed rules to the forms sufficiently clear, or should we include additional clarifying amendments? For example, would the application of proposed Article 14 to Forms 20–F, F–1 and F–3 be sufficiently clear when a registrant prepares its financial statements pursuant to IFRS as issued by the International Accounting Standards Board (''IASB'') without reconciliation to U.S. generally accepted accounting principles (''U.S. GAAP''), or should we add a related instruction to those forms?

179. Are there certain registration statements or annual reports that should be excluded from the scope of the proposed climate-related disclosure rules? For example, should we exclude Securities Act registration statements filed in connection with a registrant's initial public offering? Would such an accommodation help address concerns about the burdens of transitioning to public company status? We have not proposed to require climate-related disclosures in registration statements on Form S–8 or annual reports on Form 11–K. Should we require such disclosures?

180. Should we require climate-related disclosure in Forms S–4 and F–4, as proposed? Should we provide transitional relief for recently acquired companies? For example, should we provide that a registrant would not be required to provide the proposed climate-related disclosures for a company that is a target of a proposed acquisition under Form S–4 or F–4 until the fiscal year following the year of the acquisition if the target company is not an Exchange Act reporting company and is not the subject of foreign climate-related disclosure requirements that are substantially similar to the Commission's proposed requirements? Should such transitional relief in this instance be for a longer period than one year and, if so, for how long should such transitional relief extend?

181. We have not proposed to amend Form 40–F, the Exchange Act form used by a Canadian issuer eligible to report under the Multijurisdictional Disclosure System (''MJDS'') to register securities or to file its annual report under the Exchange Act, to include the proposed climate-related disclosure requirements. Should we require a Form 40–F issuer to comply with the Commission's proposed climate-related disclosure requirements? Should we permit a MJDS issuer to comply with Canadian climate-related disclosure requirements instead of the proposed rules if they meet certain conditions or provide certain additional disclosures and, if so, which conditions or disclosures?

182. The proposed rules would not apply to asset-backed issuers. The Commission and staff are continuing to evaluate climate-related disclosures with respect to asset-backed securities. Should we require asset-backed issuers to provide some or all of the disclosures under proposed Subpart 1500 of Regulation S–K? If so, which of the proposed disclosures should apply to asset-backed issuers? Are other types of climate disclosure better suited to asset-backed issuers? How can climate disclosure best be tailored to various asset classes?

183. Should we adopt an alternative reporting provision that would permit a registrant that is a foreign private issuer and subject to the climate-related disclosure requirements of an alternative reporting regime that has been deemed by the Commission to be substantially similar to the requirements of proposed Subpart 1500 of Regulation S–K and Article 14 of Regulation S–X to satisfy its disclosure obligations under those provisions by complying with the reporting requirements of the alternative reporting regime (''alternative reporting provision'')? If so, should we require the submission of an application for recognition of an alternative reporting regime as having substantially similar requirements for purposes of alternative reporting regarding climate-related disclosures? Should we permit companies, governments, industry groups, or climate-related associations to file such an application? Should we require the applicant to follow certain procedures, such as those set forth in 17 CFR 240.0–13?

184. If we adopt an alternative reporting provision, should we specify certain minimum standards that the alternative reporting regime must meet in order to be recognized and, if so, what standards? For example, should we specify that an alternative reporting regime must require the disclosure of a foreign private issuer's Scopes 1 and 2 emissions and related targets, the proposed financial statement metrics, as well as disclosures pursuant to the TCFD's recommendations regarding governance, strategy, and risk management disclosure? Should we specify that the alternative reporting regime must require the disclosure of Scope 3 emissions and, if so, should we deem the alternative reporting regime to be substantially similar even if its Scope 3 emissions requirements become effective after the Commission's phase in period for Scope 3 emissions disclosure requirements? Should we specify that the alternative reporting regime must require the disclosure of scenario analysis if a registrant uses scenario analysis in formulating its strategy regarding climate-related risks? Are there certain climate-related disclosure requirements that have been adopted or are in the process of being adopted in other jurisdictions that we should consider to be substantially similar to the Commission's rules for purposes of an alternative reporting provision? If so, which requirements should we consider?

185. If we adopt an alternative reporting provision, should it be a mutual recognition system, so that, as a condition of our recognition of a particular jurisdiction as an alternative reporting regime, that jurisdiction must recognize the Commission's climate-related disclosure rules as an alternative reporting system that a registrant dual-listed in the United States and the other jurisdiction may use to fulfill the foreign jurisdiction's climate-related disclosure rules?

186. If we adopt an alternative reporting provision, should we require a registrant filing the alternative climate-related disclosure to make certain changes that we deem necessary as a condition to alternative reporting? For example, should we require a registrant to comply with XBRL tagging requirements as a condition to filing alternative climate-related disclosure? Are there other specific conditions that we should impose on disclosure under an alternative climate reporting provision?

187. If we adopt an alternative reporting provision, should we require a registrant using that system to:

- State in the filing that it is relying on this alternative reporting provision;
- Identify the alternative reporting regime for which the climate-related disclosure was prepared;

• Identify the exhibit number of the filing where the alternative disclosure can be found; and

• File a fair and accurate English translation of the alternative climate-related disclosure if in a foreign language?

Would these requirements enhance the accessibility of the alternative disclosures? Are there other requirements that we should impose to enhance the transparency of the alternative climate-related disclosure?

188. If we adopt an alternative reporting provision, should we permit a registrant to follow the submission deadline of the approved alternative reporting regime even if that deadline differs from the deadline for reporting under our rules? If so, what conditions, if any, should apply to permit the use of such alternative deadline? For example, should the registrant be required to provide adequate notice, before the due date of the Commission filing in which the alternative disclosure is required to be included? Should such notice indicate the registrant's intent to file the alternative disclosure using the alternative jurisdiction's deadline? If so, what would constitute adequate notice? For example, should the deadline for filing the notice be three, five, or ten business days before the Commission filing deadline? Should we permit a registrant to provide such notice through an appropriate submission to the Commission's EDGAR system? Should we permit a registrant to indicate in its Form 20–F or other report that it will file the alternative disclosure at a later date if permitted to do so by the alternative reporting regime? In that case, should we permit the registrant to file the alternative disclosure on a Form 6–K or 8–K? Should we instead require a registrant to submit the notice via a form that we would create for such purpose? Should there be any consequences if a registrant fails to file a timely notice or fails to file the alternative disclosure by the alternative regime's due date? For example, should we preclude such a registrant from relying on the alternative reporting provision for the following fiscal year?

189. An International Sustainability Standards Board (ISSB) has recently been created, which is expected to issue global sustainability standards, including climate-related disclosure standards.[700] If we adopt an alternative reporting provision, should that provision be structured to encompass reports made pursuant to criteria developed by a global sustainability standards body, such as the ISSB? If so, should such alternative reporting be limited to foreign private issuers, or should we extend this option to all registrants? What conditions, if any, should we place on a registrant's use of alternative reporting provisions based on the ISSB or a similar body?

K. Structured Data Requirement

The proposed rules would require a registrant to tag the proposed climate-related disclosures in a structured, machine-readable data language.[701] Specifically, the proposed rules would require a registrant to tag climate-related disclosures in Inline eXtensible Business Reporting Language (''Inline XBRL'') in accordance with 17 CFR 232.405 (Rule 405 of Regulation S–T) and the EDGAR Filer Manual. The proposed requirements would include block text tagging and detail tagging of narrative and quantitative disclosures provided pursuant to Subpart 1500 of Regulation S–K and Article 14 of Regulation S–X.[702]

In 2009, the Commission adopted rules requiring operating companies to submit the information from the financial statements (including footnotes and schedules thereto) included in certain registration statements and periodic and current reports in a structured, machine-readable data language using eXtensible Business Reporting Language (''XBRL'').[703] In 2018, the Commission adopted modifications to these requirements by requiring issuers to use Inline XBRL, which is both machine-readable and human-readable, to reduce the time and effort associated with preparing XBRL filings and improve the quality and usability of XBRL data for investors.[704] In 2020, the Commission adopted Inline XBRL requirements for business development companies that will be effective no later than February 2023.[705]

Requiring Inline XBRL tagging of the proposed climate-related disclosures would benefit investors by making the disclosures more readily available and easily accessible to investors, market participants, and other users for aggregation, comparison, filtering, and other analysis, as compared to requiring a non-machine readable data language such as ASCII or HTML. This would enable automated extraction and analysis of climate-related disclosures, allowing investors and other market participants to more efficiently perform large-scale analysis and comparison of climate-related disclosures across companies and time periods. At the same time, we do not expect the incremental compliance burden associated with tagging the additional information to be unduly burdensome, because issuers subject to the proposed requirements are or in the near future will be subject to similar Inline XBRL requirements in other Commission filings.[706]

Request for Comment

190. Should we require registrants to tag the climate-related disclosures, including block text tagging and detail tagging of narrative and quantitative disclosures required by Subpart 1500 of Regulation S–K and Article 14 of Regulation S–X in Inline XBRL, as proposed? Should we permit custom tags for the climate-related disclosures?

191. Should we modify the scope of the proposed climate-related disclosures required to be tagged? For example, should we only require tagging of the quantitative climate-related metrics?

192. Are there any third-party taxonomies the Commission should

[700] *See supra* note 92.

[701] *See* proposed 17 CFR 229.1507.

[702] For the proposed Subpart 1500 disclosures, this tagging requirement would be implemented by including a cross-reference to Rule 405 of Regulation S–T in proposed Item 1507 of Regulation S–K, and by revising Rule 405(b) of Regulation S–T to include the proposed climate-related disclosures required by Subpart 1500 of Regulation S–K. The proposed Article 14 of Regulation S–X disclosures would be subject to existing requirements in Rule 405(b) to tag information in financial statements (including footnotes). Pursuant to Rule 301 of Regulation S–T the EDGAR Filer Manual is incorporated by reference into the Commission's rules. In conjunction with the EDGAR Filer Manual, Regulation S–T governs the electronic submission of documents filed with the Commission. Rule 405 of Regulation S–T specifically governs the scope and manner of disclosure tagging requirements for operating companies and investment companies, including the requirement in Rule 405(a)(3) to use Inline XBRL as the specific structured data language to use for tagging the disclosures.

[703] *Interactive Data to Improve Financial Reporting,* Release No. 33–9002 (Jan. 30, 2009) [74 FR 6776 (Feb. 10, 2009)] (''2009 Financial Statement Information Adopting Release'') (requiring submission of an Interactive Data File to the Commission in exhibits to such reports); *see also* Release No. 33–9002A (Apr. 1, 2009) [74 FR 15666 (Apr. 7, 2009)].

[704] *Inline XBRL Filing of Tagged Data,* Release No. 33–10514 (June 28, 2018) [83 FR 40846, 40847 (Aug. 16, 2018)]. Inline XBRL allows filers to embed XBRL data directly into an HTML document, eliminating the need to tag a copy of the information in a separate XBRL exhibit. *Id.* at 40851.

[705] *Securities Offering Reform for Closed-End Investment Companies,* Release No. 33–10771 (Apr. 8, 2020) [85 FR 33290 (June 1, 2020) at 33318].

[706] *See supra* notes 704 and 705. Inline XBRL requirements for business development companies will take effect beginning Aug. 1, 2022 (for seasoned issuers) and Feb. 1, 2023 (for all other issuers). *See id.* If the proposed Inline XBRL requirements are adopted in the interim, they will not apply to business development companies prior to the aforementioned effectiveness dates.

look to in connection with the proposed tagging requirements?

193. Should we require issuers to use a different structured data language to tag climate-related disclosures? If so, what structured data language should we require? Should we leave the structured data language undefined?

L. Treatment for Purposes of Securities Act and Exchange Act

We are proposing to treat the proposed required climate-related disclosures as ''filed'' and therefore subject to potential liability under Exchange Act Section 18,[707] except for disclosures furnished on Form 6–K. The proposed filed climate-related disclosures would also be subject to potential Section 11 liability[708] if included in or incorporated by reference into a Securities Act registration statement. This treatment would apply both to the disclosures in response to proposed subpart 1500 of Regulation S–K and to proposed Article 14 of Regulation S–X.

Form 6–K disclosures would not be treated as ''filed'' because the form, by its own terms, states that ''information and documents furnished in this report shall not be deemed to be ''filed'' for the purposes of Section 18 of the Act or otherwise subject to the liabilities of that section.'' [709] The treatment of disclosures on Form 6–K as furnished is a long-standing part of our foreign private issuer disclosure system.[710]

Commenters expressed differing views on whether we should treat Commission-mandated climate-related disclosures as filed or furnished. Many commenters recommended that we treat such climate-related disclosures as filed.[711] Some of these commenters stated that we should treat climate-related disclosures like financial disclosures and require them to be filed together with the rest of the Commission filing.[712] Other commenters indicated that the treatment of climate-related disclosures as filed would help ensure that investors have confidence in the accuracy and completeness of such disclosures because of the liability associated with filed documents.[713]

Other commenters recommended that we treat climate-related disclosures as furnished.[714] Some of these commenters stated that the Commission's treatment of such disclosures as filed could act as a disincentive to providing ''broader'' disclosure and would incentivize some issuers ''to disclose in the manner most limited to meet the specific requirement and avoid more robust explanation.'' [715] Other commenters stated that the treatment of climate-related disclosures as furnished would be appropriate because, in their view, much of that disclosure is based on projections and aspirational statements ill-suited to the application of a stricter liability standard.[716]

We agree with those commenters who indicated that the treatment of climate-related disclosures as filed could help promote the accuracy and reliability of such disclosures for the benefit of investors.[717] In this regard, we believe these disclosures should be subject to the same liability as other important business or financial information that the registrant includes in its registration statements and periodic reports. While we acknowledge commenters who stated that the methodology underlying climate data continues to evolve,[718] we intend to provide registrants with an ample transition period to prepare to provide such disclosure.[719] Further, much of the disclosure proposed to be required reflects discussion of a company's own climate risk assessment and strategy, which is not dependent on external sources of information. In addition, we have provided guidance and proposed rules on the applicability of safe harbors to certain disclosures under the proposed rules. For these reasons, we believe it would be appropriate for the proposed disclosures to be filed rather than furnished, except with respect to the proposed disclosure we are requiring on Form 6–K.

Request for Comment

194. Should we treat the climate-related disclosures required by proposed subpart 1500 of Regulation S–K and proposed Article 14 of Regulation S–X as filed for purposes of potential liability under the Securities Act and Exchange Act, except for the climate disclosures on Form 6–K, as proposed? Should we instead treat the climate-related disclosures required by both proposed subpart 1500 of Regulation S–K and proposed Article 14 of Regulation S–X as furnished? Are there reasons why the proposed climate-related disclosures should not be subject to Section 18 liability?

195. Should we only treat the climate-related disclosures required by proposed subpart 1500 of Regulation S–K as filed? Should we only treat the climate-related disclosures required by proposed Article 14 of Regulation S–X as filed? Is there some other subset of climate-related disclosures that should be treated as furnished rather than filed? For example, should we only treat as filed disclosures related to a registrant's Scopes 1 and 2 emissions, and treat a registrant's Scope 3 emissions as furnished?

196. Should we treat the climate disclosures on Form 6–K as filed?

M. Compliance Date

We recognize that many registrants may require time to establish the necessary systems, controls, and procedures to comply with the proposed climate-related disclosure requirements. In addition, some commenters recommended that the Commission not adopt a ''one size fits all'' approach when promulgating climate-related disclosure rules because such an approach would disproportionately impact smaller registrants.[720] In order to provide registrants, especially smaller registrants, with additional time to prepare for the proposed climate-related disclosures, we are proposing phased-in dates for complying with proposed subpart 1500 of Regulation S–K and Article 14 of Regulation S–X, which would provide additional time for certain smaller registrants. The table

[707] 15 U.S.C. 78r.

[708] 15 U.S.C. 77k.

[709] Form 6–K, General Instruction B.

[710] *See* Release No. 34–8069 (Apr. 28, 1967), [32 FR 7853 (May 30, 1967)]. Form 6–K's treatment as furnished for purposes of Section 18 has existed since the Commission adopted the form.

[711] *See, e.g.,* letters from Baillie Gifford; Rob Bonta, California Attorney General *et al.*; Calvert Research and Management; Carolyn Kohoot; Center for American Progress; Ceres *et al.*; Certified B Corporations; Clean Yield Asset Management; Climate Risk Disclosure Lab; Consumer Federation of America; Environmental Bankers Association; Friends of the Earth, Amazon Watch, and Rainforest Action Network; Garcia Hamilton & Associates (June 11, 2021); Grant Thornton; Sarah Ladin; Miller/Howard Investments; Natural Resources Defense Council; New York State Society of Certified Public Accountants; Nia Impact Capital; Teachers Insurance and Annuity Association of America; ValueEdge Advisors (July 5, 2021); and Vert Asset Management.

[712] *See, e.g.,* letters from Rob Bonta, California Attorney General *et al.*; Calvert Research and Management; and Ceres *et al.*

[713] *See, e.g.,* letters from Consumer Federation of America; and Natural Resources Defense Council.

[714] *See, e.g.,* letters from American Petroleum Institute; Associated General Contractors of America; Bank Policy Institute; Business Roundtable; Chamber of Commerce; Chevron; Cisco; ConocoPhilips; Dell Technologies; Dow; FedEx Corporation (June 11, 2021); Investment Company Institute; NACCO Industries, Inc. (June 11, 2021); KPMG, LLP; National Association of Manufacturers; National Investor Relations Institute; National Mining Association; Society for Corporate Governance; and United Airlines Holdings, Inc.

[715] Letter from American Petroleum Institute; *see also* letters from Chamber of Commerce; and National Association of Manufacturers.

[716] *See, e.g.,* letters from National Mining Association; and United Airlines Holdings.

[717] *See supra* note 713.

[718] *See, e.g.,* letter from National Association of Manufacturers.

[719] *See infra* Section II.M.

[720] *See supra* note 556.

below summarizes the proposed phase-ins for the compliance date. The table assumes, for illustrative purposes, that the proposed rules will be adopted with an effective date in December 2022, and that the registrant has a December 31st fiscal year-end.

Registrant type	Disclosure compliance date		Financial statement metrics audit compliance date
	All proposed disclosures, including GHG emissions metrics: Scope 1, Scope 2, and associated intensity metric, but excluding Scope 3.	GHG emissions metrics: Scope 3 and associated intensity metric.	
Large Accelerated Filer	Fiscal year 2023 (filed in 2024)	Fiscal year 2024 (filed in 2025)	Same as disclosure compliance date.
Accelerated Filer and Non-Accelerated Filer.	Fiscal year 2024 (filed in 2025)	Fiscal year 2025 (filed in 2026).	
SRC	Fiscal year 2025 (filed in 2026)	Exempted.	

The proposed compliance dates in the table above would apply to both annual reports and registration statements. For example, if a non-accelerated filer with a December 31st fiscal year-end filed a registration statement that was not required to include audited financial statements for fiscal year 2024 (*e.g.,* the registration statement was filed in 2023 or 2024), it would not be required to comply with the proposed climate disclosure rules in that registration statement.

A registrant with a different fiscal year-end date that results in its fiscal year 2023 commencing before the effective date of the rules would not be required to comply with subpart 1500 of Regulation S–K and Article 14 of Regulation S–X until the following fiscal year. For example, a large accelerated filer with a March 31st fiscal year-end date would not be required to comply with the proposed climate disclosure rules until its Form 10–K for fiscal year 2024, filed in June, 2024. This would provide large accelerated filers, who would have the earliest compliance date of all categories of filers, with what we believe is a reasonable amount of time to comply with the rules.

We believe that initially applying the disclosure requirements to the more limited pool of large accelerated filers would be appropriate, because many large accelerated filers are already collecting and disclosing climate-related information, have already devoted resources to these efforts, and have some levels of controls and processes in place for such disclosure.[721] In comparison, registrants that are not large accelerated filers may need more time to develop the systems, controls, and processes necessary to comply with the proposed rules, and may face proportionately higher costs. Accordingly, we propose to provide them additional time to comply.

We also recognize that obtaining the data necessary to calculate a registrant's Scope 3 emissions might prove challenging since much of the data is likely to be under the control of third parties. In order to provide sufficient time for registrants to make the necessary arrangements to begin gathering and assessing such data, we are proposing an additional one-year phase-in period for the Scope 3 emissions disclosure requirements. As previously mentioned, we also are proposing an exemption for SRCs from the proposed Scope 3 emissions disclosure provision.[722]

The proposed mandatory compliance periods are intended to provide registrants with ample time to prepare to provide the proposed disclosures. Registrants would, however, be able to provide the disclosures at any time after the effective date of the rules.

Request for Comment

197. Should we provide different compliance dates for large accelerated filers, accelerated filers, non-accelerated filers, or SRCs, as proposed? Should any of the proposed compliance dates in the table above be earlier or later? Should any of the compliance dates be earlier so that, for example, a registrant would be required to comply with the Commission's climate-related disclosure rules for the fiscal year in which the rules become effective?

198. Should we provide a compliance date for the proposed Scope 3 emissions disclosure requirements that is one year later than for the other disclosure requirements, as proposed? Should the compliance dates for the Scope 3 emissions disclosure requirements be earlier or later? Should the compliance date for the Scope 3 emissions disclosure requirements depend upon whether the registrant is a large accelerated filer, accelerated filer, or non-accelerated filer?

199. Should we provide different compliance dates for registrants that do not have a December 31st fiscal year-end?

200. Should we include rules or guidance addressing less common situations, such as, but not limited to, reverse mergers, recapitalizations, other acquisition transactions, or if a registrant's SRC (or EGC) status changes as a result of such situations?

201. Are there other phase-ins or exemptions regarding any or all of the proposed rules that we should provide?

III. General Request for Comments

We request and encourage any interested person to submit comments on any aspect of the proposed amendments, other matters that might have an impact on the proposed amendments, and any suggestions for additional changes. With respect to any comments, we note that they are of greatest assistance to our rulemaking initiative if accompanied by supporting data and analysis of the issues addressed in those comments and by alternatives to our proposals where appropriate.

IV. Economic Analysis

We are mindful of the economic effects that may result from the proposed rules, including the benefits, costs, and the effects on efficiency, competition, and capital formation.[723]

[721] *See, e.g.,* letters from Adobe; Apple; BNP Paribas; bp; Chevron; Eni SpA; and Walmart.

[722] *See supra* Section II.G.3.

[723] Section 2(b) of the Securities Act, 15 U.S.C. 77b(b), and Section 3(f) of the Exchange Act, 17 U.S.C. 78c(f), require the Commission, when engaging in rulemaking where it is required to consider or determine whether an action is necessary or appropriate in the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation. Further, Section 23(a)(2) of the Exchange Act, 17 U.S.C. 78w(a)(2), requires the Commission, when making rules under the Exchange Act, to consider the impact that the

This section analyzes the expected economic effects of the proposed rules relative to the current baseline, which consists of the regulatory framework of disclosure requirements in existence today, the current disclosure practices of registrants, and the use of such disclosures by investors and other market participants.

We anticipate the proposed rules will give rise to several benefits by strengthening investor protection, improving market efficiency, and facilitating capital formation. The primary benefit is that investors would have access to more consistent, comparable, and reliable disclosures with respect to registrants' climate-related risks, which is expected to enable investors to make more informed investment or voting decisions.[724] By providing access to this information through SEC filings for all public issuers, this enhanced disclosure could mitigate the challenges that investors currently confront in assessing the nature and extent of the climate-related risks faced by registrants and their impact on registrants' business operations and financial condition. In this way, the proposed rules may reduce information asymmetry both among investors, which can reduce adverse selection problems and improve stock liquidity,[725] and between investors and firms, which can reduce investors' uncertainty about estimated future cash flows, thus lowering the risk premium they demand and therefore registrant's cost of capital. The proposed rules could also mitigate certain agency problems between the firm's shareholders and management, thus strengthening investor protection.[726] Further, by enabling climate-related information to be more fully incorporated into asset prices, the proposed rules would allow climate-related risks to be borne by those who are most willing and able to bear them, thereby strengthening financial system resilience. Taken together, the proposed rules are expected to contribute to the efficient allocation of capital, capital formation, competition, and the maintenance of fair and orderly markets.[727]

We are also mindful of the costs that would be imposed by the proposed rules. Registrants would face increased compliance burdens in meeting the new disclosure requirements. In some cases, these additional compliance burdens could be significant while in others relatively small if companies already provide information similar to that required by our rules. Other potential costs include increased litigation risk and the potential disclosure of proprietary information about firms' operations and/or production processes.[728]

A. Baseline and Affected Parties

This section describes the current regulatory and economic landscape with respect to climate-related disclosures. It discusses the parties likely to be affected by the proposed rules, current trends in registrants' voluntary reporting on climate risks, related assurance practices, and existing mandatory disclosure rules under state and other Federal laws. These factors form the baseline against which we estimate the likely economic effects of the proposed rules.

1. Affected Parties

The proposed disclosure requirements would apply to Forms S–1, F–1, S–3, F–3, S–4, F–4, S–11, 6–K, 10, 10–Q, 10–K, and 20–F. Thus, the parties that are likely affected by the proposed rules include registrants subject to the disclosure requirements imposed by these forms, as well as investors and other market participants that use the information in these filings (*e.g.* financial analysts, investment advisors, asset managers, etc.).

The proposed rules may affect both domestic registrants and foreign private issuers (FPIs).[729] We estimate that during calendar year 2020, excluding registered investment companies, there were approximately 6,220 registrants that filed on domestic forms[730] and approximately 740 FPIs that filed on Forms 20–F. Among the registrants that filed on domestic forms, approximately 31 percent were large accelerated filers, 11 percent were accelerated filers, and 58 percent were non-accelerated filers. In addition, we estimate that approximately 50 percent of these domestic registrants were smaller reporting companies (SRCs) and 22 percent were emerging growth companies (EGCs).

2. Current Regulatory Framework

A number of the Commission's existing disclosure requirements may elicit disclosure about climate-related risks; however, many of these requirements are principles-based in nature and thus the nature and extent of the information provided depends to an extent on the judgment of management. As discussed above, in 2010, the Commission published interpretive guidance on existing disclosure requirements as they pertain to business or legal developments related to climate change.[731] The 2010 Guidance emphasized that if climate-related factors have a material impact on a firm's financial condition, disclosure may be required under current Item 101 (Description of Business), Item 103 (Legal Proceedings), Item 105 (Risk Factors), or Item 303 (MD&A) of Regulation S–K. While these provisions may elicit some useful climate-related disclosure, these provisions have not resulted in the consistent and comparable information about climate-related risks that many investors have stated that they need in order to make informed investment or voting decisions.[732]

3. Existing State and Federal Laws

There are also state and other Federal laws that require certain climate-related disclosures or reporting. For instance,

rules would have on competition, and prohibits the Commission from adopting any rule that would impose a burden on competition not necessary or appropriate in furtherance of the Exchange Act.

[724] *See infra* Section IV.C.1.

[725] *Id.*

[726] *Id.*

[727] *See infra* Section IV.D.

[728] *See infra* Section IV.C.2

[729] FPIs refer to the subset of all FPIs that file annual reports on Form 20–F, excluding MJDS filers using form 40–F.The number of domestic registrants and FPIs affected by the final amendments is estimated as the number of unique companies, identified by Central Index Key (CIK), that filed a Form 10–K, Form 20–F, or an amendment thereto, or both a Form 10–Q and a Form S–1, S–3, S–4, or S–11 with the Commission during calendar year 2020, excluding asset-backed securities issuers. For purposes of this economic analysis, these estimates do not include registrants that only filed a Securities Act registration statement during calendar year 2020, or only filed a Form 10–Q not preceded by a Securities Act registration statement (in order to avoid including entities such as certain co-issuers of debt securities). We believe that most registrants that have filed a Securities Act registration statement or a Form 10–Q not preceded by a Securities Act registration statement, other than such co-issuers, would be captured by this estimate. The estimates for the percentages of SRCs, EGCs, accelerated filers, large accelerated filers, and non-accelerated filers are based on data obtained by Commission staff using a computer program that analyzes SEC filings, with supplemental data from Ives Group Audit Analytics and manual review of filings by staff.

[730] This number includes approximately 20 FPIs that filed on domestic forms in 2020 and approximately 90 BDCs.

[731] *See Commission Guidance Regarding Disclosure Related to Climate Change,* Release No. 33–9106 (Feb. 2, 2010) [75 FR 6290 (Feb, 8, 2010)] (''2010 Climate Change Guidance''), *available at https://www.sec.gov/rules/interp/2010/33-9106.pdf* (The guidance did not create new legal requirements nor modify existing ones. Instead, it highlighted climate-related topics that registrants should consider in seeking to meet their existing disclosure obligations (*e.g.,* the impact of legislation, regulation, international accords, indirect consequences, physical risks, etc.) and in what section they should be discussed (*e.g.,* risk factors, MD&A, etc.)). *See* also discussion in Section I.A.

[732] *See* Section I.B.

there are requirements for mandatory climate risk disclosure within the insurance industry. As of 2021, 14 states[733] and the District of Columbia require any domestic insurers that write more than $100 million in annual net written premium[734] to disclose their climate-related risk assessment and strategy via the NAIC Climate Risk Disclosure Survey.[735] Survey question topics include climate risk governance, climate risk management, modeling and analytics, stakeholder engagement, and greenhouse gas management. In fiscal year 2020, there were 66 publicly traded insurance companies that may be required to provide disclosure pursuant to these state law provisions and that also would be subject to the proposed rules.

There also exist Federal- and state-level reporting requirements related to greenhouse gas (GHG) emissions. Federal GHG reporting requirements consist of the U.S. Environmental Protection Agency's (EPA) 2009 Mandatory Reporting of Greenhouse Gases Rule.[736] This rule requires large direct emitters and suppliers of fossil fuels to report their emissions to the EPA.[737] Specifically, the rule requires each facility that directly emits more than 25,000 metric tons of CO_2e per year to report these direct emissions. Additionally, facilities that supply certain products that would result in over 25,000 metric tons of CO_2e if those products were released, combusted, or oxidized must similarly report these ''supplied'' emissions.[738] The resulting emissions data are then made public through their website.

Due to the nature of the EPA's reporting requirements, their emissions data does not allow a clean disaggregation across the different scopes of emissions for a given registrant. The EPA requires reporting of facility-level direct emissions, which can contribute to a registrant's Scope 1 emissions (but can typically be considered a subset, to the extent that the registrant has other non-reporting facilities), and facility-level supplied emissions, which can contribute to a registrant's Scope 3 emissions (but can also be very different from it).[739] Gases required to be reported by the EPA include all those referenced by the GHG Protocol and included within the proposed definition of ''greenhouse gases.''[740] The EPA estimates that the required reporting under their rule covers 85–90% of all GHG emissions from over 8,000 facilities in the United States.[741]

In addition, at least 17 states have specific GHG emissions reporting requirements.[742] States' rules vary with respect to reporting thresholds and emissions calculation methodologies, but most tend to focus on direct emissions (*i.e.,* Scope 1), with certain exceptions. For example, New York requires the reporting of direct emissions from any owner or operator of a facility that directly emits or has the potential to emit 100 tons per year or more of GHGs, and 100,000 tons per year or more of carbon dioxide equivalent (CO_2e).[743] Colorado excludes oil and gas that is exported out of state, but includes both imported and exported electricity when calculating the state's emissions inventory.[744] California requires annual reporting of GHG emissions by industrial sources that emit more than 10,000 metric tons of CO_2e, transportation and natural gas fuel suppliers, and electricity importers.[745] As a result of these federal and state-level emissions reporting requirements, some registrants affected by the proposed rules may already have in place certain processes and systems to measure and disclose their emissions.

4. International Disclosure Requirements

Issuers with operations abroad may also be subject to those jurisdictions' disclosure requirements. Many jurisdictions' current and/or proposed requirements are based on the TCFD's framework for climate-related financial reporting.[746] In 2015, the Financial Stability Board (FSB) established the TCFD, an industry-led task force charged with developing a framework for assessing and disclosing climate-related financial risk. In 2017, the TCFD published disclosure recommendations that provide a framework to evaluate climate-related risks and opportunities through an assessment of their projected short-, medium-, and long-term financial impact on an issuer. The framework establishes eleven disclosure topics related to four pillars that reflect how companies operate: Governance, strategy, risk management, and metrics and targets.[747] The TCFD forms the framework for the recently published climate prototype standard that the IFRS Foundation is considering as a potential model for standards by the IFRS Foundation's International Sustainability Standards Board (ISSB). As of September 2021, the TCFD

[733] The 14 states are California, Connecticut, Delaware, Maine, Maryland, Massachusetts, Minnesota, New Mexico, New York, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington.

[734] Net written premium is defined as the premiums written by an insurance company, minus premiums paid to reinsurance companies, plus any reinsurance assumed.

[735] *See* NAIC, *Assessments of and Insights from NAIC Climate Risk Disclosure Data* (Nov. 2020), *available at https://content.naic.org/article/news_release_naic_assesses_provides_insight_insurer_climate_risk_disclosure_survey_data.htm.*

[736] *See* 40 CFR part 98 (2022); see also EPA, *EPA Fact Sheet: Greenhouse Gases Reporting Program Implementation* (2013), *available at https://www.epa.gov/sites/default/files/2014-09/documents/ghgrp-overview-factsheet.pdf.*

[737] According to the EPA, ''direct emitters'' are facilities that combust fuels or otherwise put GHGs into the atmosphere directly from their facility. An example of this is a power plant that burns coal or natural gas and emits carbon dioxide directly into the atmosphere. The EPA estimates that the GHGRP data reported by direct emitters covers about half of total U.S. emissions. ''Suppliers'' are those entities that supply products into the economy which if combusted, released or oxidized emit greenhouse gases into the atmosphere. These fuels and industrial gases are not emitted from the supplier facility but instead distributed throughout the country and used. An example of this is gasoline, which is sold in the U.S. and primarily burned in cars throughout the country. The majority of GHG emissions associated with the transportation, residential and commercial sectors are accounted for by these suppliers.

[738] The EPA's emissions data does not include emissions from agriculture, land use, or direct emissions from sources that have annual emissions of less than 25,000 metric tons of CO_2e.

[739] On this latest point, in particular, facility-level supplied emissions cannot necessarily be characterized as a portion of the registrant's Scope 3 emission as the boundaries of the entity required to report under the EPA reporting regime (the facility) are different from the boundaries of the entity required to report under our proposed rules (the registrant).

[740] The EPA requires emissions reporting only for domestic facilities, while the proposed rule would not be limited to U.S. facilities and includes indirect emissions. The EPA also requires some gases (*e.g.* fluorinated ethers, perfluoropolyether) that are considered optional under the GHG Protocol and that are not included within the proposed definition of ''greenhouse gases.''

[741] *See supra* note 736.

[742] *See* NCSL, *Greenhouse Gas Emissions Reduction Targets and Market-Based Policies* (2021), *available at https://www.ncsl.org/research/energy/greenhouse-gas-emissions-reduction-targets-and-market-based-policies.aspx.* The 17 states with GHG reporting requirements are Hawaii, Washington, Oregon, California, Nevada, Colorado, Minnesota, Iowa, Virginia, Pennsylvania, New York, New Jersey, Maryland, Connecticut, Massachusetts, Vermont, and Maine.

[743] *See* Air Compliance and Emissions (ACE) Reporting, *available at https://www.dec.ny.gov/chemical/54266.html.*

[744] *See* M. Sakas, Colorado Greenhouse Gas Producers Are Now Required To Report Emissions Data To The State, *Colorado Public Radio News* (2020), *available at https://www.cpr.org/2020/05/22/colorado-greenhouse-gas-producers-are-now-required-to-report-emissions-data-to-the-state.*

[745] *See* Cal. Air Res. Bd., *Mandatory Greenhouse Gas Reporting 2020 Emissions Year Frequently Asked Questions* (Nov. 4, 2021), *available at https://www.arb.ca.gov/cc/reporting/ghg-rep/reported-data/2020mrrfaqs.pdf?_ga=2.110314373.182173320.1638196601-1516874544.1627053872.*

[746] *See* Section I.D.

[747] *See* TCFD, *Overview* (Mar. 2021) (''TCFD_Booklet_FNL_Digital_March-2020''), *available at https://assets.bbhub.io/company/sites/60/2020/10/TCFD_Booklet_FNL_Digital_March-2020.pdf.*

reported that eight jurisdictions have implemented formal TCFD-aligned disclosure requirements for domestic issuers: Brazil, the European Union, Hong Kong, Japan, New Zealand, Singapore, Switzerland, and the United Kingdom.[748] In these jurisdictions, disclosures are already being provided by in-scope issuers or are expected to start between 2022 and 2025. Plans to expand the scope of current requirements have also been announced in several countries, including the United Kingdom,[749] the European Union,[750] and Japan.[751] In addition, several other jurisdictions have proposed TCFD-aligned disclosure requirements, issued policies or guidance in line with the TCFD recommendations, or otherwise indicated support for the TCFD recommendations, including Australia, Canada,[752] Denmark, France, Ireland, Italy, Malaysia, Norway, Russia and South Korea.[753] Insofar as issuers have operations abroad, they would already be subject to these mandatory disclosure requirements, policies and guidance.

5. Current Market Practices

a. Climate-Related Disclosures in SEC Filings

The Commission's staff reviewed 6,644 annual reports (Forms 10–K, 40–F, and 20–F) submitted from June 27, 2019 until December 31, 2020 to determine how many contain any of the following keywords: ''climate change'', ''climate risk'', or ''global warming''. The presence of any of the keywords in any part of the annual report is indicative of some form of climate-related disclosure.[754] Table 1 (presented as a graph in Figure 1) shows that 33% of all annual reports contain some disclosure related to climate change, with a greater proportion coming from foreign registrants (the corresponding percentages for Forms 20–F and 40–F are 39% and 73%, respectively). Table 2 (presented as a graph in Figure 2) provides a breakdown by accelerated filer status. Among large accelerated filers, 49% of filings discussed climate change, while the figures for accelerated filers and non-accelerated filers are 29% and 17%, respectively. Table 3 (presented as a graph in Figure 3), which provides a breakdown by industry groups, shows that the industries with the highest percentage of annual reports containing climate-related disclosure include maritime transportation, electric services, oil and gas, steel manufacturing, and rail transportation, among others.

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TABLE 1—FILINGS WITH CLIMATE-RELATED KEYWORDS BY FORM TYPE

Form	Has keyword	All filings	Percent
10–K	1,785	5,791	31
20–F	286	729	39
40–F	91	124	73
Total	2,162	6,644	33

This table presents the analysis of annual filings submitted to the Commission between June 27, 2019, and Dec. 31, 2020. For each form type, the table indicates how many contain any of the climate-related keywords, which include ''climate change,'' ''climate risk,'' and ''global warming.''

[748] *See* TCFD, *2021 Status Report* (Oct. 2021), *available at https://assets.bbhub.io/company/sites/60/2021/07/2021-TCFD-Status_Report.pdf.*

[749] For example, the United Kingdom's Financial Conduct Authority (FCA) issued a policy statement in 2021 expanding its TCFD-aligned disclosure requirements to standard issuers and formally incorporating references to the TCFD's Oct. 2021 guidance on metrics, targets and transition plans and updated implementation annex. This policy will apply for accounting periods beginning on or after Jan. 1, 2022. The FCA requirements are currently on a comply-or-explain basis; the FCA has announced that it plans to consult on making these requirements mandatory alongside future proposals adapting the rules to any future ISSB climate standard, once issued. *See* FCA, *PS21/23: Enhancing Climate-Related Disclosures by Standard Listed Companies* (Dec. 2021), available at *https://www.fca.org.uk/publication/policy/ps21-23.pdf.* In addition, the United Kingdom has adopted TCFD-aligned disclosure requirements for asset managers and certain asset owners, effective Jan. 1, 2022, with certain phase-ins. *See* FCA, *PS21/24: Enhancing Climate-Related Disclosures by Asset Managers, Life Insurers and FCA-Regulated Pension Providers* (Dec. 2021), *available at https://www.fca.org.uk/publication/policy/ps21-24.pdf.*

[750] In the European Union, the European Commission (EC) adopted a proposal for a Corporate Sustainability Reporting Directive (CSRD), which would revise existing company reporting rules and aim to provide more comparable and consistent information to investors. The CSRD proposal enlarges the scope of the reporting requirements and would cover nearly 50,000 companies in the European Union. The CSRD proposal acknowledges the importance of the IFRS' efforts to establish the ISSB and seeks compatibility with the TCFD recommendations, along with other international frameworks. The EC aims to have the new CSRD reporting requirements in place for reporting year 2023. *See Proposal for Directive of the European Parliament and of the Council amending Directive 2013/34/EU, Directive 2004/109/EC, Directive 2006/43/EC and Regulation (EU) No 537/2014, as regards corporate sustainability reporting,* COM (2021) 189 final (Apr. 21, 2021), *available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC018.* Additionally, the EC is progressing work on reporting standards for meeting the proposed CSRD requirement. The European Financial Reporting Advisory Group (''EFRAG'') published a climate standard prototype in Sept. 2021 that is based on the TCFD framework. *See* EFRAG, *Climate Standard Working Paper,* (Sept. 8, 2021), *available at https://www.efrag.org/News/Project-527/EFRAG-PTF-ESRS-welcomes-Climate-standard-prototype-working-paper?AspxAutoDetectCookieSupport=1.*

[751] Japan's Financial Services Agency (FSA) is planning to make it mandatory for large companies to make climate-related disclosures aligned with the TCFD framework from as early as Apr. 2022. In addition, climate disclosures have been part of Japan's corporate governance code since June 2021; however, the code is not legally binding and the disclosures were introduced on a 'comply-or-explain' basis. In Apr. 2022, the Tokyo Stock Exchange (TSE) will be replacing its First and Second sections, the ''Mothers'' market for startups and the tech-focused JASDAQ, with three new segments: Prime, Standard and Growth. According to Nikkei, companies listed on the Prime market will be required to comply with disclosure requirements aligned with the TCFD recommendations starting in Apr. 2022. *See* Japan's FSA to Mandate Climate Disclosures from Apr. 2022, (Oct. 2021), *available at https://www.esginvestor.net/japans-fsa-to-mandate-climate-disclosures-from-april-2022/.*

[752] The Canadian Securities Administrators (CSA) is considering proposed climate-related disclosure requirements largely consistent with the TCFD recommendations, with a few exceptions. The proposed requirements would elicit disclosure by issuers related to the four pillars of the TCFD recommendations (Governance, Strategy, Risk management, and Metrics and targets). The CSA anticipates that the proposed requirements would come into force in 2022 and would be phased in over one and three year periods. *See* Consultation: Climate-Related Disclosure Update and CSA and Request for Comment, *available at https://www.osc.ca/sites/default/files/2021-10/csa_20211018_51-107_disclosure-update.pdf.*

[753] *See TCFD 2021 Status Report, available at https://assets.bbhub.io/company/sites/60/2021/07/2021-TCFD-Status_Report.pdf.*

[754] One limitation of using this keyword search is that it is unable to discern the extent or quality of climate-related disclosures, nor can it determine specific sub-topics within climate-related disclosures. For these reasons, the analysis was supplemented by natural language processing (NLP) analysis, as described later in this section.

Figure 1. Filings with Climate-related Keywords by Form Type

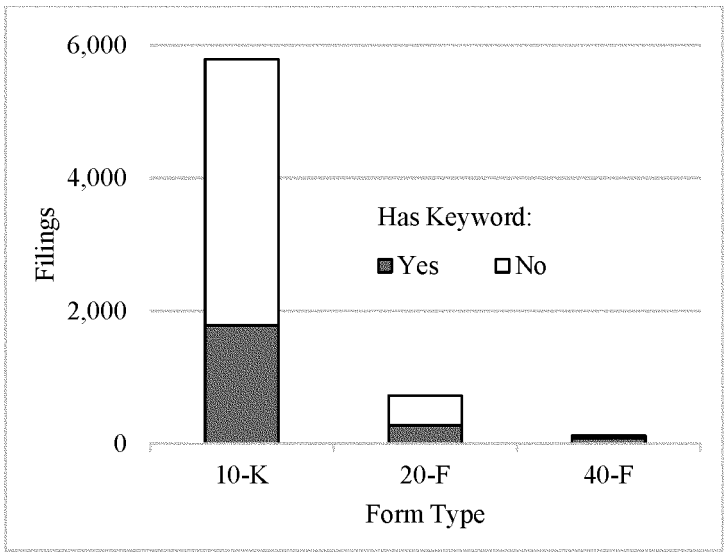


TABLE 2—FILINGS WITH CLIMATE-RELATED KEYWORDS BY ACCELERATED FILER STATUS

Filer status	Has keyword	All filings	Percent
LAF	1,117	2,280	49
AF	371	1,290	29
NAF	465	2,754	17
Other	209	320	65
Total	2,162	6,644	33

This table presents the analysis of annual filings submitted to the Commission between June 27, 2019, and Dec. 31, 2020. Filer status consists of large accelerated filers (LAF), accelerated filers (AF), and non-accelerated filers (NAF). For each filer status, the table indicates how many contain any of the climate-related keywords, which include ''climate change,'' ''climate risk,'' and ''global warming.''

Figure 2. Filings with Climate-related Keywords by Accelerated Filer Status

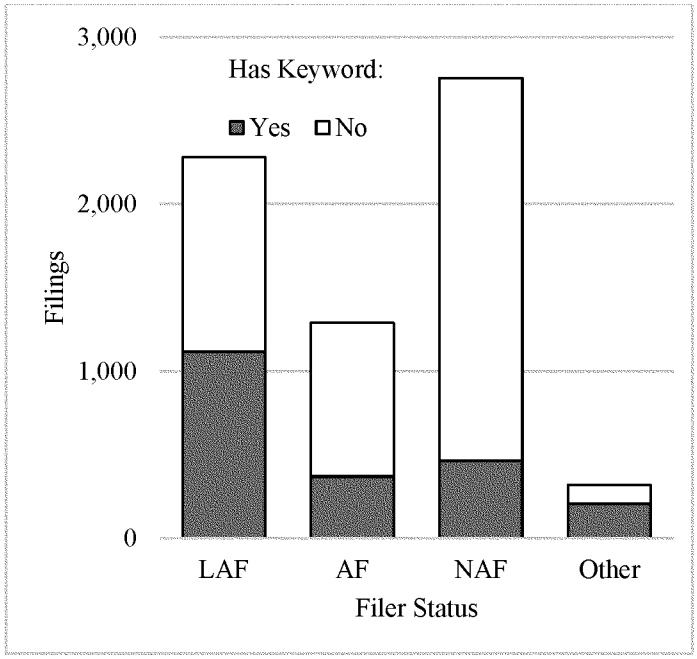
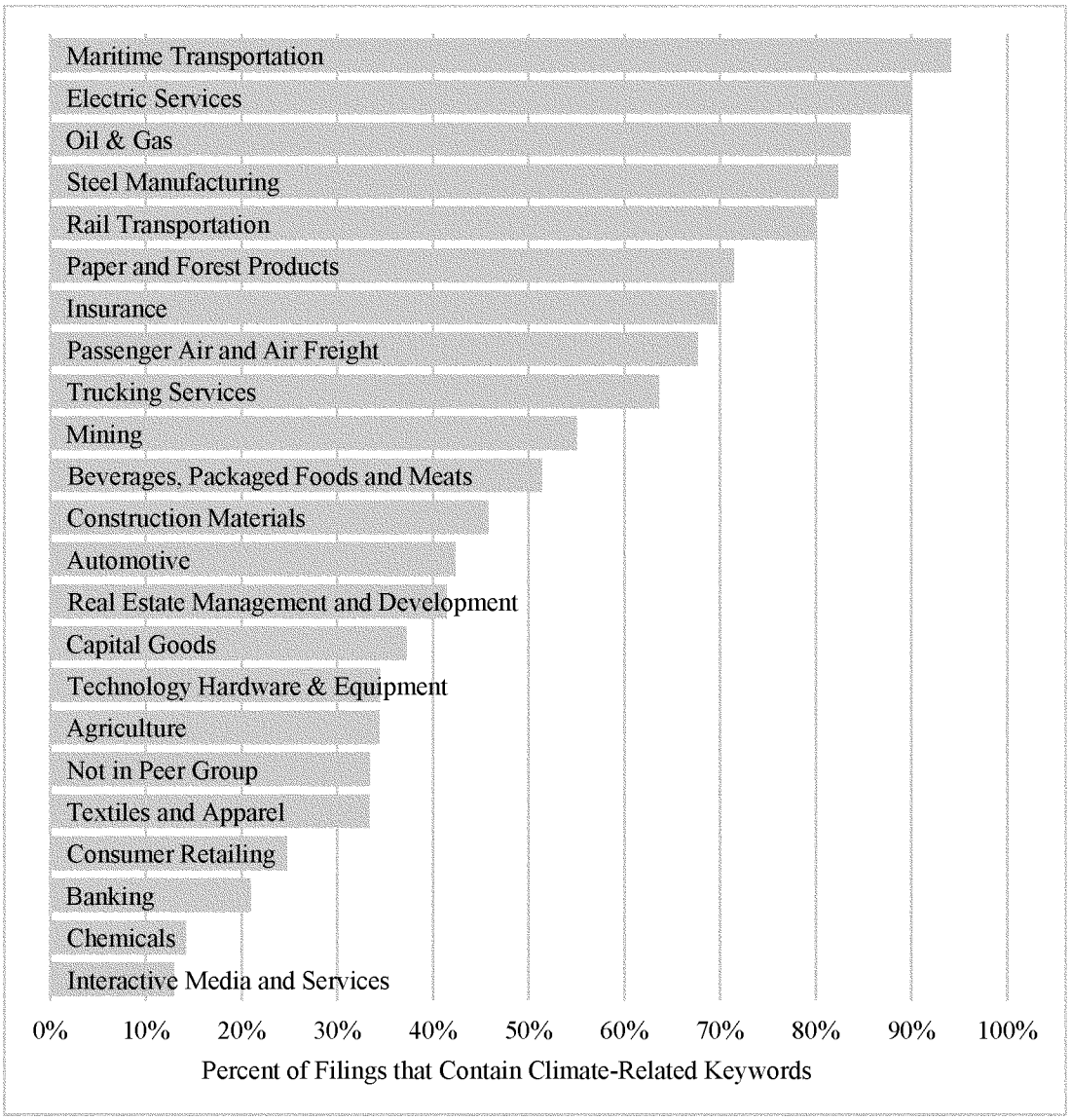


TABLE 3—FILINGS WITH CLIMATE-RELATED KEYWORDS BY INDUSTRY

Industry	Has keyword	All filings	Percent
Maritime Transportation	64	68	94
Electric Services	154	171	90
Oil and Gas	169	202	84
Steel Manufacturing	14	17	82
Rail Transportation	8	10	80
Paper and Forest Products	20	28	71
Insurance	46	66	70
Passenger Air and Air Freight	23	34	68
Trucking Services	14	22	64
Mining	109	198	55
Beverages, Packaged Foods and Meats	56	109	51
Construction Materials	54	118	46
Automotive	11	26	42
Real Estate Management and Development	274	661	41
Capital Goods	41	110	37
Technology Hardware & Equipment	61	177	34
Agriculture	11	32	34
Textiles and Apparel	12	36	33
Not in Peer Group	478	1,431	33
Consumer Retailing	138	558	25
Banking	158	754	21
Chemicals	131	922	14
Interactive Media and Services	116	894	13
Total	2,162	6,644	33

This table presents the analysis of annual filings submitted to the Commission between June 27, 2019, and Dec. 31, 2020. For each industry, the table indicates how many contain any of the climate-related keywords, which include ''climate change,'' ''climate risk,'' and ''global warming.''

Figure 3. Filings with Climate-related Keywords by Industry

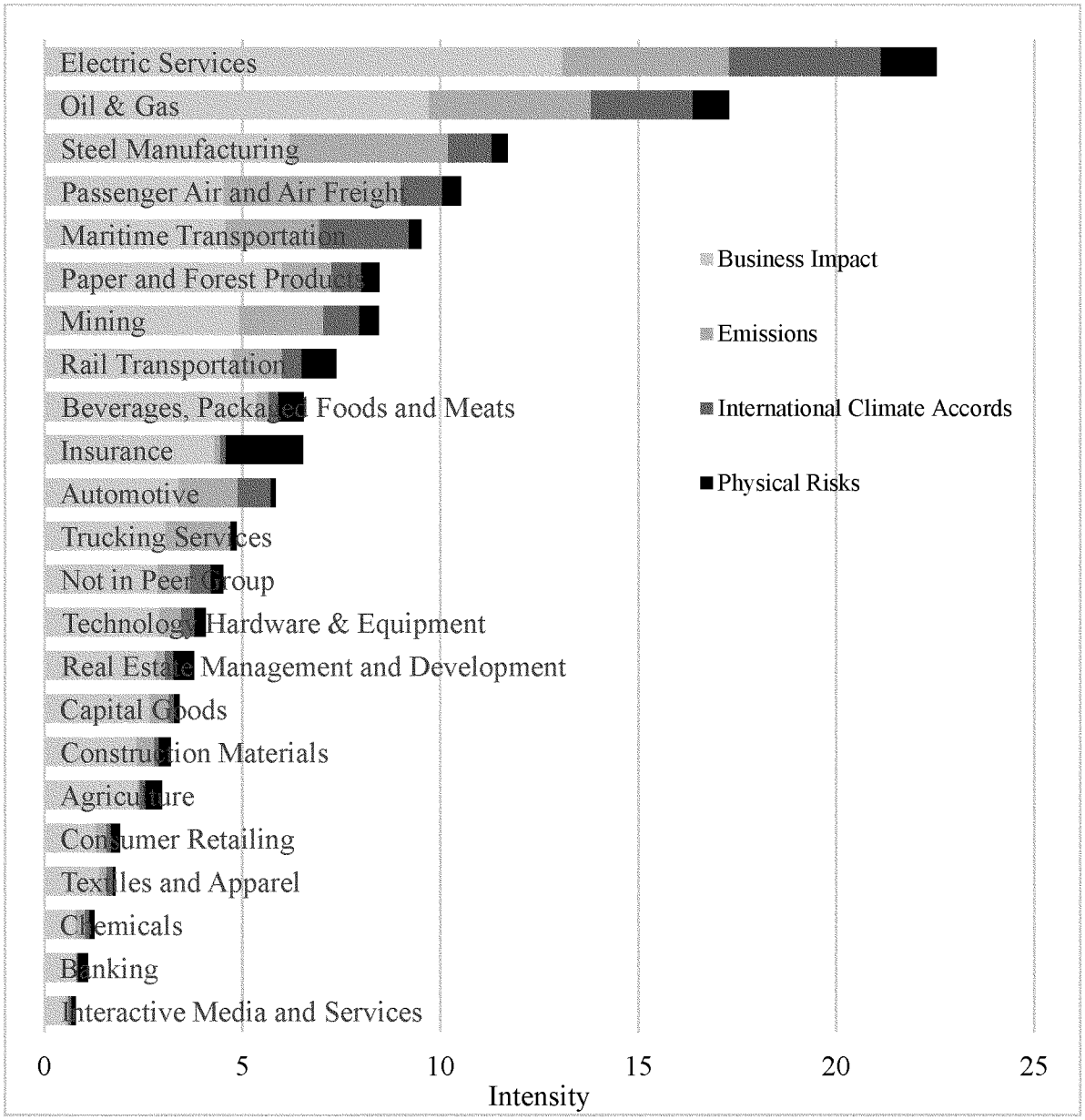


Using the same sample of annual reports, additional analysis was conducted by Commission's staff using natural language processing (NLP), which can provide insight on the semantic meaning of individual sentences within registrants' climate-related disclosures and classify them into topics (*i.e.* clusters).[755] The NLP analysis suggests that climate-related disclosures can be broadly organized into four topics: Business impact, emissions, international climate accords, and physical risks. The analysis finds significant heterogeneity, both within the quantity and content, of climate-related disclosures across industries, as shown in Figures 4 and 5. Figure 4 presents the intensity of disclosure for domestic filings. The intensity refers to sentences per firm, which is calculated by taking the aggregate number of sentences in an industry and dividing it by the total number of firms within the industry (including those that do not discuss climate change at all). Thus, the intensity represents a more comparable estimate across industries.

Figure 4 shows that firms in the following industries have the most ample climate-related discussion, on average: Electric services, oil and gas, steel manufacturing, passenger air and air freight, and maritime transportation. The majority of the discussion is on business impact, followed by emissions, international climate accords, and physical risks. Figure 5 presents the corresponding information for foreign filings (Forms 40–F and 20–F). Overall, the analysis indicates that the majority of the disclosure is focused on transition risks, with comparatively fewer mentions of physical risk.

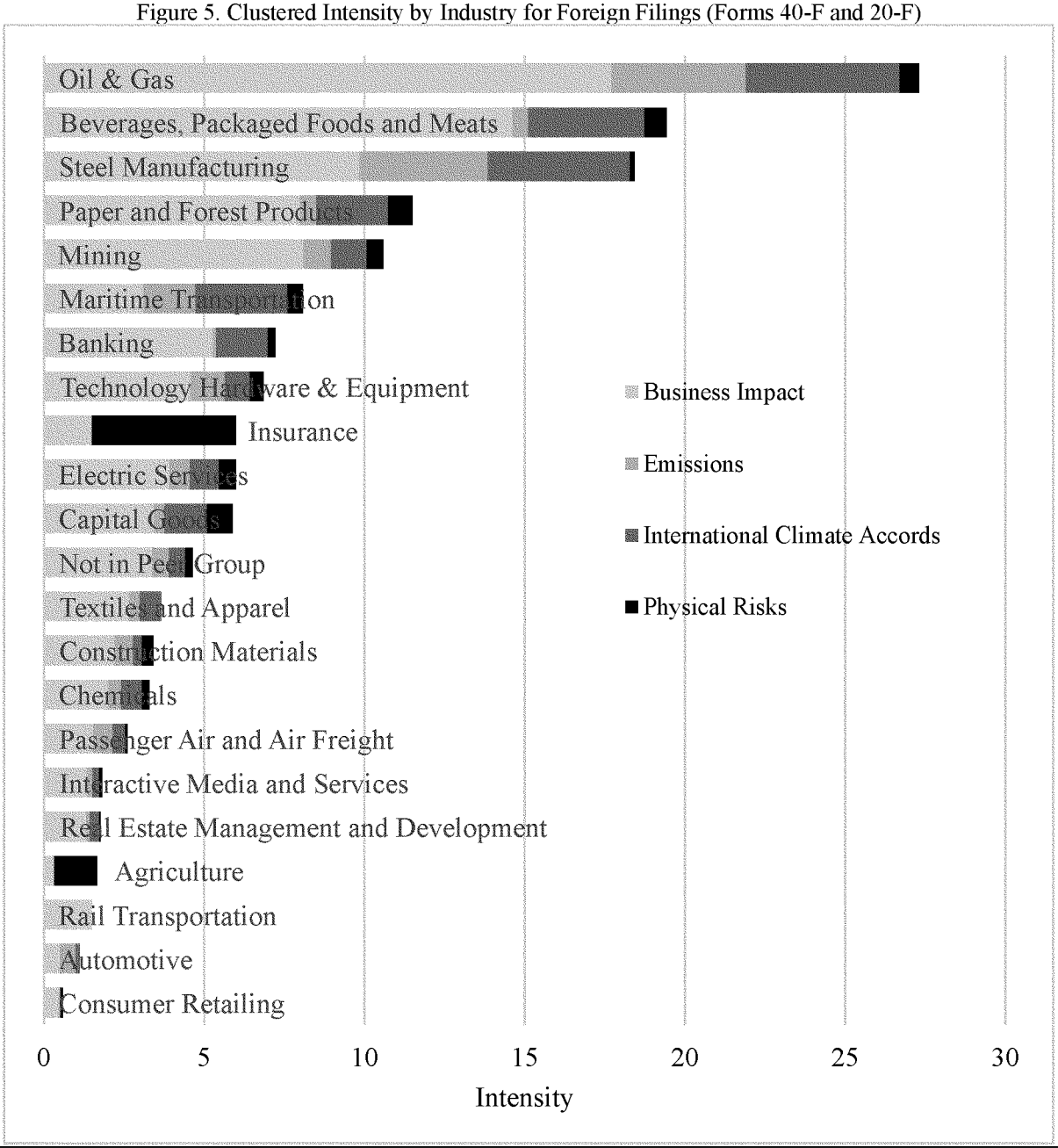
[755] The specific NLP method used in this analysis is word embedding, which utilizes Google's publicly available, pre-trained word vectors that are then applied to the text of climate-related disclosures within regulatory filings. While this NLP analysis can be used to identify the general topic and the extent of disclosures, it is limited in its ability to discern the quality or decision-usefulness of disclosures from investors' perspective.

Figure 4. Clustered Intensity by Industry for Forms 10-K



This figure presents the analysis of Form 10-K annual filings submitted to the Commission between June 27, 2019, and Dec. 31, 2020. Natural language processing (NLP) is used to analyze sentences contained within the annual filings and classify them into four broad topics (i.e. clusters): business impact, emissions, international climate accords, and physical risks. Intensity refers to sentences per firm, which is calculated by taking the aggregate number of sentences in an industry and dividing it by the total number of firms within the industry

Figure 5. Clustered Intensity by Industry for Foreign Filings (Forms 40-F and 20-F)



This figure presents the analysis of Forms 40-F and 20-F annual filings submitted to the Commission between June 27, 2019, and Dec. 31, 2020. Natural language processing (NLP) is used to analyze sentences contained within the annual filings and classify them into four broad topics (i.e. clusters): business impact, emissions, international climate accords, and physical risks. Intensity refers to sentences per firm, which is calculated by taking the aggregate number of sentences in an industry and dividing it by the total number of firms within the industry.

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The staff's findings are consistent with academic studies that have looked at the extent of climate-related disclosures by SEC registrants. Bolstad et al. (2020) systematically reviewed Form 10–K filings from Russell 3000 firms over the last 12 years and found that the majority of climate-related disclosure is focused on transition risks as opposed to physical risks.[756] They further report that while 35% of Russell 3000 firms provided climate-related information in 2009, this figure grew to 60% in 2020,[757] representing a significant increase. They also found that the extent of disclosure for a given report has increased. In 2009, firms mentioned climate risks 8.4 times on average in their Form 10–K. This figure grew to 19.1 times in 2020.

[756] *See* P. Bolstad, S. Frank, E. Gesick, and D. Victor, Flying Blind: What Do Investors Really Know About Climate Change Risks in the U.S. Equity and Municipal Debt Markets, *Hutchins Center Working Paper* 67 (2020).

[757] *Id.* The methodology uses a series of keywords to determine whether a company provides climate-related disclosures. Some keywords may occur in non-climate contexts, with the authors noting that the statistics are biased.

b. Additional Trends in Climate-Related Disclosures

While Commission staff reviewed certain firms' sustainability reports for climate-related disclosures, they did not conduct a systematic review of a large, representative sample of sustainability reports. However, as discussed below, a number of industry and advocacy groups have examined the scope of voluntary ESG reporting, including climate-related disclosures and their findings could be relevant to an assessment of the proposed rules' impact.

The U.S. Chamber of Commerce's Center for Capital Markets Competitiveness (CCMC), in collaboration with several other organizations, conducted a survey (''CCMC Survey'') on a sample of U.S. public companies—436 companies across 17 industries that range from small to large in terms of market capitalization.[758] According to the survey, over half of the companies (52%) are currently publishing a corporate social responsibility (CSR), sustainability, ESG or similar report whose content commonly includes information regarding climate-related risks. The most frequently discussed topics there are energy (74%), emissions (70%), environmental policy (69%), water (59%), climate mitigation strategy (57%), and supplier environmental policies (35%). Among the registrants that report climate-related information to the public, the majority disclose such information via external reports or company websites rather than regulatory filings. Similar to the Commission staff review, the CCMC Survey finds that about a third (34%) of the respondents disclose climate change, greenhouse gas emissions, or energy sourcing in their SEC filings information on risks. Among these firms, 82% disclose such information in Risk Factors, 26% in the MD&A, 19% in the Description of Business, and 4% in Legal Proceedings.

The Governance & Accountability Institute[759] (''G&A'') analyzed sustainability reports by the companies belonging to the Russell 1000 Index and found that in 2020, 70% published sustainability reports—up from 65% in 2019 and 60% in 2018.[760]

Other sources confirm that, at least within samples of larger firms, a sizeable portion already measure and disclose their emissions, though not necessarily through their regulatory filings. The CDP[761] reports that out of the 524 U.S. companies in their Climate High Impact Sample,[762] 402 disclosed through the CDP system in 2021, up from 379 in 2020, and 364 in 2019. Out of the sample of reviewed companies, 22.1% (89 out of 402 companies) reported Scope 3 emissions in 2021. This reflects an increase from the previous two years, during which 18% (67 out of 379 companies) reported such information in 2020, and 17% (62 out of 364 companies) in 2019.[763] One commenter stated that there is significant variation in disclosure rates of GHG emissions across various industries.[764] The commenter, using a sample of the 1,100 U.S. companies included within the Sustainalytics dataset, reports that the disclosure rate of material Scopes 1, 2, and 3 emissions is 59.5%.[765] Furthermore, the International Platform on Sustainable Finance found that among the U.S. listed firms present in the Refinitiv dataset, 10.8% disclosed Scope 1 emissions in 2019, representing 55.4% of U.S. market capitalization.[766] To the extent that registrants' current climate-related disclosures overlap with the proposed rules, registrants may face lower incremental compliance costs, as discussed in further detail below.[767]

c. Use of Third-Party Frameworks

Some companies follow existing third-party reporting frameworks when developing climate-related disclosures for SEC filings or to be included in CSR, sustainability, ESG, or similar reports. For instance, the CCMC Survey finds that 59% of respondents follow one or more such frameworks. Among these respondents, 44% use the SASB,[768] 31% use the GRI,[769] 29% use the TCFD,[770] and 24% use the CDP.[771] Similar statistics on the usage of different reporting frameworks are also provided by other studies. The G&A report[772] finds that 53% of the Russel 1000 reporters either mention or align with SASB,[773] 52% utilized GRI reporting standards,[774] 30% either

[758] *See* Climate Change & ESG Reporting from the Public Company Perspective (2021), *available at https://www.centerforcapitalmarkets.com/wp-content/uploads/2021/08/CCMC_ESG_Report_v4.pdf.*

[759] Governance & Accountability Institute Inc. (''G&A, Inc.'') is a consulting and research organization providing services to publicly traded and privately owned companies to help enhance their public environmental, social and governance (ESG) and sustainability profiles.

[760] *See* G & A Inc., Sustainability Reporting in Focus (2021), *available at https://www.ga-institute.com/research/ga-research-collection/sustainability-reporting-trends/2021-sustainability-reporting-in-focus.html.*

[761] CDP operates a global disclosure system that enables companies, cities, states and regions to measure and manage their environmental risks, opportunities and impacts. Despite not being a framework like GRI, SASB and TCFD, CDP's questionnaires gather both qualitative and quantitative information from across governance, strategy, risk, impact and performance. To aid comparability and ensure comprehensiveness, CDP includes sector-specific questions and data points. In 2018, CDP aligned its climate change questionnaire with the TCFD.

[762] The CDP Climate High Impact sample identifies companies deemed high impact based on two main considerations—market cap and GHG emissions.

[763] *See* Letter from CDP North America (Dec. 13, 2021).

[764] *See* Letter from Aron Szapiro, Head of Policy Research, Morningstar (June 9, 2021).

[765] *Id.* The comment letter does not disaggregate the disclosure rate across the different scopes of emissions.

[766] *See State and Trends of ESG Disclosure Policy Measures Across IPSF Jurisdictions, Brazil, and the US,* International Platform on Sustainable Finance (2021) (The disclosure rates are calculated using data from Refinitiv), *available at https://ec.europa.eu/info/sites/default/files/business_economy_euro/banking_and_finance/documents/211104-ipsf-esg-disclosure-report_en.pdf.*

[767] *See* Section IV.C.2.3.

[768] The SASB standards are designed for communication by companies to investors about how sustainability issues impact long-term enterprise value. SASB standards guide the disclosure of financially material sustainability information by companies to their investors. SASB standards, which are available for 77 industries, identify the subset of ESG issues most relevant to financial performance in each industry. The SASB standards can be both complementary with the core elements of the TCFD recommendations, as well as used by organizations to operationalize them. *See https://www.sasb.org/about/sasb-and-other-esg-frameworks/.*

[769] The GRI standards outline both how and what to report regarding the material economic, social and environmental impacts of an organization on sustainable development. For 33 potentially material sustainability topics, the GRI standards contain disclosure requirements. Three series of GRI standards support the reporting process: The GRI Topic Standards, each dedicated to a particular topic and listing disclosures relevant to that topic; the GRI Sector Standards, which are applicable to specific sectors; and the GRI Universal Standards, which apply to all organizations. The GRI Standards can be used in sustainability reports, as well as in annual or integrated reports that are oriented at a broad range of stakeholders. *See https://www.globalreporting.org/standards/.*

[770] The TCFD recommended disclosures cover four core elements: Governance, Strategy, Risk Management and Metrics and Targets. Each element has two or three specific disclosures (as shown in Table 4) to be made in the organization's mainstream report (*i.e.* annual financial filings). These are meant to generate comparable, consistent and reliable information on climate-related risks. The TCFD provides both general, and in some cases, sector-specific guidance for each disclosure, while simultaneously framing the context for disclosure, and offering suggestions on what and how to disclose in the mainstream report. *See https://www.fsb-tcfd.org/recommendations/.*

[771] *See supra* note 761.

[772] *See* supra note 760.

[773] Of the Russell 1000 reporting companies, 39% indicate that they are in alignment with SASB standards, while the other 14% simply mention the standards.

[774] Of those reporters utilizing the GRI standards, G&A finds that a small portion (5%) utilizes the ''Comprehensive'' level of reporting, the majority (64%) chose to report in accordance with the ''Core'' option, while the remaining portion (31%)

mention or align with TCFD recommendations,[775] and 40% responded to the CDP Climate Change questionnaire. The law firm White & Case also conducted an in-depth review of website sustainability disclosures by 80 small- and mid-cap firms across five different industries and found comparable numbers.[776]

While these various frameworks are distinct, they overlap in their alignment with the TCFD. In particular, the CDP questionnaire fully incorporates the TCFD framework and thus exhibits full alignment.[777] The Corporate Reporting Dialogue[778] also provides a detailed assessment of the various frameworks' degrees of alignment with each TCFD disclosure item, ranging from maximum to minimum alignment as follows: Full, Reasonable, Moderate, Very Limited, and None. They report that the GRI exhibits ''Reasonable'' alignment, while the SASB generally exhibits ''Moderate'' or ''Reasonable'' alignment with the majority of the TCFD disclosure items. Thus, companies that report following the CDP, SASB, or GRI frameworks are, to varying degrees, already producing disclosures that are in line with parts of the TCFD. However, because each framework takes different approaches (*e.g.* intended audience, reporting channel) and because certain differences exist in the scope and definitions of certain elements, investors may find it difficult to compare disclosures under each framework. Table 4 reports the rate of disclosure for each TCFD disclosure element for a sample of 659 U.S. companies in 2020/21.

TABLE 4—DISCLOSURE RATE OF TCFD ELEMENTS AMONG U.S. FIRMS[779]

TCFD disclosure element	Rate of disclosure (%)
Governance:	
(a) Describe the board's oversight of climate-related risks and opportunities	17
(b) Describe management's role in assessing and managing climate-related risks and opportunities	10
Strategy:	
(a) Describe the climate-related risks and opportunities the organization has identified over the short, medium, and long term	45
(b) Describe the impact of climate-related risks and opportunities on the organization's businesses, strategy, and financial planning	34
(c) Describe the resilience of the organization's strategy, taking into consideration different climate-related scenarios, including a 2 °C or lower scenario	5
Risk Management:	
(a) Describe the organization's processes for identifying and assessing climate-related risks	15
(b) Describe the organization's processes for managing climate-related risks	17
(c) Describe how processes for identifying, assessing, and managing climate-related risks are integrated into the organization's overall risk management	16
Metrics and Targets:	
(a) Describe the metrics used by the organization to assess climate-related risks and opportunities in line with its strategy and risk management process	21
(b) Disclose Scope 1, Scope 2, and, if appropriate, Scope 3 greenhouse gas (GHG) emissions, and the related risks	19
(c) Describe the targets used by the organization to manage climate-related risks and opportunities and performance against targets	25

d. Climate-Related Targets, Goals, and Transition Plan Disclosures

Carbon reduction targets or goals have become an increasing focus for both companies and countries.[780] For example, 191 countries, including the United States and European Union, have signed the Paris Climate Agreement. The agreement aims to strengthen the global response to the threat of climate change by keeping a rise in global temperatures to well below 2 °Celsius above pre-industrial levels this century, as well as pursue efforts to limit the temperature increase even further to 1.5° degrees Celsius.[781] As of 2020, according to one source, about two-thirds of S&P 500 companies have established a target for carbon emissions—a number that has nearly doubled over the past decade.[782] Approximately one-fifth of these companies have science-based targets in-line with a 1.5 degree Celsius limit

utilizes ''GRI-Referenced'' reports, which are not fully in accordance with the GRI standards. GRI-Referenced reports contain the GRI Content Index and reference certain disclosures.

[775] Of the Russell 1000 reporting companies, 17% indicate that they are in alignment with the TCFD recommendations, while the other 13% simply mention the recommendations.

[776] *See* White & Case and the Society for Corporate Governance: A Survey and In-Depth Review of Sustainability Disclosures by Small- and Mid-Cap Companies, *available at https://www.whitecase.com/publications/article/survey-and-depth-review-sustainability-disclosures-small-and-mid-cap-companies* (Among the firms reviewed, 41 firms (51%) provided some form of voluntary sustainability disclosure on their websites. Further, only nine of those 41 firms indicated the reporting standards with which they aligned their reporting, with the majority of the nine companies not following any one set of standards completely. Additionally, six firms followed the GRI, while three firms stated that they follow both the TCFD and SASB).

[777] *See* How CDP is Aligned to the TCFD (2018), *available at https://www.cdp.net/en/guidance/how-cdp-is-aligned-to-the-tcfd.*

[778] The Corporate Reporting Dialogue is a platform, convened by the Value Reporting Foundation, to promote greater coherence, consistency and comparability between corporate reporting frameworks, standards and related requirement. *See Driving Alignment in Climate-related Reporting, Corporate Reporting Dialogue* (2019), *available at https://www.integratedreporting.org/wp-content/uploads/2019/09/CRD_BAP_Report_2019.pdf.*

[779] *See* Moody's Analytics, *TCFD-Aligned Reporting by Major U.S. and European Corporations,* (2022), *available at https://www.moodysanalytics.com/articles/pa/2022/tcfd_aligned_reporting_by_major_us_and_european_corporations.* To arrive at these statistics, Moody's conducted an artificial intelligence (AI) based review of all public filings, including financial filings, annual reports, integrated reports, sustainability reports, and other publicly available reports that were associated with companies' annual reporting on sustainability. Non-public disclosures, such as CDP reports, were not included in the analysis.

[780] *See* Commitments to Net Zero Double in Less Than a Year, United Nations Climate Change (Sept. 21, 2020), *available at https://unfccc.int/news/commitments-to-net-zero-double-in-less-than-a-year.*

[781] *See* Section I.

[782] *See, e.g.,* J. Eaglesham, Climate Promises by Businesses Face New Scrutiny, *The Wall Street Journal* (2021), *available at www.wsj.com/articles/climate-promises-by-businesses-face-new-scrutiny-11636104600.*

on global warming.[783] In addition, a growing number of companies or organizations have signed on to the Climate Pledge, which indicates a commitment to achieve net-zero emissions by 2040.[784] The trend in companies disclosing other climate-related targets (*e.g.* water usage) has also been increasing over time.[785]

Despite the increasing prevalence in stated targets and goals, monitoring which firms are taking steps to implement them is difficult given the lack of required recurring standardized metrics for progress. Absent such a monitoring device, investors have insufficient information to gauge the credibility of the targets. Moreover, without knowing the specific strategy that registrants intend on adopting in pursuit of their targets, investors are unable to determine how the targets will impact the company's financial position (*e.g.,* a company that plans to only purchase offsets may face different risks and costs over time than a company that invests in renewable energy or carbon capture technology).[786]

Consistent with this need for an oversight or monitoring mechanism, research suggests that the prevalence of ''green bonds'' and positive cumulative abnormal stock returns surrounding their announcements may arise, at least in part, because they help signal credible value-enhancing targets in the absence of mandatory standardized public disclosures.[787] These findings suggest a demand for such an oversight or monitoring mechanism for targets and goals among investors that would facilitate their understanding of registrants' stated climate-related targets and progress and the impact on the registrant's business.

e. Third-Party Assurance of Climate-Related Disclosures

Among the companies that provide climate-related disclosures, a considerable portion include some form of third-party assurance for these disclosures. The G&A study[788] finds that 35% of Russell 1000 index firms, which are virtually all large accelerated filers, obtained third-party assurance for their sustainability reports in 2020, up from 24% in the year prior. The rate of assurance is concentrated among the larger half of the sample firms (*i.e.,* the S&P 500 firms). Among the firms that obtained assurance, however, only 3% obtained assurance for the entire report. The remaining firms were evenly split between obtaining assurance on specified sections only and GHG emissions only. Regarding the level of assurance, the overwhelming majority (90%) obtained limited assurance while only 7% obtained reasonable assurance. Regarding service providers, 14% of firms received assurance from an accounting firm, 31% from small consultancy/boutique firms, and 55% from engineering firms. Because these statistics are limited to Russell 1000 firms, corresponding figures for the full sample of U.S. registrants may be lower to the extent that the practice of obtaining third-party assurance is concentrated in large firms.[789]

B. Broad Economic Considerations

1. Investors' Demand for Climate Information

Investors have expressed a need for information on climate-related risks as they relate to companies' operations and financial condition.[790] The results of multiple recent surveys indicate that climate risks are among the most important priorities for a broad set of large asset managers.[791] PWC reported in their Annual Global CEO Survey that in 2016, only 39% of asset and wealth management CEOs reported that they were concerned about the threats posed by physical risks brought about climate change, whereas this figure increased to 70% in 2021.[792]

[783] *See* memorandum, dated Nov. 30, 2021, concerning staff meeting with representatives of Persefoni. This statistic is compiled by Persefoni using information from the Science Based Targets Initiative. This and the other staff memoranda referenced below are available at *https://www.sec.gov/comments/s7-10-22/s71022.htm.*

[784] As of Jan. 25, 2022, The Climate Pledge has acquired 217 signatories. *See* The Climate Pledge, *available at https://www.theclimatepledge.com/us/en/Signatories.*

[785] For example, the percentage of both global and U.S. companies with water reduction targets grew by 4% in 2019 on a year-over-year basis. This represented 28% of major global companies (*i.e.* those listed on the S&P Global 1200 index) and 27% of major (*i.e.* those listed in the S&P 500 index)) U.S. companies publicly disclosing these targets. *See* State of Green Business 2021, *available at https://www.spglobal.com/marketintelligence/en/news-insights/research/state-of-green-business-2021.*

[786] *See* S. Lu, *The Green Bonding Hypothesis: How do Green Bonds Enhance the Credibility of Environmental Commitments?* (2021), *available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3898909.*

[787] *See* C. Flammer, Corporate Green Bonds, *Journal of Financial Economics,* 499–516 (2021). (Green bonds may only be a partial solution to achieving credible targets given that they have implications beyond commitment.)

[788] *See supra* note 760.

[789] Other studies also report evidence of third-party assurance among smaller samples of companies analyzed. For example, according to a recent study by the International Federation of Accountants, in 2019, 99 out of the 100 largest U.S. firms by market capitalization provided some form of sustainability disclosure, which may contain climate-related information among other sustainability-related topics. Seventy of those firms obtained some level of third-party assurance, with the vast majority being ''limited assurance'' according to the study. Of the 70 firms that obtained assurance, the study reports that 54 obtained ''limited assurance,'' eight obtained ''reasonable assurance,'' five obtained ''moderate assurance,'' and three did not disclose any assurance. Of the 81 unique assurance reports examined in the study, nine were found to be issued by an auditing firm, while 72 were issued by another service provider. *See* International Federation of Accountants (''IFAC''), The State of Play in Sustainability Assurance (2021), *available at https://www.ifac.org/knowledge-gateway/contributing-global-economy/publications/state-play-sustainability-assurance.* Among the sample of 436 companies included in the CCMC Survey, 28% disclosed that they engaged a third party to provide some form of assurance regarding their climate-related disclosure (the frequency of these disclosures was 52% among the 436 companies in the sample). *See supra* note 758.

[790] *See* 2021 Global Investor Statement to Governments on the Climate Crisis (2021) (this statement has been signed by 733 investors collectively managing over US$52 trillion in assets), *available at https://theinvestoragenda.org/wp-content/uploads/2021/09/2021-Global-Investor-Statement-to-Governments-on-the-Climate-Crisis.pdf; See also* Alexander Karsner, *Testimony Before the House Financial Services Subcommittee on National Security,* International Development and Monetary Policy (Sept. 11, 2019), *available at https://financialservices.house.gov/uploadedfiles/hhrg-116-ba10-wstate-karsnera-20190911.pdf.* A recent report examined how climate change could affect 22 different sectors of the U.S. economy and found that if global temperatures rose 2.8 °C from pre-industrial levels by 2100, climate change could cost $396 billion each year. If temperatures increased by 4.5 °C, the yearly costs would reach $520 billion. *See* Jeremy Martinich and Allison Crimmins, *Climate Damages and Adaptation Potential Across Diverse Sectors of the United States,* Nature Climate Change 9, 397–404 (2019); *available at https://www.nature.com/articles/s41558-019-0444-6.* Similarly, the Swiss Re Institute estimated how global warming could affect 48 countries—representing 90% of the world economy—and found that the decrease in GDP in North America could range from −3.1% if Paris Agreement targets are met (a well-below 2 °C increase), to −9.5% if no mitigating actions are taken (3.2 °C increase); *See* The Economics of Climate Change: No Action Not an Option, *available at https://www.swissre.com/dam/jcr:e73ee7c3-7f83-4c17-a2b8-8ef23a8d3312/swiss-re-institute-expertise-publication-economics-of-climate-change.pdf.*

[791] *See, e.g.,* Emirhan Ilhan, Climate Risk Disclosure and Institutional Investors, *Swiss Fin. Inst. Research Paper Series* (Working Paper No. 19–66), (last revised Jan. 7, 2020), *available at https://ssrn.com/abstract=3437178* (noting that a survey of 439 large institutional investors shows that 79% of respondents believe that climate risk reporting is as important as traditional financial reporting, and almost one-third consider it to be more important); *See also Macquaire Asset Management 2021 ESG Survey Report* (2021), *available at https://www.mirafunds.com/assets/mira/our-approach/sustainability/mam-esg-survey/mam-2021-esg-survey-report.pdf* (noting that in a survey of 180 global institutional real assets investors, including asset managers, banks, consultants and investment advisors, foundations and endowments, insurance companies, and pension funds, who combined represent more than $21 trillion of assets under management, more than half of responding investors selected climate change as their primary ESG concern).

[792] *See* PWC, *The Economic Realities of ESG* (Oct. 28, 2021), *available at https://www.pwc.com/gx/en/*

Investors' demand for climate-related information may also be related to the transition risks that companies face (*e.g.* changes in future regulation, shifts in investor, consumer, counterparty preferences or other market conditions, and other technological challenges or innovations). For example, the United States' commitment to the Paris Agreement may have contributed to investors' demand for information on registrants' emissions and exposure to potential transition risk, as well as whether they have in place emissions targets with credible pathways of achievement.[793] The 2021 Institutional Investors Survey solicited the views of 42 global institutional investors managing over $29 trillion in assets (more than a quarter of global assets under management (AUM)) and found that climate risk remains the number one investor engagement priority. A significant majority (85%) of surveyed investors cite climate risk as the leading issue driving their engagements with companies. These institutional investors also indicated that they consider climate risk to be material to their investment portfolios and are demanding robust and quantifiable disclosure around its impacts and the plan to transition to net zero.[794]

State Street Global Advisors (SSGA) and Blackrock, two of the world's largest investment managers, recently announced the focus areas for their asset stewardship program for 2022, with climate change at the top of their priority list. One of the key expectations set by SSGA this year is a requirement for companies to provide disclosures aligned with TCFD recommendations, including reporting on board oversight on climate-related risks and opportunities, Scope 1 and 2 GHG emissions, and targets for emissions reduction.[795] Similarly, Blackrock expects to continue encouraging companies to demonstrate that their plans are resilient under likely decarbonization pathways, and to ask that companies disclose a net zero-aligned business plan that is consistent with their business model to demonstrate how their targets are consistent with the long-term economic interests of their shareholders.[796]

Investors, including large institutional investors, have also formed initiatives aimed in part at improving corporate disclosures on climate-related risks. These initiatives include the Climate Disclosure Project, Climate Action 100+,[797] the Global Investor Coalition on Climate Change (''GIC''),[798] the Institutional Investors Group on Climate Change (''IIGCC''),[799] and the Transition Pathway Initiative (''TPI''),[800] with many of these groups seeing increasing membership in recent years.[801] In addition to stated demand, revealed preferences from investment decisions and asset price responses to ESG-related news and climate change risk suggest substantive demand for information on climate-related risks.[802] Investors have also demonstrated their interest in climate-related issues through an increase in climate-related shareholder proposals[803] and increased flows into mutual funds with environmental goals in their investment mandates.[804]

2. Impediments to Voluntary Climate-Related Disclosures

a. General Impediments to Voluntary Climate-Related Disclosures

In practice, however, investors' demand for climate-related information is often met by inconsistent and incomplete disclosures due to the considerable variation in the coverage, specificity, location, and reliability of information related to climate risk. Multiple third-party reporting frameworks and data providers have emerged over the years; however, these resources lack mechanisms to ensure compliance and can contribute to reporting fragmentation.[805] Due to deficiencies in current climate-reporting practices, investor demand for comparable and reliable information does not appear to have been met.[806] As a result, investors may face difficulties locating and assessing climate-related information when making their investment or voting decisions.[807]

services/audit-assurance/corporate-reporting/esg-investor-survey.html.

[793] *See* Section IV.A.5.d.

[794] *See* Morrow and Sodali, Institutional Investor Survey (2021), *available at https://higherlogicdownload.s3.amazonaws.com/GOVERNANCEPROFESSIONALS/a8892c7c-6297-4149-b9fc-378577d0b150/UploadedImages/Institutional_Investor_Survey_2021.pdf.*

[795] *See https://www.esgtoday.com/state-street-to-require-companies-to-provide-tcfd-aligned-climate-disclosures/.*

[796] *See* BlackRock Investment Stewardship (BIS), *Policies Updated Summary* (2022), *https://www.blackrock.com/corporate/literature/fact-sheet/blk-responsible-investment-engprinciples-global-summary.pdf.*

[797] Climate Action 100+ is composed of 615 global investors across 33 markets with more than US$60 trillion in AUM. *See* Climate Action 100+, *available at https://www.climateaction100.org/about/.*

[798] As of Apr. 2018, GIC was signed by 409 investors representing more than U.S. $24 trillion in AUM, *available at https://climateinitiativesplatform.org/index.php/Global_Investor_Coalition_on_Climate_Change_(GIC).*

[799] IIGCC has more than 330 members, mainly pension funds and asset managers, across 22 countries, with over $33 trillion in AUM. *See* The Institutional Investors Group on Climate Change, *available at https://www.iigcc.org/.*

[800] The TPI is supported globally by 108 investors with more than $29 trillion combined AUM. *See* Transition Pathway Initiative, *available at https://www.transitionpathwayinitiative.org/.*

[801] For example, Climate Action 100+ launched in 2017 with 225 investors with more than USD $26.3 trillion AUM to engage with 100+ of the world's highest emitting companies to reduce material climate risks. In 2021, Climate Action 100+ has grown to 615 investors, $60 trillion in assets, engaging with 167 companies that represent 80%+ of global industrial emissions.

[802] *See* P. Krüger, *Corporate Goodness and Shareholder Wealth,* 115(2) Journal of Financial Economics 304–329 (2015); G. Capelle-Blancard, A. Petit, *Every Little Helps? ESG News and Stock Market Reaction,* Journal of Business Ethics 157, 543–565 (2019); and G. Serafeim and A. Yoon, *Which Corporate ESG News Does the Market React To?* (Forthcoming) Financial Analysts Journal (2021) (for evidence of stock market responses to ESG news). *See also* A. Bernstein, M. Gustafson, and R. Lewis, *Disaster on the Horizon: The Price Effect of Sea Level Rise,* 134.2 Journal of Financial Economics 253–300 (2019) A. Bernstein, S. Billings, M. Gustafson, and R. Lewis, *Partisan Residential Sorting on Climate Change Risk* (Forthcoming), Journal of Financial Economics (2021); M. Baldauf, L. Garlappi, and C. Yannelis, *Does Climate Change Affect Real Estate Prices? Only If You Believe In It,* 33 (3) Review of Financial Studies 1256–1295 (2020) (for evidence of responses of investor demand in equilibrium prices and investment choice (based on heterogeneous preferences and beliefs) in real estate markets).

[803] A recent 2021 proxy season review by the Harvard Law School found that shareholder climate-related proposals have increased for the second consecutive year. The authors also note that, in 2021, environmental proposals were withdrawn at a meaningfully higher rate relative to the prior year. This is an indication of stronger commitments from companies to take actions towards the specified environmental goals, or at the very least provide the related disclosures. Many companies may prefer engaging with a proponent rather than taking the proposal to a vote. *See* 2021 Proxy Season Review: Shareholder Proposals on Environmental Matters, *available at https://corpgov.law.harvard.edu/2021/08/11/2021-proxy-season-review-shareholder-proposals-on-environmental-matters/.*

[804] *See* S.M. Hartzmark and A.B. Sussman, *Do Investors Value Sustainability? A Natural Experiment Examining Ranking and Fund Flows,* 74 (6) The Journal of Finance 2789–2837 (2019). Data from fund tracker Morningstar Inc. compiled by Goldman Sachs Group Inc. shows that, since the start of 2019, a net $473 billion has flowed into stock mutual and exchange-traded funds with environmental goals as part of their mandates, compared to a net $103 billion going into all other stock funds. *See* Scott Patterson and Amrith Ramkumar, *Green Finance Goes Mainstream, Lining Up Trillions Behind Global Energy Transition,* Wall Street Journal (May 22, 2021), *available at https://www.wsj.com/articles/green-finance-goes-mainstream-lining-up-trillions-behind-global-energy-transition-11621656039?mod=article_inline.*

[805] *See* Section IV.B.2.b.

[806] *See* IOSCO, *Report on Sustainability-Related Registrant Disclosures* (2021), *available at https://www.iosco.org/library/pubdocs/pdf/IOSCOPD678.pdf.*

[807] *See* GAO, Climate-Related Risks (2018) *available at https://www.gao.gov/assets/gao-18-188.pdf* (reporting that ''investors may find it difficult to navigate through the filings to identify, compare, and analyze the climate-related disclosures across filings'').

Below we describe some key market failures with regard to disclosure, for example (1) disclosures are not costless; (2), there are agency problems; [808] (3) managers may inaccurately present information; and (4) investor responses may be unpredictable and non-unfirm.[809] In addition, there may be other problems, *e.g.* a lack of consistency, that may indicate Commission action.

(1) Disclosures Are Not Costless

In practice, firms can still approach full disclosure voluntarily if there are costs to disclosure, as long as these costs are relatively low.[810] This is not the case, however, if individual firms' private benefits of disclosure are also small, yet those same disclosures provide positive informational externalities. For example, disclosures by one registrant may provide investors with useful information via inference with respect to peer firms. Consistent with this theory, research in the accounting literature has documented that earnings announcements by one firm can provide predictive signals about the earnings of other firms in the same industry.[811] In these cases, disclosures can benefit investors in the aggregate (though not necessarily investors of a specific firm) by allowing them to make comparisons across firms, which can aid in their capital allocation decisions.

This illustrates how, theoretically, in the absence of mandated disclosure requirements, registrants fully internalize the costs of disclosure but not the benefits, which may lead them to rationally under-disclose relative to what is optimal from the investors' perspective.[812] As a result, a tension can exist between investors (in the aggregate) and managers, where investors prefer more disclosure and managers prefer less. In such instances, there may be scope for regulation to substantially increase information provision since absent regulation, investors are not able to fully ascertain the risks and opportunities that firms face.

(2) Agency Problems

In order for voluntary disclosure to result in the complete revelation of all relevant private information, there would need to be no agency problems (*i.e.,* no conflicts of interest between managers and shareholders) such that managers' sole objective with respect to such disclosures would be to maximize shareholder information and, ultimately, shareholder value. However, if managers have other objectives and incentives for making voluntary disclosures (*i.e.,* there exist agency problems), then the voluntary disclosures may not result in the same complete information.[813] Moreover, when agency problems exist, investors can no longer be sure if the absence of disclosure under a voluntary regime reflects good or bad news for the firm, given that some managers may have self-serving incentives. For example, managers may have career concerns which could incentivize them to withhold disclosing information they expect to be favorably received until it is useful to balance out bad news. In contrast, when the disclosure requirements are mandatory, the relevant, complete information should be disclosed regardless of managers' objectives or incentives, and investors would accordingly have more confidence in the completeness of the resulting disclosures. For these reasons, the benefits of a mandatory reporting regime may be more pronounced in settings in which disclosure-related conflicts of interests exist between managers and shareholders.

(3) Misrepresentation by Managers

If investors are unable to verify that managerial disclosures are complete and truthful (*e.g.,* if investors have difficulty in determining the extent of managers' selective disclosure of metrics or methods of computation, exaggeration, obfuscation, outright misreporting, etc.), then voluntary disclosures may not be fully revealing. For example, managers may be able to engage in misleading reporting (*i.e.,* they can apply a favorable bias to their disclosures), but they incur a cost that increases with the magnitude of the misreporting.[814] Under these circumstances, theoretical research suggests that, in equilibrium, they may not accurately report their private information. This is because investors would not be able to distinguish truthful disclosures from those that are misleading (*i.e.,* favorably biased). In this setting, all managers would then have an incentive to misreport by providing disclosures with a favorable bias, the extent of which depends on the cost of misreporting. Furthermore, because misreporting comes at a cost, this would violate the assumption of costless disclosure, which can exacerbate the issue of incomplete disclosures.[815]

If, on the other hand, misreporting has no costs for managers, then this results in what is referred to as a cheap talk equilibrium.[816] In this setting, any misalignment of incentives between managers and investors could again result in a situation in which not all relevant private information is fully revealed. While this could be driven by agency problems stemming from managerial self-interest, it also occurs when investors have heterogeneous preferences that cause differing incentives or if managers are concerned with strategic disclosures that may be viewed by not only investors, but also competitors, regulators, and customers.

In this case, a mandatory reporting regime would be beneficial to investors to the extent that voluntary disclosures are unverifiable and possibly misleading. These include situations where managers obfuscate certain information in their disclosures, convey information in a complex or difficult manner, or conceal the discretionary choices with respect to what was reported.

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[808] Agency problems are those conflicts of interest between shareholders (*i.e.,* the principals) and managers (*i.e.,* the agents) of a firm.

[809] *See* Beyer, Cohen, Lys, and Walther, *The Financial Reporting Environment: Review of The recent Literature,* J. Acct. Econ. 296–343 (2010) for a more technical and detailed discussion of these and other additional assumptions.

[810] *See* for example R.E. Verrecchia, *Discretionary Disclosure,* 5 Journal of Accounting and Economics 365–380 (1983).

[811] *See* Robert Freeman and Senyo Tse, *An Earnings Prediction Approach to Examining Intercompany Information Transfers,* 15(4) J. Acct. Econ. 509–523 (1992).

[812] It is worth noting that in some cases, undertaking costly signals can allow agents to credibly signal their type to investors. In these cases, costly disclosures can lead to a separating equilibrium where it may otherwise not exist. *See* D. Kreps and J. Sobel, 2(1) *Signaling,* Handbook of Game Theory with Economic Applications, 849–867 (1994); J. Riley, *Silver Signals: Twenty-Five Years of Screening and Signaling,* 39(1) Journal of Economic Literature 432–478, (2001).

[813] *See* E. Einhorn. *Voluntary Disclosure Under Uncertainty About the Reporting Objective,* 43 Journal of Accounting and Economics 245–274 (2007).

[814] *See* E. Einhorn, and A. Ziv, *Biased Voluntary Disclosure,* Review of Accounting Studies 420–442 (2012) (Biases in reporting can be any number of costs in these models. These include not only inefficient actual investments associated with the cost of distorted reporting, but also the risk of litigation, reputation erosion, and/or future flexibility in reporting.).

[815] If misrepresentation becomes sufficiently costly, then there may be no managers who find it advantageous to misrepresent, despite any potential benefits. In this case, purposeful misrepresentation would not occur, thereby fulfilling one of the assumptions of the standard full revelation argument. Clear guidelines for disclosure and imposed costs upon the discovery of misrepresentation are important mechanisms for enforcing and promoting the transmission of information to investors.

[816] *See* V. Crawford, J. Sobel, *Strategic Information Transformation,* 50 Econometrica 1431–1451 (1982).

(4) Uncertain Investor Responses

Another condition necessary for voluntary reporting to be fully revealing is that managers must be certain of investor responses to disclosures. However, if investors have heterogeneous prior beliefs, such that managers cannot determine whether investors will consider a given disclosure good or bad news, then not all managers will choose to disclose, resulting in certain private information remaining undisclosed.[817] Similarly, if there are varying levels of sophistication among investors in their ability to understand disclosures, then again, some managers may be uncertain about how reports may be interpreted, leading them to abstain from some disclosures.[818] In this respect, mandatory disclosure is more likely to benefit investors in settings where the types of disclosures are complex or divisive, such that managers may not be certain how they will be perceived by investors with differing prior beliefs and/or sophistication.

b. Climate-Specific Factors That Exacerbate Impediments to Voluntary Disclosure

In the context of climate-related disclosure, these impediments may be made worse due to agency problems arising from the potentially long-term nature of certain climate-related risks and other issues related to the complexity and uncertainty of climate-related factors. We explore each of these impediments in further detail.

Impediments to climate-related disclosures may be exacerbated due to agency problems related to potential conflicts between short-term profitability and long-term climate risk horizons. Physical and transition risks can materialize over time horizons ranging from the immediate future to several decades.[819] Likewise, shareholders may have interests in maximizing their investment returns over both the short- and long-term. Agency problems can worsen to the extent that the investment horizons of a firm's shareholders and its management are misaligned.[820] If management prioritizes short-term results[821] due to pressures to perform along certain metrics,[822] management may fail to assess and provide relevant disclosures on certain climate-related risks,[823] particularly those that are medium- or long-term in nature.[824] Stock-based management compensation has the potential to mitigate this issue, provided that the stock price reflects the value of the company in the long-run. However, under the current regime, certain climate-related risks may be unobservable or obfuscated, and hence not fully reflected into stock prices, giving short-term-focused managers an incentive to initiate or continue projects exposed to these risks to maximize their compensation at the expense of long-term shareholder value.

Impediments to voluntary climate-related disclosures can also be exacerbated due to the uncertainty and complexity of climate-related risks and the multidimensional nature of the information being disclosed. First, this uncertainty and complexity may lead to misrepresentation of disclosures, which, as discussed previously, violates a condition for the full revelation of material information in a voluntary reporting environment. The complexity of these risks has led to many types of methodologies, metrics, and statements that can be provided to communicate potential economic impacts and risks.[825] This multitude of choices to represent such risks may therefore allow managers substantial discretion to selectively choose metrics that appear favorable. If this managerial discretion is more difficult to be verified by investors, managers may face lower costs for their misreporting. Moreover, the complex and multidimensional nature of certain climate-related risks may further impede investors' abilities to detect misreporting. This could lead to a cheap-talk equilibrium, which, as previously discussed, could lead to climate-related information remaining undisclosed.

The uncertainty and complexity of climate-related risks may also be an impediment to voluntary disclosure if managers are less able to anticipate how investors may respond to such disclosures. As noted above, predictable investor responses to disclosures is one of the key assumptions necessary for the full revelation of material information in a voluntary reporting environment.[826] Uncertainty in responses means mandatory disclosures have the potential to improve information provision to investors. The challenge in anticipating investor responses to climate-related disclosure may stem, in part, from the fact that the impact of these risks on registrants' financial outcomes and operations can vary significantly. This challenge may be compounded by the uncertainty surrounding the future path of climate change and the evolving nature of the science and methodologies measuring their economic impacts.[827] The uncertainty and complexity of climate-related risks are likely to cause substantial heterogeneity with respect to investors' interpretation of related disclosures and their understanding of firms' exposures to such risks, resulting in heterogeneous and unpredictable

[817] *See* J. Suijs, *Voluntary Disclosure Of Information When Firms Are Uncertain Of Investor Response,* 43 Journal of Accounting and Economics 391–410 (2007).

[818] *See* R.A. Dye, *Investor Sophistication and Voluntary Disclosures,* 3 Review of Accounting Studies 261–287 (1998).

[819] Longer horizons, for example, tend to involve changes in chronic physical risks—sea-level rise, drought, etc. Shorter-term horizons may, instead, be relevant for any increase in acute physical risks such as hurricanes, wildfires, and heatwaves. *See* ING Climate Risk Report 2020, *available at https://www.ing.com/MediaEditPage/ING-Climate-Risk-report-2020.htm.*

[820] A stream of literature examines the association of climate-related disclosures with corporate governance structures and managerial characteristics. *See, e.g.,* M. Kılıç and C. Kuzey, *The Effect of Corporate Governance on Carbon Emission Disclosures: Evidence from Turkey,* 11–1 International Journal of Climate Change Strategies and Management 35–53 (2019). *See also* S. Yunus, E.T. Evangeline, and S. Abhayawansa, *Determinants of Carbon Management Strategy Adoption: Evidence from Australia's Top 200 Publicly Listed Firms,* 31–2 Managerial Auditing Journal 156–179 (2016).

[821] Henry M. Paulson Jr., *Short-Termism and the Threat From Climate Change,* Perspectives on the Long Term: Building a Stronger Foundation for Tomorrow (Apr. 2015), *available at https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/short-termism-and-the-threat-from-climate-change.*

[822] Factors including corporate executive compensation and attention to quarterly earnings and reporting are thought to contribute to excessive focus on short-term goals. *See, e.g., Short-Termism Revisited, available at https://corpgov.law.harvard.edu/2020/10/11/short-termism-revisited/.*

[823] *See How to Take the Long-Term View in a Short-Term World,* Moral Money (Financial Times), (Feb. 25, 2021), *available at https://www.ft.com/content/5bc1580d-911e-4fe3-b5b5-d8040f060fe1.*

[824] *See* Richard Mahony and Diane Gargiulo, *The State of Climate Risk Disclosure: A Survey of U.S. Companies* (2019) (A recent survey conducted on the members of the Society for Corporate Governance (SCG) about the state of U.S. climate risk disclosures revealed that tying executive compensation to progress on climate goals is beginning to emerge among some companies, but it is far from a common practice. Only 6% of respondents said their board linked compensation to climate objectives.), *available at https://www.dfinsolutions.com/sites/default/files/documents/2019-10/TCFD_II_Climate_Disclosure_V10_revisedFINAL.pdf.*

[825] *See, e.g.,* TCFD, *Recommendations of the Task Force on Climate-Related Financial Disclosures,* at 16 (June 2017), *available at https://www.fsb-tcfd.org/wp-content/uploads/2017/06/FINAL-2017-TCFD-Report-11052018.pdf.*

[826] In other words, this assumes that all investors uniformly interpret (and react to) managers' disclosures or their absence and that investors' interpretation and reaction is known to managers. *See, e.g.,* A. Beyer, D.A. Cohen, T.Z. Lys, and B.R. Walther, *The Financial Reporting Environment: Review of the Recent Literature,* 50 (2) Journal of Accounting and Economics 296–343 (2010).

[827] *See, e.g.,* TCFD, *Recommendations of the Task Force on Climate-Related Financial Disclosures,* at 16 (June 2017), *available at https://www.fsb-tcfd.org/wp-content/uploads/2017/06/FINAL-2017-TCFD-Report-11052018.pdf.*

investor responses. In this circumstance, managers may prefer to withhold applicable disclosures.[828]

Due to these impediments, companies may not report (or may report only limited amounts of) relevant climate-related information, and hence, the stock price that investors observe may not reflect the companies' true exposures to physical and transition risks.[829] Even when companies assess and disclose climate-related risks, reporting fragmentation can present substantial obstacles to investors in processing this information.[830] This is because disclosures currently vary considerably in terms of coverage, location, and presentation across companies, making it difficult for investors to navigate through different information sources and filings to identify, compare, and analyze climate-related information.[831] Moreover, these disclosures are often vague and boilerplate, creating further challenges for investors.[832] While it may seem that more information is always better, when the incentives of investors and managers diverge, evidence suggests such amorphous statements could reduce the quality of communication both in theory [833] and in practice.[834]

The current regulatory regime leaves substantial uncertainty around the type of climate-related information that should be disclosed and how it should be presented. Multiple third-party climate reporting frameworks have emerged to try to fill this reporting gap.[835] Due to the voluntary nature of third-party frameworks, however, companies often disclose some but not all components, and the components that are disclosed may not be the same across companies.[836] The location, format, and granularity of the information provided may also vary, although the substance may be similar. This has resulted in considerable heterogeneity in firms' existing disclosure practices.[837] The wide range of reporting practices and frameworks makes it difficult to assess how much material climate-related information firms currently are disclosing and may leave opportunities for companies to omit unfavorable information.[838] Some studies point to the potential for substantial underreporting of material climate-related information within the current voluntary reporting regime.[839]

The proposed rules aim to address these market failures by requiring more specificity around the way registrants disclose climate-related risks and their impacts on business activities and operations in the short, medium, and long-term. By requiring comprehensive and standardized climate-related disclosures along several dimensions, including disclosure on governance, business strategy, risk management, financial statement metrics, GHG emissions, and targets and goals, the proposed rules would provide investors with climate-related information that is more comparable, consistent, and reliable and presented in a centralized location.

C. Benefits and Costs

Below we discuss the anticipated economic effects that may result from the proposed rules. Where possible, we have attempted to quantify these economic effects, including the benefits and costs. In many cases, however, we are unable to reliably quantify these potential benefits and costs. For example, existing empirical evidence does not allow us to reliably estimate how enhancements in climate-related disclosure affect information processing by investors or firm monitoring. Nevertheless, there is a large body of studies examining the effects of corporate disclosure in general, as well as a subset focusing on sustainability-related disclosures (*e.g.* ESG- or CSR-related disclosures).[840] We draw on existing empirical evidence and theoretical arguments from these studies to the extent they are applicable to disclosures on climate-related information specifically.

Similarly, we qualitatively describe the factors that may affect disclosure costs but we are unable to accurately quantify these costs. Costs related to preparing climate-related disclosures are generally private information known only to the issuing firm, hence such data are not readily available to the Commission. There is also likely considerable variation in these costs depending on a given firm's size, industry, complexity of operations, and other characteristics, which makes comprehensive estimates difficult to obtain.

We encourage commenters to provide us with relevant data or empirical evidence related to the costs of preparing climate-related disclosures and, more generally, to provide us with

[828] *See, e.g.,* M.J. Fishman and K.M. Hagerty, *Mandatory versus Voluntary Disclosure in Markets With Informed and Uninformed Customers,* 19 (1) Journal of Law, Economics, & Organization 45–63 (2003); P. Bond and Y. Zeng, *Silence Is Safest: Information Disclosure When the Audience's Preferences Are Uncertain* (forthcoming), Journal, of Financial Economics (2021); D. Butler, and D. Read, *Unravelling Theory: Strategic (Non-) Disclosure of Online Ratings,* 12 Games 73 (2021).

[829] *See* J.A. Bingler, M. Kraus, and M. Leippold, *Cheap Talk and Cherry-Picking: What Climate Bert Has to Say on Corporate Climate Risk Disclosures* (2021) *available at, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3796152.*

[830] Carbon Disclosure Project (''CDP''), *Pitfalls of Climate-Related Disclosures* (2020), *available at* Pitfalls-of-Climate-Related-Disclosure.pdf (*rackcdn.com*).

[831] *See* SASB, *The State Of Disclosure: An Analysis of the Effectiveness of Sustainability Disclosure in SEC Filings,* (2017), *available at https://www.sasb.org/knowledge-hub/state-of-disclosure-2017/.*

[832] The SASB reports that about 50% of SEC registrants provide generic or boilerplate sustainability information in their regulatory filings.

[833] *See* Vincent P. Crawford and Joel Sobel, *Strategic Information Transmission,* Econometrica: Journal of the Econometric Society 1431–1451 (1982).

[834] *See, e.g.,* Robert Forsythe, Russell Lundholm and Thomas Rietz, *Cheap Talk, Fraud, and Adverse Selection In Financial Markets: Some Experimental Evidence,* 12 (3) The Review of Financial Studies 481–518 (July 1999), *available at https://doi.org/10.1093/revfin/12.3.0481.*

[835] The TCFD, the SASB, the GRI, the Principles for Responsible Investment, the PCAF, and the CDP (among others), have all developed standards and systems that aim to help firms and investors identify, measure, and communicate climate-related information and incorporate that information into their business practices. Multiple frameworks have emerged, in part, because each seeks to provide different information or fulfill different functions when it comes to disclosing information related to climate-related risks or other ESG factors that may be important to investors.

[836] *See* Climate Risk Disclosures & Practices, *available at https://climatedisclosurelab.duke.edu/wp-content/uploads/2020/10/Climate-Risk-Disclosures-and-Practices.pdf.*

[837] *See* Section IV.A.5. A recent survey of members of the Society for Corporate Governance (SCG) regarding the state of U.S. climate risk disclosures revealed that companies are using many of the existing frameworks to present emissions, environmental data, and other information on ESG issues. Many of the respondents indicated that their companies are now reporting using CDP, GRI, SASB and other standards, with corporate registrants expressing a desire for greater clarity regarding how to make adequate climate disclosures. The survey results indicate that many companies are grappling with how best to provide useful information to investors regarding complex and interrelated risks. *See* Richard Mahony and Diane Gargiulo, *The State of Climate Risk Disclosure: A Survey of U.S. Companies* (2019), *available at https://www.dfinsolutions.com/sites/default/files/documents/2019-10/TCFD_II_Climate_Disclosure_V10_revisedFINAL.pdf.*

[838] *See* Lee Reiners and Charlie Wowk, *Climate-Risk-Disclosures-and-Practices* (2021), *available at https://climatedisclosurelab.duke.edu/wp-content/uploads/2020/10/Climate-Risk-Disclosures-and-Practices.pdf.*

[839] A past study using ESG disclosure data in Bloomberg on US-listed firms, found that, on average, from 2007 to 2015, firms provided only about 18% (median: 13%) of the prescribed SASB disclosure items (which serve as benchmark for financially material disclosures). *See* J. Grewal, C. Hauptmann and G. Serafeim, *Material Sustainability Information and Stock Price Informativeness,* Journal of Business Ethics (Forthcoming) (2020), *available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2966144.*

[840] *See* H.B. Christensen, L. Hail, and C. Leuz, *Mandatory CSR and Sustainability Reporting: Economic Analysis and Literature Review,* Review of Accounting Studies 1–73 (2021).

any type of data that would allow us to quantitatively assess the costs and benefits of the proposed rules.

1. Benefits

The primary benefit of the proposed rules is that investors would have access to more comparable, consistent, and reliable disclosures with respect to registrants' climate-related risks. As discussed in the previous sections, investors currently face obstacles in accessing comparable, consistent, and reliable climate-related information due to a combination of registrants not disclosing this information at all, or registrants disclosing this information but with varying degrees of coverage and specificity and in varying formats and locations, including company websites, standalone reports, and SEC filings.

Investors are expected to benefit from the required disclosures given that material climate-related information would be provided to the market more consistently across registrants of different sizes and filer status, whether domestic or foreign issuers, and regardless of industry. Investors are also expected to benefit from the more consistent content of the disclosures. Specifically, the proposed rules would enhance comparability by requiring registrants to provide disclosures on a common set of qualitative and quantitative climate-related disclosure topics in their filings.

In addition to the standardized content, investors are expected to benefit from a common location of the disclosures in regulatory filings. The proposed rules would require registrants to place all relevant climate-related disclosures in Securities Act or Exchange Act registration statements and Exchange Act annual reports in a separately captioned ''Climate-Related Disclosure'' section, or alternatively, to incorporate by reference from another section, such as Risk Factors, Description of Business, or MD&A. By mandating that standardized climate-related information be disclosed, and requiring it to be placed in a centralized location within regulatory filings, the proposed rules could reduce investors' search costs and improve their information-processing efficiency. These factors can also lead to positive information externalities—as more firms disclose how measures of climate risk affect their business operations, investors would gain a better understanding of how those same climate risks may affect other similar firms.[841]

Furthermore, by requiring this information to be *filed* with the Commission as opposed to posted on company websites or *furnished* as exhibits to regulatory filings, the proposed rules are expected to improve the reliability of information provided to investors moving forward.[842] Several commenters indicated that the treatment of climate-related disclosures as filed would help improve investor confidence in the accuracy and completeness of such disclosures.[843] Recent academic work provides evidence of firms' engagement in obfuscation and other misleading efforts (so-called ''greenwashing'') [844] to manipulate the set of information available on corporate websites and sustainability reports with the goal of attaining higher ESG ratings, which are relied upon, in particular, by unsophisticated investors for the value of institutional certification.[845] Direct disclosures may also reduce reliance on these ESG ratings, which are not necessarily standardized nor fully transparent with respect to their methodologies. In fact, several studies found low correlations of classifications across ESG providers.[846] Additionally, a study suggested that models and metrics used by ESG providers for appropriately classifying funds are not always transparent and consistent across ESG providers.[847]

As discussed in Section IV.B.1, surveys of institutional investors indicate that climate risk is one of the most prominent issues driving their investment decisions and engagements with companies. Evidence from the stock market response appears consistent with this, with increased mandatory ESG disclosure being associated with aggregate stock price movement.[848] Such stock price effects tend to display cross-sectional heterogeneity with, for example, firms disclosing large GHG emissions experiencing price declines.[849] Similar effects have also been observed in derivatives markets.[850] Investor responses in real estate markets potentially affected by physical risks,[851] as well as revealed preferences from flows into mutual funds with environmental goals in their investment mandates,[852] provide further evidence of investors' interest in disclosures pertaining climate risks. Taken together, the mandatory and standardized nature of the proposed climate-related disclosures could benefit investors by improving their ability to assess these risks and their impact on registrants' financial condition and operations, thereby allowing investors to make better-informed investment decisions and enhancing investor protection.

[841] One study documents how investors can use information from one firm to make inferences of other similar firms in the context of earnings announcements. *See* supra note 812.

[842] By proposing to treat the proposed required climate-related disclosures as ''filed,'' we are therefore subjecting them to potential liability under Exchange Act Section 18, except for disclosures made on Form 6–K. The proposed filed climate-related disclosures would also be subject to potential Section 11 liability if included in or incorporated by reference into a Securities Act registration statement. *See* Section II.C.4 (discussions within).

[843] *See* Section II.H.k.

[844] A review of several academic papers reveal that there is no universally accepted definition of ''greenwashing.'' Though the term ''greenwashing'' is often used in industry discussions regarding ESG, the Commission does not define ''greenwashing'' in this proposal, rules, or form amendments. Greenwashing is typically described as the set of activities conducted by firms or funds to falsely convey to investors that their investment products or practices are aligned with environmental or other ESG principles.

[845] *See* Ruoke Yang, *What Do We Learn From Ratings About Corporate Social Responsibility?,* R&R Journal of Financial Intermediation (2021), *available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3165783.*

[846] Florian Berg, Julian Kölbel, Roberto Rigobon, *Aggregate Confusion: The Divergence of ESG Ratings,* MIT Sloan School (Working Paper 5822–19) (May 17, 2020), *available at https://ssrn.com/abstract=3438533* or *http://dx.doi.org/10.2139/ssrn.3438533.* Authors found that the correlations between six different ESG ratings are on average 0.54, and range from 0.38 to 0.71, while the correlations between credit ratings were 0.99. *See also* OECD, *OECD Business and Finance Outlook 2020,* Sustainable and Resilient Finance (Sept. 29, 2020), *available at https://www.oecd.org/daf/oecd-business-and-finance-outlook-26172577.htm.* OECD analyzed different rating providers, such as Bloomberg, MSCI and Refinitiv and found wide differences in the ESG ratings assigned, with an average correlation of 0.4. When OECD analysis then compared ESG ratings with the issuer credit rating by major providers, it found that credit scores for selected issuers vary much less. *See also* International Monetary Fund, Global Financial Stability Report (Oct. 2019), *available at https://www.imf.org/en/Publications/GFSR/Issues/2019/10/01/global-financial-stability-report-october-2019.* It found that only 37% of Lipper ethical funds also carry a sustainable designation by Bloomberg.

[847] *See* OECD Business and Finance Outlook 2020, *Sustainable and Resilient Finance* (Sept. 29, 2020); H. Friedman, M. Heinle, and I. Luneva, *A Theoretical Framework for Environmental and Social Impact Reporting* (Working Paper) (2021).

[848] *See* J. Grewal, E.J. Riedl, and G. Serafeim, *Market Reaction to Mandatory Nonfinancial Disclosure,* 65 (7) Management Science 3061–3084 (2019).

[849] *See* V. Jouvenot and P. Kruger, *Mandatory Corporate Carbon Disclosure: Evidence from a Natural Experiment* (Working Paper) (2021); P. Bolton and M. Kacperzcyk, *Signaling through Carbon Disclosure* (Working Paper) (2020).

[850] E. Ilhan, Z. Sautner, G. Vilkov, *Carbon Tail Risk,* 34 (3) Review of Financial Studies 1540–1571 (2021).

[851] *See supra* note 802.

[852] *See supra* note 804.

Improving and standardizing climate disclosures also could mitigate adverse selection problems that may arise in the presence of asymmetric information [853] by making more accurate and standardized information available to the general public.[854] Improved disclosure could make it easier for investors to process information more effectively and improve the estimation of firm's future cash flows, leading to more accurate firm valuation.[855] In particular, the enhanced disclosures may yield further benefits for the disclosures of financial firms. Because financial firms can have significant exposures to climate-related risks through their portfolio companies, any enhancements in the portfolio companies' disclosures can subsequently be leveraged by these financial firms in assessing the risks to their portfolios and to the firm as a whole.[856]

Another benefit of the proposed rules is that it could allow firm's shareholders to better monitor management's decisions and mitigate certain agency problems stemming from management's discretionary choices with respect to climate disclosure. Agency problems could occur when management act opportunistically in their own self-interest at the expense of shareholders by disclosing only certain climate-related information at their discretion. As previously discussed in Section IV.B.2.b, management may be motivated to selectively disclose only climate-related information,[857] while omitting harder to verify risks.[858] In the context of climate-related risks, agency issues may be exacerbated by the potential conflicts between short-term profitability and long-term climate risk horizons [859] and the misalignment of interests and incentives between long-term shareholders and management,[860] whereby the latter may unduly focus on short-term results [861] given pressures to demonstrate performance.[862] Under the current regime, many climate-related risks may be unobservable or obfuscated, giving short-term-focused managers an incentive to initiate projects exposed to these risks without properly informing investors.

Agency problems might be exacerbated by registrants' use of boilerplate language or selective disclosure (*i.e.,* ''cherry picking''),[863] which might reduce transparency and impair investors' ability to effectively monitor firm management. The lack of a standardized disclosure framework could make it easier for registrants to forego the use of certain metrics or scopes and omit information that might otherwise indicate shortcomings.[864] Previous studies have found that more detailed reporting can mitigate agency problems as it facilitates the scrutiny and discipline of firm management, allowing investors to monitor firms' operations more closely and thus evaluate whether managers have acted in the best interests of shareholders.[865] By requiring registrants to provide comprehensive and detailed climate-related information to investors, the proposed rules are expected to reduce the likelihood of unreliable or boilerplate disclosures. This can enable investors to better monitor firm's management, reducing agency problems and ultimately strengthening investor protection. In the following sections, we discuss how specific aspects of the proposed rules could contribute to the aforementioned benefits.

The proposed rules would mandate more detailed and comprehensive disclosure with respect to climate-related risks. More consistent, comparable, and reliable disclosures could lead to capital market benefits in the form of improved liquidity, lower costs of capital, and higher asset prices

[853] Asymmetric information occurs when one party to an economic transaction possesses greater material knowledge than the other party. Adverse selection occurs when the more knowledgeable party only chooses to transact in settings that, based on their private information, is advantageous for them. Less informed parties aware of their informational disadvantage might be less inclined to transact at all for fear of being taken advantage of. *See* George Akerlof, *The Market for 'Lemons, Quality Uncertainty and the Market Mechanism,* 84 (3) Quarterly Journal of Economics 488–500 (1970).

[854] *See* R.E. Verrecchia, Essays on Disclosure, 32 *Journal of Accounting and Economics* 1–3, 97–180 (2001).

[855] *See* R. Lambert, C. Leuz, and R.E. Verrecchia, *Accounting Information, Disclosure, and the Cost of Capital,* 45 (2) Journal of Accounting Research 385–420 (2007).

[856] In 2021, the CDP coordinated with 168 financial institutions, with a combined AUM of $17 trillion USD, to engage over 1,300 companies to request climate-related information, among other topics. *See* CDP Non-Disclosure Campaign: 2021 Results, *available at https://cdn.cdp.net/cdp-production/cms/reports/documents/000/006/069/original/CDP_2021_Non-Disclosure_Campaign_Report_10_01_22_%281%29.pdf?1642510694.*

[857] *See supra* note 830 (A recent study, for example, shows that absent mandatory requirements from regulators, voluntary disclosures following third-party frameworks are generally of poor quality and that firms making these disclosures cherry-pick to report primarily non-material climate risk information.).

[858] *See* World Economic Forum, *How to Set Up Effective Climate Governance on Corporate Boards: Guiding Principles and Questions* (2019), *available at https://www3.weforum.org/docs/WEF_Creating_effective_climate_governance_on_corporate_boards.pdf.* In addition, there are a number of academic studies examining the association of climate-related disclosures with corporate governance structures and managerial characteristics. *See, e.g.,* M. Kılıç and C. Kuzey, *The Effect of Corporate Governance on Carbon Emission Disclosures: Evidence from Turkey,* 11–1 International Journal of Climate Change Strategies and Management 35–53 (2019); S. Yunus, E.T. Evangeline, and S. Abhayawansa, *Determinants of Carbon Management Strategy Adoption: Evidence from Australia's Top 200 Publicly Listed Firms,* 31–2 Managerial Auditing Journal 156–179 (2016); Caroline Flammer, Michael W. Toffel, and Kala Viswanathan, *Shareholder Activism and Firms' Voluntary Disclosure of Climate Change Risks,* 42–10 Strategic Management Journal 1850–1879 (Oct. 2021).

[859] Physical and transition climate risks can materialize over time horizons ranging from the immediate future to several decades. Long horizons, for example, tend to involve changes in chronic physical risks—(sea-level rise, drought, etc.). Shorter-term horizons may, instead, be relevant for increase in acute physical risks such as hurricanes, wildfires, and heatwaves. *See* ING Climate Risk Report 2020, *available at https://www.ing.com/2021-Climate-Report.htm.*

[860] A report by the Environmental Audit Committee of the UK House of Commons on Greening Finance, issued in June 2018, found that short-termism is a pervasive problem in corporate decision making and leaves business ill-equipped to consider and incorporate long term risks, such as climate change and sustainability. *See* Envtl. Audi Comm., House of Commons, U.K. Parliament, *Greening Finance: Embedding Sustainability in Financial Decision Making* (June 6, 2018), *available at https://publications.parliament.uk/pa/cm201719/cmselect/cmenvaud/1063/106302.htm.*

[861] *See* Henry M. Paulson Jr., *Short-Termism and the Threat From Climate Change, Perspectives on the Long Term: Building a Stronger Foundation for Tomorrow* (Apr. 2015), *available at https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/short-termism-and-the-threat-from-climate-change.*

[862] Factors including corporate executive compensation and attention to quarterly earnings and reporting are thought to contribute to excessive focus on short-term goals. *See, e.g., https://corpgov.law.harvard.edu/2020/10/11/short-termism-revisited.*

[863] *See supra* note 806; see also Morningstar, *Corporate Sustainability Disclosures* (2021), *available at https://www.morningstar.com/en-uk/lp/corporate-sustainability-disclosures.* (''Companies will disclose the good and hide the bad while disclosure remains voluntary.'').

[864] *See* JE Fisch, *Making Sustainability Disclosure Sustainable,* 107 Georgetown Law Journal 923–966 (2019). *See* Climate Risk Disclosures & Practices: Highlighting the Need for a Standardized Regulatory Disclosure Framework to Weather the Impacts of Climate Change on Financial Markets, (2020), *available at https://climatedisclosurelab.duke.edu/wp-content/uploads/2020/10/Climate-Risk-Disclosures-and-Practices.pdf.*

[865] *See* C. Kanodia and D. Lee, *Investment and Disclosures: The Disciplinary Role of Performance Reports,* 36(1) Journal of Accounting Research 33–55 (1998); P. Healy, and K. Palepu, *Information Asymmetry, Corporate Disclosure, and the Capital Markets: A Review of the Empirical Disclosure Literature,* 31 (1–3) Journal of Accounting and Economics 405–440 (2001); Huang Pinghsun and Yan Zhang, *Does Enhanced Disclosure Really Reduce Agency Costs? Evidence from the Diversion of Corporate Resources,* 87(1) The Accounting Review, 199–229 (2012); R.M. Bushman and A.J. Smith, *Financial Accounting Information and Corporate Governance,* 32 (1–3) Journal of Accounting and Economics 237–333 (2001); R. Lambert, C. Leuz, and R.E. Verrecchia, *Accounting Information, Disclosure, and the Cost of Capital,* 45 (2) Journal of Accounting Research 385–420 (2007).

(or firm valuations).[866] These benefits would stem from reductions in information asymmetries brought about by the required disclosure of climate-related information, both among investors and between firms and their investors. In the first case, less information asymmetry among investors could mitigate adverse selection problems by reducing the informational advantage of informed traders. This is likely to improve stock liquidity which, in turn, can attract more investors, thereby reducing the cost of capital. In the second case, less information asymmetry between firms and their investors could allow investors to better estimate future cash flows, which could reduce investors' uncertainty, as well as the risk premium they demand, thus lowering the costs of capital for registrants. Economic theory illustrates how, all else equal, a drop in the cost of capital leads to a boost in equity valuation, which can further benefit investors.

a. Disclosure Regarding Climate-Related Risks and Their Impacts on Strategy, Business Model, and Outlook

The proposed rules would require registrants to identify their climate-related risks that are reasonably likely to have a material impact on the registrant's business or consolidated financial statements over the short, medium, and long-term and describe the actual and potential impacts of those risks on its strategy, business model, and outlook. Registrants would specifically be required to disclose impacts on, or any resulting significant changes made to, their: (i) Business operations, including the types and locations of its operations; (ii) products or services; (iii) supply chain or value chain; (iv) activities to mitigate or adapt to climate-related risks; and (v) expenditures for research and development.

If, as part of its net emissions reduction strategy, a registrant uses carbon offsets or RECs, the proposed rules would require it to disclose specific information around the role that carbon offsets or RECs play in the registrant's climate-related business strategy. If a registrant uses an internal carbon price, the proposed rules would require it to disclose information around the boundaries for measurement of overall CO_2e, the price per metric ton of CO_2e, as well as how the total price is estimated to change over time, if applicable. Similarly, to the extent that the registrant uses analytical tools such as scenario analysis, the proposed rules would require a description of those analytical tools, including the assumptions and methods used.

The specific disclosures required by the proposed rules are expected to improve investors' understanding of what the registrant considers to be the relevant short-, medium-, and long-term climate-related risks that are reasonably likely to have a material impact on its business, taking into consideration the useful life of the organization's assets or infrastructure and the fact that climate-related risks may manifest themselves over the medium and longer terms. Compared to the baseline, investors would be better able to identify and assess how climate-related risks may affect a registrant's businesses, strategy, and financial planning in several areas, including products and services, supply chain and/or value chain, adaptation and mitigation activities, investment in research and development, operations (including types of operations and location of facilities), acquisitions or divestments, and access to capital. Investors would gain insight into how climate-related risks may serve as an input to the registrant's financial planning process and the time period(s) used for this process.

For example, investors may gain better insights into the registrant's estimated costs of any operational changes expected to be implemented to achieve emission reduction targets. Alternatively, investors may gain valuable information on how certain climate events may impact the registrant's property, workforce, or its production schedule across the different physical sites where the registrant conducts business. Adverse climate-related events may impact the useful lives and/or valuation reserves of balance sheet assets. For example, sea level increases and other climate related patterns may adversely impact the estimated useful lives of coastal facilities. Similarly, more extreme weather patterns may adversely impact agricultural regions and the value of related equipment and lands. This information is expected to be useful for investors in assessing how climate-related risks are managed, and whether and how these risks may affect a registrant's financial condition and results of operations. The required disclosure around the role that carbon offsets or RECs play in the registrant's climate-related business strategy could help investors better understand that strategy, including how resilient it is to changes in costs or the availability or value of offsets or RECs over the short, medium and long-term. The required disclosures around internal carbon price, when used by a registrant, could provide investors with more standardized and detailed information regarding how the registrant developed a particular business strategy and help investors assess whether a registrant's internal carbon pricing practice is reasonable and whether its overall evaluation and planning regarding climate-related factors is sound. The required disclosure around the assumptions and methods used by a registrant when employing analytical tools or conducting scenario analysis can improve investors' assessment of the resiliency of a registrant's strategy and business model in light of foreseeable climate-related risks and improve investors' ability to compare said resiliency among registrants.

The proposed requirement to identify material climate-related risks over the short-, medium-, and long-term could also help mitigate agency problems deriving from the potential misalignment of planning horizons between the firm's shareholders and its managers. The information required to be disclosed about the firm's business operations, products or services, supply or value chain, activities to mitigate or adapt to climate-related risks, and expenditure for research and development could allow investors to assess how climate-related issues may impact the registrant's financial performance (*e.g.,* revenues, costs) and financial condition (*e.g.,* assets, liabilities). These disclosures should allow investors to gain valuable insights on how resources are being used by management to mitigate climate-related risks and to facilitate investors' evaluation of whether managers are taking appropriate steps to address such risks.

b. Governance Disclosure

The proposed rules would require a registrant to disclose information concerning the board's oversight of climate-related risks as well as management's role in assessing and managing those risks. The proposed rules would require a registrant to disclose whether any member of its board of directors has expertise in climate-related matters and the processes and frequency by which the board discusses climate-related factors. When describing management's role in assessing and managing climate-related factors, a registrant would be required to disclose whether certain management positions are responsible for assessing and managing climate-related factors and the processes by which the responsible managers are informed

[866] *See* Section IV.D for more information on capital market benefits.

about and manage climate-related factors.

The disclosures required by the proposed rules should enable investors to better understand how the firm is informed about climate-related factors and how frequently the firm considers such factors as part of its business strategy, risk management, and financial oversight. Investors would be expected to gain better information around whether the organization has assigned climate-related responsibilities to management-level positions or committees and, if so, whether those responsibilities include assessing and/or managing climate-related risks. As a result, investors may be better able to understand and evaluate the processes by which management is informed about and monitors climate-related risks. For example, investors may be better positioned to assess whether and how the firm's board and management consider climate-related risks when reviewing and guiding business strategy and major plans of action, when setting and monitoring implementation of risk management policies and performance objectives, and when reviewing and approving annual budgets.

With detailed information about climate expertise among the registrant's directors, investors could more effectively evaluate the firm's governance practices related to the identification and management of climate-related risks. In particular, investors may be able to exercise closer oversight of management's actions as they assess implementation of risk management policies and performance objectives, review and approve annual budgets, and oversee major capital expenditures, acquisitions, and divestitures.

c. Risk Management Disclosure

The proposed rules would require registrants to describe their processes for identifying, assessing, and managing climate-related risks. This includes disclosure on how registrants assess materiality, whether they consider likely future regulatory actions, how they prioritize, mitigate, or adapt to climate-related risks, and overall how climate-related factors are integrated into the registrants' risk management systems or processes. Registrants would also be required to provide detailed descriptions on any transition plans,[867] as applicable, including relevant targets and metrics, how physical and transition risks are managed, and actions taken and progress made toward the plan's targets or goals.[868]

The disclosures required by the proposed disclosures could inform investors regarding how proactive and diligent registrants may be with respect to climate-related risks. Investors can use this information to acquire a more detailed understanding of how resilient registrants' risk management systems may be towards climate-related risks, which could contribute to better-informed investment or voting decisions. These disclosures could allow investors to better monitor and assess whether registrants have in place adequate risk management systems and whether they are aligned with investor preferences.

Conversely, investors may be better able to detect whether certain registrants' risk management systems would fail to account for certain types of climate factors such as change in consumer preferences, adjustments of business models, and technological challenges or innovations, which may have implications on companies' operations and financial conditions. These disclosures may also allow investors to assess whether registrants are evaluating these risks over specific time horizons, which may be particularly relevant in cases in which management may be more concerned with short-term performance while neglecting longer term risks. Accordingly, this provision could help address agency problems related to the misalignment of planning horizons.

d. Financial Statement Metrics

The proposed rules would require registrants to disclose certain disaggregated climate-related metrics in its financial statements under the following categories: (i) Financial impact metrics; (ii) financial expenditure metrics; and (iii) financial assumptions. The proposed rules would require a registrant to disclose the impact of climate-related events (severe weather events and other natural conditions and physical risks identified by the registrant) and transition activities (including transition risks identified by the registrant) on its consolidated financial statements, if the disclosure threshold is met. For each type of metric, the provisions would require the registrant to disclose contextual information to enable the reader to understand how it derived the metric, including a description of significant inputs and assumptions used to calculate the specified metrics, thus providing the necessary transparency for facilitating investors' understanding and peer comparisons. To avoid potential confusion and to maintain consistency with the rest of the financial statements, the proposed financial statement metrics would be required to be calculated using financial information that is consistent with the scope of the rest of the registrant's consolidated financial statements included in the filing. The proposed rules would specify the basis of calculation for the climate-related financial statement metrics and clarify how to apply these accounting principles when calculating the climate-related financial statement metrics.

With respect to financial impact metrics, the proposed rules would require a registrant to disclose the impacts arising from climate-related events, including physical risks identified by the registrant and severe weather events and natural conditions, such as flooding, drought, wildfires, extreme temperatures, and sea level rise. In addition to physical risks, registrants also would be required to disclose the financial impact of transition activities (including transition risks identified by the registrant), such as efforts to reduce GHG emissions or otherwise mitigate exposure to transition risks on any relevant line items in the registrant's consolidated financial statements. The proposed rule would require registrants to reflect the impact of the climate-related events or transition activities on each line item of the registrant's consolidated financial statements (*e.g.,* line items of the consolidated income statement, balance sheet, or cash flow statement) unless the aggregate impact of the events and transition activities is less than one percent of the total line item. By exempting such line item reporting when the aggregate impact of the events is less than one percent, the proposed rule would reduce overall costs for firms associated with disclosures for instances where the impact is likely to be quite small, while providing assurance to investors that more significant impacts are reflected in line item reporting.[869]

We expect that the proposed financial statement metrics impact would provide additional transparency into the nature

[867] Transition plans would be defined as a registrant's strategy and implementation plan to reduce climate-related physical and transition risks and increase climate-related opportunities, including by reducing its own emissions. If the registrant has made a public commitment to reduce its GHG emissions by a certain date, it must disclose such date and its plan to achieve its public commitment.

[868] *See* Section IV.C.1.f for a more detailed discussion of the potential benefits of targets and goals disclosure.

[869] The choice of a one percent threshold is consistent with what the Commission currently uses in other contexts for disclosure of certain items within the financial statements and without (*e.g.,* §§ 210.5–03.1(a), 210.12–13, and 229.404(d)).

of a registrant's business and the significance of many of the climate-related risks and impacts on its overall financial condition. Such disclosures are expected to provide investors with valuable insights into potential changes to, among others, revenue or costs from disruptions to business operations or supply chains; impairment charges and changes to the carrying amount of assets due to the assets being exposed to physical risks; revenue or cost due to new emissions pricing or regulations resulting in the loss of a sales contract and; operating, investing, or financing cash flow from changes in upstream costs, such as transportation of raw materials. Separately reporting the financial statement impacts from the specified climate-related events and transition activities could improve comparability of both the registrant's year-to-year disclosure and between the disclosures of different registrants. Because the risks presented by the climate-related events and transition activities may be correlated across different registrants and across time, future climate-related risks could manifest in such a way that a large subset of registrants are affected, making them potentially a non-diversifiable risk. In this case, separate financial impact disclosures could inform investors of their exposure to these risks not just for a single registrant, but across all the registrants in their portfolios. Such disclosures could be beneficial as they would be informative of both individual registrant exposures to climate-related risks, and the level of climate-related risks in the aggregate, thus allowing investors to more effectively evaluate and manage the risk of their entire portfolio. Moreover, to the extent that registrants are not aware of climate-related risks in the aggregate, these disclosures would allow for a greater understanding of the climate-related risks they face, providing them the opportunity *to make more informed investment decisions taking into account such risks.*

With respect to financial expenditure metrics, the proposed rules would require a registrant to disclose the positive and negative impacts associated with the same climate-related events and transition activities as the proposed financial impact metrics. The expenditure metrics would require a registrant to separately aggregate amounts of expenditure expensed and capitalized costs incurred during the fiscal years presented. For each of those categories, a registrant would be required to disclose separately the amount incurred during the fiscal years presented toward positive and negative impacts associated with the specified climate-related events and to mitigate exposure to transition risks. The expenditure metrics would also be subject to the same disclosure threshold as the financial impact metrics, which should promote consistency and clarity.

Together, these disclosures are expected to provide investors with information about the total expenditure toward or capitalized costs incurred for specified climate-related events. As such, they are expected to increase the resilience of assets or operations, retire or shorten the estimated useful lives of impacted assets, relocate assets or operations at risk, or otherwise reduce the future impact of severe weather events and other natural conditions on business operations. The proposed rules also would provide investors with information about the amount of expenditure expensed or capitalized costs incurred for climate-related transition activities related, among others, to research and development of new technologies, purchase of assets, infrastructure, or products that are intended to reduce GHG emissions, increase energy efficiency, or improve other resource efficiency.

With respect to financial assumptions, the proposed rules would require registrants to disclose whether the estimates and assumptions used to produce the consolidated financial statements were impacted by risks and uncertainties associated with, or known impacts from, severe weather events and other natural conditions, such as flooding, drought, wildfires, extreme temperatures, and sea level rise. If so, the registrant would be required to provide a qualitative description of how such events have impacted the development of the estimates and assumptions used to prepare such financial statements. Similarly, if the estimates and assumptions were impacted by potential transition risks, the registrant would be required to provide a qualitative description of how the development of the estimates and assumptions were impacted by such a transition. We expect that the proposed disclosures would provide transparency to investors on the impact of climate-related events and transition activities on the estimates and assumptions used by the registrant to prepare the financial statements and allow investors to evaluate the reasonableness of the registrant's estimates and assumptions.

Prior evidence shows that existing climate-related disclosures often contain boilerplate language or are ''cherry-picked'' to present information that is favorable to the company.[870] Accordingly, registrants under the current regulatory regime may choose to provide only brief, qualitative descriptions of certain climate-related factors while omitting concrete, quantitative information on how climate-related factors can impact individual financial statement line items. The proposed rule may mitigate these types of agency problems by requiring registrants to disclose specific, quantitative metrics according to standardized scopes and methodologies, thereby helping investors processing information more effectively.

The proposed financial metrics would be part of the financial statements and thus audited by an independent public accounting firm in accordance with existing Commission rules and PCAOB auditing standards.[871] Subjecting these climate-related disclosures to reasonable assurance pursuant to an audit would require the auditor to assess the risk of material misstatement related to the estimates and judgments, including through evaluation of the method of measurement and reasonableness of the assumptions used, and to understand management's risk management processes, including the accuracy of the proposed disclosure, thereby alleviating possible concerns about the data's reliability and comparability, and improving investor confidence in such disclosure.[872] Academic research finds that assurance procedures can increase the relevance and reliability of disclosures, particularly for those involving significant estimation uncertainties. [873]

e. GHG Emissions Metrics

The proposed rules would require all registrants to disclose Scope 1 and Scope 2 GHG emissions. Given the

[870] *See supra* note 830 and 806.

[871] Such audits could increase the probability of discovering and penalizing any misrepresentation. Since this would increase the expected costs of engaging in misrepresentation, as discussed in Section IV.B.2, this would also be likely to increase the odds of accurate revelation of material information.

[872] *See* Section II.F.5.

[873] *See* M. DeFond and J.A. Zhang, *A Review of Archival Auditing Research,* 58(2–3) *Journal of Accounting and Economics* 275–326 (2014); V.K. Krishnan, *The Association Between Big 6 Auditor Industry Expertise and the Asymmetric Timeliness of Earnings* 20 *Journal of Accounting, Auditing and Finance* 209–228 (2005); W. Kinney and R. Martin, *Does Auditing Reduce Bias in Financial Reporting? A Review of Audit-Related Adjustment Studies,* 13 Auditing: A Journal of Practice & Theory 149–156 (1994); K.B. Behn, J.H. Choi, and T. Kang, (2008), *Audit Quality and Properties of Analyst Earnings Forecasts* 83 The Accounting Review 327–349 (2008). Some commenters expressed similar views. *See, e.g.,* Comment Letters from CAQ, Ceres; Impax Asset Management; San Francisco Employees' Retirement System; and UNEP–FI.

possibility of a transition to a lower-carbon economy, investors and other market participants may be concerned about registrants that have high GHG emissions since these registrants may be more exposed to certain transition risks, such as regulations that restrict emissions or the potential impacts of changing consumer preferences or market conditions. Should a transition to a low-carbon economy gain momentum, registrants with higher amounts of Scope 1 and 2 emissions may be more likely to face sharp declines in cash flows, either from greater costs of emissions or the need to scale back on high-emitting activities, among other reasons, as compared to firms with lower amounts of such emissions.

Understanding the extent of this potential exposure to transition risks could help investors in assessing their risk exposures with respect to the companies in which they invest. Greater consistency in emissions disclosures can further benefit investors as it can facilitate comparisons between the registrants and their peers and assist in understanding the overall risk of their portfolios. As described below, emissions disclosures would also help inform investors about the extent to which a company has been or is following through with its disclosed strategies and transition plans. As further discussed in Section IV.D, we expect this provision to lower uncertainty for investors, thereby reducing the cost of capital. This may make it easier to raise equity and debt, or to obtain loan financing.

Besides the direct risk to cash flows through cost of emissions or the need to scale back on high-emitting activities, such a transition could also cause a registrant's assets to suffer from unanticipated or premature write-downs, devaluations, and/or adverse adjustments in reserves. The proposed Scope 1 and 2 emission disclosures would allow investors to identify registrants whose assets may be more likely to become obsolete or non-performing or lose economic value ahead of their anticipated useful life due to a potential transition to a lower-carbon economy, and more generally allow investors to discern whether certain investments are unlikely to earn the anticipated economic return due to such transition. The proposed disclosures would also allow investors to more closely monitor whether a firm's management is properly accounting for the impairment of such stranded assets to ensure that they are recorded on the balance sheet as a loss of profit and are not carried at more than their recoverable amount. Given the significant possibility that Scope 1 and 2 emissions will affect the valuation of the registrant through impacts on earnings, cost of capital, investor demand, or potentially some other channel, investor protection would be enhanced by requiring disclosure of this information.

Moreover, by specifying that the information should be provided by all registrants, investors would benefit from having access to a more comprehensive set of emissions data against which to measure a registrant's progress in meeting any stated emissions goals or otherwise managing its climate-related risks, as a part of assessing the registrant's overall business and financial condition. In the absence of the proposed rules, some registrants may choose to selectively omit quantitative emissions metrics. The resulting state of disclosures is less meaningful and less transparent, making it significantly more difficult for investors to assess the degree of risk in individual firms, to compare across firms, and to value securities.

As discussed in Section IV.A, some registrants currently report emissions via the EPA's 2009 mandatory Greenhouse Gas Reporting Program.[874] However, the nature of the reporting requirements and the resulting data is more suited to the purpose of building a national inventory of GHG emissions, not of assessing emissions-related risks to individual registrants. Specifically, direct emitters must report their emissions at the facility-level (not registrant-level) and suppliers of certain products must report their ''supplied emissions,'' conditional on these emissions exceeding a specified threshold.[875] In addition, as previously discussed, the EPA emissions data does not allow a clean disaggregation across the different scopes of emissions for a given registrant.[876] From the point of view of an investor seeking greater information regarding a registrant, the EPA's emissions data may be difficult for investors to use, because the data are made public by facility and not by company. While each facility is matched to its parent company, this company may not be the entity registered with the SEC and thus of interest to investors. Taken together, the EPA emissions data is not well suited to enabling investors to fully assess the degree to which each registrant is exposed to transition risks.

The proposed rules would result in more comprehensive and tailored emissions information by requiring disclosure of Scope 1, Scope 2, and in some cases Scope 3 emissions by registrants in SEC filings. Prior evidence has shown that when information that is already publicly available elsewhere is included within SEC filings, the public becomes more aware of the information.[877] While there are numerous differences with regard to EPA reporting, this evidence suggests that even were these differences not to exist, and the only change were to be inclusion in SEC filings, there would nonetheless be an advantage in improving consistency and reliability and decreasing search costs.

The proposed rules would also provide informational benefits beyond the voluntary disclosure of emissions in sustainability reports. While currently disclosed information reflects investor demand, the overall information disclosed to the market may be biased due to its voluntary nature, in that companies that have more favorable data (*e.g.,* lower emissions) may be more likely to make these voluntary disclosures. Requiring all registrants to provide consistent disclosures, as proposed, would reduce the bias that can result from a voluntary regime. Moreover, as discussed above, locating the information in SEC filings may make it more accessible to investors and contribute to greater consistency and reliability.

Specific provisions are designed to facilitate comparability across registrants and industries. For example, requiring the disclosure of GHG intensity in terms of metric tons of CO_2e per unit of total revenue and per unit of production would allow investors to directly assess the efficiency of the registrant's operations and compare across different industries and firms of varying size. Increased standardization in the reporting of these metrics may allow investors to assess more effectively a registrant's transition risk against that of its competitors. As another example, the proposed rules would require a registrant to set the organizational boundaries for its GHG emissions disclosure using the same scope of entities, operations, assets, and other holdings within its business organization structure as those included in its consolidated financial statements. Requiring a consistent approach would

[874] *See* Section IV.A.3.

[875] *See* supra note 737.

[876] *See* Section IV.A.3.

[877] *See* H.B. Christensen, E. Floyd, L.Y. Liu, and M Maffett, *The Real Effects of Mandated Information on Social Responsibility in Financial Reports: Evidence from Mine-Safety Records,* 64 (2–3) Journal of Accounting and Economics 284–304 (2017).

avoid potential investor confusion about the reporting scope used in the financial statements and enhance comparability across registrants,[878] helping investors in assessing a registrant's transition risk against that of its competitors.

The proposal would also require non-SRC registrants to disclose Scope 3 emissions if material or if the registrant has a target or goal related to Scope 3.[879] In addition, specified registrants would also be required to disclose the methodology used to compute emissions, the breakdown of the different GHGs, as well as upstream and downstream activities, and data quality.[880] Scope 3 emissions GHG emissions can represent the majority of the carbon footprint for many companies, in some cases as high as 85% to 95%.[881] For example, according to Morgan Stanley Capital International (MSCI), the Scope 3 emissions of the integrated oil and gas industry are more than six times the level of its Scope 1 and 2 emissions.[882] Companies may have indirect control over their Scope 3 emissions through choices they make, for example in selecting suppliers, designing products, or sourcing inputs more efficiently. Nevertheless, the majority of companies do not typically report this information. As of July 10, 2020, for example, within the sample of companies belonging to the MSCI ACWI Investable Market Index (IMI),[883] the total Scope 3 average intensity was almost three times greater than the combined Scope 1 and 2 intensity. Yet, only 18% of constituents of the MSCI ACWI IMI reported Scope 3 emissions, with even lower reporting percentages when looking at the individual Scope 3 categories.[884]

The reporting of Scope 3 emissions for these registrants would provide additional benefits for investors. Scope 3 emissions information may be material in a number of situations to help investors gain a more complete picture of the transition risks to which a registrant may be exposed. Relative to registrants with substantial Scope 1 and 2 emissions, future regulations that restrict emissions may impact registrants with high Scope 3 emissions differently. In certain industries, a transition to lower-emission products or processes may already be underway, triggered by existing policies, a shift in consumer preferences, technological changes, or other market forces.

Registrants with significant Scope 3 emissions may be more likely to face disruptions not only in their cash flows, but also in their business models or value chains to the extent that these registrants are compelled to make changes in their products, suppliers, distributors, or other commercial partners.[885] Moreover, if consumer demand changes to favor less carbon intensive products, companies with high Scope 3 emissions may see a marked reduction in demand for their products, and companies that are not aware of these risks could be less profitable relative to those that understand these risks and are prepared to mitigate them. Alternatively, companies that can source inputs that involve less GHG emissions could achieve potential cost savings and those that could produce products that generate less GHG emissions by the end user could potentially enjoy higher demand. Some registrants may plan to shift their activities to capitalize on these changes and thus may need to allocate capital to invest in lower emissions equipment or to create new types of products. Investors would need information about the registrants' full GHG emissions footprint and intensity to determine and compare how exposed a registrant is to the financial risks associated with a transition to lower-carbon economy.

Over the last few years, a number of studies have shown that firms try to reduce their local carbon footprints by outsourcing their carbon emissions to suppliers in states or countries with weaker environmental policies.[886] These studies provide evidence of the substitutional relationship between direct and outsourced GHG emissions. Recent studies have also analyzed the substitution effects between Scope 1 and Scope 3 GHG emission activities of U.S. firms. The findings show that the relative share of Scope 1 emissions out of a firm's total emissions tend to fall at the expense of the rising proportion of its supplier-generated Scope 3 emissions and that a firm's imports further augment the substitutional relationship between its Scope 1 and Scope 3 emissions.[887] In addition to the outsourcing incentives related to regulatory arbitrage, the authors of these studies posit that firms may also be outsourcing emissions abroad to exploit investors' current difficulties in assessing the firm's carbon emissions through imports along the upstream supply chain. By requiring the disclosure of Scope 3 GHG emissions, the proposed rules would make it more difficult for non-SRC registrants to avoid investors' scrutiny by outsourcing all or part of their activities abroad.

Finally, as described in Section IV.A5.d, many companies have set emissions targets, and it is not always clear whether these targets pertain to Scope 3 emissions or not. As explained in Section IV.C.1.g, registrants would be required to disclose whether the targets pertain to Scope 3 emissions, and as described above, if they do, they would need to report such emissions. Without reporting of Scope 3 emissions amounts and categories, investors would not have the information they need to understand the scale and scope of actions the company may need to take to fulfill its commitment, and thus the overall financial implications of a registrant's targets. For example, a registrant's disclosure of its Scope 3

[878] Unlike the GHG Protocol, which currently provides different options for setting organizational boundaries, the proposed rules would require that the scope of consolidation and reporting be consistent for financial data and GHG emissions data.

[879] The proposed rules include a safe harbor for Scope 3 emissions disclosure from certain forms of liability under the federal securities laws.

[880] In calculating Scope 3 emissions, registrants have the flexibility to choose a methodology they deem fit, however, the specific methodology must be disclosed. Estimates or ranges are permitted. Emissions reporting must be presented as CO_2e as well as disaggregated into the different types of GHGs.

[881] *See* Eric Rosenbaum, Climate experts are worried about the toughest carbon emissions for companies to capture (Aug. 18, 2021) *available at https://www.cnbc.com/2021/08/18/apple-amazon-exxon-and-the-toughest-carbon-emissions-to-capture.html#:~:text=Scope%203%20carbon%20emissions%2C%20or,as%2085%25%20to%2095%25.*

[882] *See also* MSCI, *Emissions: Seeing the Full Picture* (Sept. 17, 2020), *available at https://www.msci.com/www/blog-posts/scope-3-carbon-emissions-seeing/02092372761.*

[883] The MSCI ACWI Investable Market Index (IMI) captures large, mid and small cap representation across 23 Developed Markets and 25 Emerging Markets countries, covering approximately 99% of the global equity investment opportunity set.

[884] *Ibid.*

[885] Scope 3 upstream and downstream emissions represents a substantial portion of global GHG emissions. For example, according to a recent report, Scope 3 downstream emissions that happen after a product or service leaves a company's control/ownership represented about 49% of global GHG emissions in 2019. Capital goods (87%), banks (81%) and retailing (80%) were among the industries with the highest percentage of Scope 3 downstream emissions relative to their total emissions. These downstream emissions can come from a variety of sources. For example, capital goods activities include emissions from raw material manufacturing and transport. Banks emit few GHGs to run their operations—but finance the emissions of other companies through loans and investments. *See* State of Green Business 2021, *available at https://www.spglobal.com/marketintelligence/en/news-insights/research/state-of-green-business-2021.*

[886] *See, e.g.* I Ben-David, Y. Jang, S. Kleimeier, and M. Viehs, *Exporting Pollution: Where Do Multinational Firms Emit CO_2?* 36 (107) Economic Policy 377–437 (2021); X. Li and Y.M. Zhou, *Offshoring Pollution While Offshoring Production?* 38 Strategic Management Journal 2310–2329 (2017).

[887] *See* R. Dai, R. Duan, H. Liang, and L. Ng, *Outsourcing Climate Change* (SSRN Working Paper) (2021), *available here https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3765485.*

emissions, together with the proposed financial statement metrics, could allow investors to assess the potential (additional) investments the registrant may need to make to meet a certain goal. Moreover, as described further below, reporting of Scope 3 emissions gives a quantitative metric for investors to track, thus reducing opportunities for misleading claims on the part of the registrant.

Because the value of a firm's equity is largely derived from expected future cash flows, disclosure of Scope 1, 2, and 3 emissions can help investors incorporate risks associated with such future cash flows into asset values today. Indeed, the academic literature indicates that equity is a long-term asset, meaning that even risks related to regulatory changes in the distant future could be priced today.[888] Thus, for many registrants, reasonable investors may view GHG emissions as necessary to assess the registrants' exposure to climate-related risks, particularly transition risks, and whether they have developed strategies to reduce their carbon footprint in the face of potential regulatory, policy, and market constraints. This may be particularly important in light of the investor demand documented in IV.B.1 and the potential price impact, as discussed in IV.D.

f. Assurance of GHG Scopes 1 and 2 Emissions Disclosures for Large Accelerated Filers and Accelerated Filers

The proposed rules would require registrants that are large accelerated filers and accelerated filers to provide an attestation report for the registrant's Scope 1 and 2 GHG emissions disclosures. Large accelerated filers constitute approximately 31% of the universe of registrants that filed annual reports during calendar year 2020 (1,950 out of 6,220), but account for 93.6% of market cap within the same universe. Accelerated filers constitute approximately 10% of the universe of registrants that filed annual reports during calendar year 2020 (645 out of 6,220) and account for 0.9% of market cap within the same universe.

The proposed rules provide specific transition periods for obtaining attestation reports. Large accelerated filers would be required to provide Scopes 1 and 2 emissions disclosures in the fiscal year immediately following rule adoption. Next, they would be required to obtain limited assurance over these disclosures in fiscal years 2 and 3 after adoption. They would then be required to obtain reasonable assurance over these disclosures in fiscal year 4 after adoption and going forward. Accelerated filers would follow the same timeline but with a delay of one fiscal year. Specifically, accelerated filers would be required to provide Scopes 1 and 2 emissions disclosures in fiscal year 2 after adoption. Next, they would be required to obtain limited assurance over these disclosures fiscal years 3 and 4 after adoption. They would then be required to obtain reasonable assurance over these disclosures in fiscal year 5 after adoption and going forward.

The proposed transition periods for assurance over large accelerated filers' and accelerated filers' Scopes 1 and 2 GHG emission disclosures are intended to provide these registrants time to familiarize themselves with the GHG emissions disclosure requirements, develop the relevant DCP, and provide the market with an opportunity to develop enough expertise to satisfy the increased demand for GHG emission assurance services. We expect that during the proposed transition periods, the market for assurance services would further mature with respect to institutional knowledge, procedural efficiency, and overall competition, thus lowering costs for registrants and improving the quality of service. Although Scope 3 GHG emissions can constitute a large portion of a registrant's total emission, the proposed rules would exclude Scope 3 GHG emission disclosures from the attestation requirement due to the unique challenges associated with their measurement, which is based on data sources not owned by the registrant,[889] as well as the potential higher costs associated with their verification.

Section IV.A.5.e above discusses survey evidence on the frequency with which firms obtain assurance in sustainability reports. This evidence suggests that a significant fraction of large companies already obtain some form, albeit limited, of assurance. Practices appear to be fragmented with respect to the levels of assurance provided, the assurance standards used, the types of service providers, and the scope of disclosures covered by the assurance. One consequence of such fragmentation has been a lack of clarity about the nature of assurance provided, which can lead to confusion for investors when assessing the quality of disclosures. Moreover, as noted above, the voluntary nature of the reporting could result in biased or incomplete data. The fact, however, that a significant proportion of large companies already obtain some form of assurance over this information is indicative of investors' and companies' need for such disclosures to be reliable.

The importance of assurance for climate-related information also is highlighted by the International Federation of Accountants, which recently published its Vision for High-Quality Sustainability Assurance.[890] As discussed earlier, contrary to other quantitative information that is provided outside of the financial statements, and which is typically derived from the same books and records that are used to generate a registrant's audited financial statements, GHG emissions disclosures are not developed from information that is included in the registrant's books and records.[891] Accordingly, such quantitative disclosure is not be subject to audit procedures as part of the audit of the financial statements in the same filing. Because of this, the proposed requirement of a third-party attestation report may be particularly beneficial to verify the reliability of such quantitative information and enhance its accuracy. In general, subjecting climate-related disclosures to assurance would require the assurance provider to assess the risk of material misstatements related to the estimates and judgments, including through evaluation of the method of measurement and reasonableness of the assumptions used, and an understanding of management's risk management processes, including the risks identified and the actions taken to address those risks.[892] Moreover, by specifying minimum standards for the assurance provided with respect to GHG Scope 1 and 2 emissions disclosures, we expect the proposed rules to promote accuracy and consistency in the reporting of this information, while also providing investors with a baseline level

[888] *See* J. van Binsbergen, *Duration-Based Stock Valuation: Reassessing Stock Market Performance and Volatility* (2021), *available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3611428;* D. Greenwald, M. Leombroni, H. Lustig, and S. van Nieuwerburgh, *Financial and Total Wealth Inequality with Declining Interest Rates* (2021), *available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789220*. Both of these papers find that the Macauley duration of equity, the weighted average length of time which investors will receive the cash flows from the asset, is in excess of 35 years as of 2019. This indicates that changes in cash flows in the distant future can impact equity prices today.

[889] *See* Section II.G.3.

[890] *See* IFAC Charts the Way Forward for Assurance of Sustainability Information (Dec. 6, 2021), *available at https://www.ifac.org/news-events/2021-12/ifac-charts-way-forward-assurance-sustainability-information*.

[891] *See* Section II.H.1 for more information.

[892] *See* PCAOB, AS 2110 Identifying and Assessing Risks of Material Misstatement (2010).

of reliability against which to evaluate the disclosures.[893]

Academic research finds that assurance procedures can increase the relevance and reliability of disclosures,[894] particularly for those involving significant estimation uncertainties. While most of this academic evidence focuses on the effects of reasonable assurance procedures, we cannot preclude the possibility that such findings may have implications for limited assurance as well. Experimental evidence has found that both limited and reasonable assurance can increase perceived reliability of sustainability reports, but those same studies do not find a statistically significant difference between limited and reasonable assurance.[895] Obtaining assurance for sustainability reports, which as noted above is typically limited assurance, has also been associated with firms with lower costs of capital, increased analyst coverage, and decreased analyst forecast errors and forecast dispersion.[896]

The proposed rules would require the attestation report to identify the criteria against which the subject matter was measured or evaluated, the level of assurance provided, the nature of the engagement, and the attestation standard used. In particular, the proposed rules would require the attestation report to include a description of the work performed as a basis for the attestation provider's conclusion and for that conclusion to be provided pursuant to standards that are established by a body or group that has followed due process procedures, including the broad distribution of the framework for public comment. We expect this provision would help ensure that the standards upon which the attestation report is based were the result of a transparent and reasoned process. In this way, the requirement should help to protect investors who may rely on the attestation report by limiting the standards used to those that are appropriate for the subject matter and purpose. Further, we expect this provision to enhance the transparency of the GHG emissions attestation report for investors by providing them with additional information about the general procedures undertaken by the attestation provider. For example, under the proposed rules, an attestation report providing limited assurance would need to state that the procedures performed vary in nature and timing from, and are less extensive than, a reasonable assurance engagement, thus helping investors understand the level of assurance provided.

The GHG emissions attestation report would also be required to include a statement that describes any significant limitations associated with the measurement or evaluation of the subject matter against the criteria. The provision would require disclosure about the estimation uncertainties inherent in the quantification of GHG emissions, driven by reasons such as the state of the science and assumptions used in the measurement and reporting processes. By eliciting disclosure with respect to the procedures undertaken by the attestation provider, such as inquiries and analytical procedures, and the methodology used in the attestation process, the proposed provision would enhance the transparency of the GHG emissions attestation quality, thus allowing investors to gain a better understanding of the emission related information. This could help investors process emission related information more effectively. More informed investment decisions by investors also may benefit registrants by lowering their cost of capital.

The proposed rules would also require registrants to disclose whether the attestation provider has a license from any licensing or accreditation body to provide assurance and whether the GHG emissions attestation engagement is subject to any oversight inspection program and record-keeping requirements with respect to the work performed for the GHG emissions attestation. These requirements are expected to benefit investors by helping them to better understand the qualifications of the GHG emissions attestation provider, which in turn would allow them to make better informed decisions about the reliability of such information.

Finally, the proposed rules would require that the GHG emissions attestation report be prepared and signed by a provider that is an expert in GHG emissions and independent with respect to the registrant, and any of its affiliates, for whom it is providing the attestation report. These qualification and independence requirements should help ensure that the attestation provider is capable of exercising informed, objective and impartial judgment. Academic research has found that the independence of assurance providers can be important in certain settings for disclosure quality.[897] Academic research has also found that equity prices respond to analyst forecast even after management has released the exact same information, highlighting more generally the perceived value of external evaluations of firm disclosures and resulting investor confidence in the related disclosures.[898]

g. Targets and Goals Disclosure

The proposed rules would require a registrant to disclose whether it has set any climate-related targets or goals and, if so, how it intends to meet those targets and goals. Such climate-related targets or goals might relate to the reduction of GHG emissions or address energy usage, water usage, conservation or ecosystem restoration. Associated disclosure would include the scope of activities and emissions included in the target, the unit of measurement, and the defined time horizon. Additionally, disclosures include the baseline emissions for measuring progress, any interim targets, how it intends to meet these targets or goals, and data showing any progress toward achieving these targets, including how that progress was

[893] *See* K. Hodge, K., N. Subramaniam, J. Stewart, *Assurance of Sustainability Reports: Impact on Report Users' Confidence and Perceptions of Information Credibility,* (19) *Australian Accounting Review* 178–194 (2009), *available at https://doi.org/10.1111/j.1835-2561.2009.00056.x.*

[894] *See* supra note 874.

[895] *See, e.g.,* K. Hodge, K., N. Subramaniam, and J. Stewart, *Assurance of Sustainability Reports: Impact on Report Users' Confidence and Perceptions of Information Credibility,* 19 Australian Accounting Review 178–194 (2009), *available at https://doi.org/10.1111/j.1835-2561.2009.00056.x;* Mark Sheldon, *User Perceptions of CSR Disclosure Credibility with Reasonable, Limited and Hybrid Assurances* (Dissertation) (2016) *available at https://vtechworks.lib.vt.edu/bitstream/handle/10919/65158/Sheldon_MD_D_2016.pdf.* This absence of evidence, however, is not necessarily evidence of absence. It is possible that reasonable assurance can have benefits over limited assurance that are not easily identifiable.

[896] *See* R.J. Casey and J.H. Grenier, Understanding and contributing to the enigma of corporate social responsibility (CSR) assurance in the United States, 34(1) Auditing: A Journal of Practice & Theory 97, 97–130 (2015). The authors also find that the lower costs of capital are in excess of estimated assurance costs (*i.e.,* 5% to 10% of total audit fees) for the majority of companies. We acknowledge, however, that the benefits cited in this study may be overstated to the extent that they reflect a selection bias. Specifically, companies that anticipate a net loss due to assurance would choose to forgo obtaining such assurance, thereby removing themselves from the treatment group. This potential limitation in interpreting such findings is also supported by evidence of systematic differences in companies voluntarily reporting higher assurance levels. *See* C.H. Cho, G. Michelon, D.M. Patten, and R.W. Roberts, *CSR report assurance in the USA: An empirical investigation of determinants and effects,* 5(2) Sustainability Accounting, Management and Policy Journal 130, 130–148 (2014), *available at https://doi.org/10.1108/SAMPJ-01-2014-0003.*

[897] *See* N. Tepalagul, and L. Lin, Auditor Independence And Audit Quality: A Literature Review, 30(1) Journal of Accounting, Auditing & Finance 101–121 (2015) (for a more detailed discussion on academic evidence on independence in auditing).

[898] *See* Marco Grotteria, and Roberto Gomez Cram, *Do Financial Investors Underreact To Voluntary Corporate Disclosure?* (Working Paper) (2022).

achieved, and details about any carbon offsets of RECs that have been used.

For example, in 2019 Amazon and Global Optimism co-founded The Climate Pledge, a commitment to net zero carbon by 2040. Since then, a growing list of major companies and organizations have signed on to the Climate Pledge, which indicates a commitment to the following three principles: (i) Measure and report greenhouse gas emissions on a regular basis; (ii) Implement decarbonization strategies in line with the Paris Agreement; (iii) Neutralize any remaining emissions with additional offsets to achieve net zero annual carbon emissions by 2040.[899] The proposed rules would help to make such commitments more transparent by requiring disclosure on the unit of measurement, time horizon, and baseline for measuring progress, including how that progress was achieved (*e.g.,* through efficiency improvements, renewable energy adoption, materials reductions, and other carbon emission elimination strategies).

Such standardized reporting as a form of an oversight or monitoring mechanism might be critical in overcoming agency problems in the presence of asymmetric information. Investment in achieving targets could be value-enhancing in the long-run, but reduce cash flow in the short-run. Companies may decide that it is an optimal strategy to bear the costs up front of shifting its operations to those that have fewer emissions or upgrading their equipment, rather than bearing the risk that these costs will be borne in an unpredictable and possibly disorderly way in the future. In the absence of a means to credibly convey that efforts to achieve these long-term targets are being undertaken diligently, however, investors might be unable to observe which registrants are actually following through on such actions. For example, if registrants are incurring costs in the short-run to undertake investments to reduce Scope 1, 2, and 3 emissions, reducing short-run profitability, but are unable to convey to investors that they are meaningfully following through on achieving potential long-term value-enhancing strategies, there could be a disincentive for investors to invest in the firm, thus undermining its value in the long-run. This has been put forth as one potential explanation for some private sector attempts at addressing these problems, such as green bonds, which commit firms to recurring, more standardized disclosure requirements for progress in achieving stated targets and goals.[900] The proposed rules would provide enhanced transparency about targets and goals so that investors can identify registrants with credible goals and track their progress over time. This can not only reduce incentives for misleading goal disclosures, but can also allow investors to recognize goals that generate long-term value despite short run costs, which can attract capital and increase firm value.

As explained above, the pursuit of targets could have a material impact, either in the short-term or long-term, on a registrant's operations or financial condition.[901] At this time, however, there is little consistency with respect to the extent of disclosure and the relevant details concerning such climate-related targets and goals. This can result in insufficient information for investors' monitoring or decision-making needs. The proposed disclosure could provide more comparable, consistent, and reliable metrics of any climate-related targets or goals. It would require a registrant to clearly define baselines for targets, the scope of activities and emissions covered by the target, the unit of measurement, the defined time horizon, and how progress is made towards the targets. For example, the disclosure would require the registrant to state whether or not the targets pertain to Scope 3 emissions. If targets do include Scope 3 emissions, disclosure of Scope 3 emission sources and amounts would be required so that investors would understand the scale and scope of changes the company would need to undertake, and thus the full financial impact of meeting the target.[902] Such disclosures would also enable investors to monitor progress firm management has made and plans to make towards achieving climate-related targets or goals, assess the credibility of its goal, and evaluate the effectiveness of the company's investments to achieve its goals. As described above, this required disclosure could make targets more credible and serves as an oversight or monitoring mechanism.

h. Structured Data Requirement

Under the proposed rules, the new climate-related disclosures would be tagged in the Inline XBRL structured data language. The provision requiring Inline XBRL tagging of climate-related disclosures would benefit investors by making those disclosures more readily available for aggregation, comparison, filtering, and other enhanced analytical methods.[903] These benefits are expected to reduce search costs and substantially improve investors' information-processing efficiency.[904] XBRL requirements for public company financial statement disclosures have been observed to reduce information-processing costs, thereby decreasing information asymmetry and increasing transparency by incorporating more company-specific information into the financial markets.[905] In addition, the proposed Inline XBRL requirement for the climate-related disclosures may further limit agency problems, as XBRL requirements for financial statement tagging have been observed to facilitate external monitoring of firms through the aforementioned reduction of information processing costs.[906]

[899] As of Jan. 25, 2022, The Climate Pledge has acquired 217 signatories. *See The Climate Pledge, available at https://www.theclimatepledge.com/us/en/Signatories.*

[900] *See* S. Lu, *The Green Bonding Hypothesis: How do Green Bonds Enhance the Credibility of Environmental Commitments?* (2021), *available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3898909.*

[901] *See* supra Sections II.G.1.b. and III C.1.e.

[902] *See id.*

[903] For example, structuring climate-related disclosures would enable more advanced analyses than those described in the aforementioned Commission staff review that used keyword searches and NLP. *See supra* IV.A.5.a.

[904] The findings on XBRL cited in the following paragraphs are not necessarily focused on climate-related disclosures and metrics, but we expect the findings to be generally applicable and to result in similar benefits for investors.

[905] *See, e.g.,* Y. Cong, J. Hao, and L. Zou, *The Impact of XBRL Reporting on Market Efficiency,* 28 J. Info. Sys. 181 (2014) (finding support for the hypothesis that ''XBRL reporting facilitates the generation and infusion of idiosyncratic information into the market and thus improves market efficiency''); Y. Huang, J.T. Parwada, Y.G. Shan, and, J. Yang, *Insider Profitability and Public Information: Evidence From the XBRL Mandate* (Working Paper) (2019) (finding XBRL adoption levels the informational playing field between insiders and non-insiders); J. Efendi, J.D. Park, and C. Subramaniam, *Does the XBRL Reporting Format Provide Incremental Information Value? A Study Using XBRL Disclosures During the Voluntary Filing Program,* 52 Abacus 259 (2016) (finding XBRL filings have larger relative informational value than HTML filings); J. Birt, K. Muthusamy, and P. Bir, XBRL and the Qualitative Characteristics of Useful Financial Information, 30 Account. Res. J. 107 (2017) (finding ''financial information presented with XBRL tagging is significantly more relevant, understandable and comparable to non-professional investors''); S.F. Cahan, S. Chang, W.Z. Siqueira, and K. Tam, *The Roles of XBRL and Processed XBRL in 10–K Readability,* J. Bus. Fin. Account. (2021) (finding Form 10–K file size reduces readability before XBRL's adoption since 2012, but increases readability after XBRL adoption, indicating ''more XBRL data improves users' understanding of the financial statements'').

[906] *See, e.g.,* P.A. Griffin, H.A. Hong, J.B. Kim, and J.H. Lim, *The SEC's XBRL Mandate and Credit Risk: Evidence on a Link between Credit Default Swap Pricing and XBRL Disclosure,* 2014 American Accounting Association Annual Meeting (2014) (attributing the negative association between XBRL information and credit default swap spreads to ''(i) a reduction in firm default risk from better outside monitoring and (ii) an increase in the quality of information about firm default risk from lower

Investors with access to XBRL analysis software may directly benefit from the availability of the climate-related disclosures in Inline XBRL, whereas other investors may indirectly benefit from the processing of Inline XBRL disclosures by asset managers and by information intermediaries such as financial analysts.[907] In that regard, XBRL requirements for public company financial statement disclosures have been observed to increase the number of companies followed by analysts, decrease analyst forecast dispersion, and, in some cases, improve analyst forecast accuracy.[908] Should similar impacts on the analysts' informational environment arise from climate-related disclosure tagging requirements, this would likely benefit retail investors, who have generally been observed to rely on analysts' interpretation of financial disclosures rather than directly analyzing those disclosures themselves.[909]

2. Costs

Below we discuss the anticipated direct and indirect costs of the proposed rules. Direct costs would include compliance burdens for registrants in their efforts to meet the new disclosure requirements. These direct costs could potentially be significant; however, the incremental costs would be lower to the extent that registrants already provide the required disclosures. Indirect costs may include heightened litigation risk and the potential disclosure of proprietary information.[910] We proceed by discussing these various costs.

a. Direct Costs

The primary direct costs that the proposed rules would impose on registrants are compliance costs. To the extent that they are not already gathering the information required to be disclosed under the proposed rules, registrants may need to re-allocate in-house personnel, hire additional staff, and/or secure third-party consultancy services. Registrants may also need to conduct climate-related risk assessments, collect information or data, measure emissions (or, with respect to Scope 3 emissions, gather data from relevant upstream and downstream entities), integrate new software or reporting systems, seek legal counsel, and obtain assurance on applicable disclosures (*i.e.,* Scopes 1 and 2 emissions). In addition, even if a registrant already gathers and reports the required information, some or all of this information may be in locations outside of SEC filings (such as sustainability reports posted on company websites or emissions data reported to the EPA). These registrants may face lower incremental costs by virtue of already having the necessary processes and systems in place to generate such disclosures; however they may still incur some additional costs associated with preparing this information for inclusion in SEC filings.

(1) General Cost Estimates

In this section, we review sources that provide insight into the magnitude of the potential costs associated with the proposed rules. With some exceptions discussed in further detail, these sources provide information at the level of general costs for climate disclosures. We acknowledge that these sources are limited in scope or representativeness and thus may not directly reflect registrants' compliance costs. For instance, some third-party sources may present cost estimates that do not include all items required under the proposed rules (*e.g.,* assurance costs), or else they may aggregate the costs of multiple items (including those not required under the proposed rules) into a single cost figure. However, these sources may serve as useful references to the extent that they overlap with specific disclosure elements required in the proposed rules. For example, third-party cost estimates of preparing TCFD reports or completing the CDP questionnaire can offer a rough approximation of potential compliance costs due to their similarity with the proposed rules. Below, we request further data to assist us in estimating potential costs.

As discussed in Section V, for purposes of the Paperwork Reduction Act of 1995 (''PRA''),[911] we estimate the annual costs over the first six years of compliance with the proposed rules.[912] For non-SRC registrants, the costs in the first year of compliance are estimated to be $640,000 ($180,000 for internal costs and $460,000 for outside professional costs), while annual costs in subsequent years are estimated to be $530,000 ($150,000 for internal costs and $380,000 for outside professional costs). For SRC registrants, the costs in the first year of compliance are estimated to be $490,000 ($140,000 for internal costs and $350,000 for outside professional costs), while annual costs in subsequent years are estimated to be $420,000 ($120,000 for internal costs and $300,000 for outside professional costs). These costs are expected to decrease over time for various reasons, including increased institutional knowledge,

information cost''); J.Z. Chen, H.A. Hong, J.B. Kim, and J.W. Ryou, Information Processing Costs and Corporate Tax Avoidance: Evidence from the SEC's XBRL Mandate, 40 (2) J. Account Pub. Pol. (2021) (finding XBRL reporting decreases likelihood of firm tax avoidance, because ''XBRL reporting reduces the cost of IRS monitoring in terms of information processing, which dampens managerial incentives to engage in tax avoidance behavior'').

[907] Additional information intermediaries that have used XBRL disclosures may include financial media, data aggregators and academic researchers. *See, e.g.,* N. Trentmann, *Companies Adjust Earnings for Covid–19 Costs, but Are They Still a One-Time Expense?* The Wall Street Journal (2020), *available at https://www.wsj.com/articles/companies-adjust-earnings-for-covid-19-costs-but-are-they-still-a-one-time-expense-11600939813* (citing XBRL research software provider Calcbench as data source); *Bloomberg Lists BSE XBRL Data, XBRL.org* (2018), *available at https://www.xbrl.org/news/bloomberg-lists-bse-xbrl-data/*; R. Hoitash, and U. Hoitash, *Measuring Accounting Reporting Complexity with XBRL,* 93 Account. Rev. 259–287 (2018). *See 2019 Pension Review First Take: Flat to Down,* Goldman Sachs Asset Management (2020) (an example of asset manager use of XBRL data), *available at https://www.gsam.com/content/dam/gsam/pdfs/common/en/public/articles/2020/2019_Pension_First_Take.pdf?sa=n&rd=n* (citing XBRL research software provider Idaciti as a data source).

[908] *See, e.g.,* A.J. Felo, J.W. Kim, and J. Lim, Can XBRL *Detailed Tagging of Footnotes Improve Financial Analysts' Information Environment?,* 28 Int'l J. Account. Info. Sys. 45 (2018); Y. Huang, Y.G. Shan, and J.W. Yang., *Information Processing Costs and Stock Price Informativeness: Evidence from the XBRL Mandate,* 46 Aust. J. Mgmt., 110–131 (2020) (finding ''a significant increase of analyst forecast accuracy post-XBRL''*);* M. Kirk, J. Vincent, and D. Williams, *From Print to Practice: XBRL Extension Use and Analyst Forecast Properties* (Working Paper 2016) (finding ''the general trend in forecast accuracy post-XBRL adoption is positive''); C. Liu, T. Wang, and L.J. Yao, *XBRL's Impact on Analyst Forecast Behavior: An Empirical Study,* 33 J. Account. Pub. Pol. 69–82 (2014) (finding ''mandatory XBRL adoption has led to a significant improvement in both the quantity and quality of information, as measured by analyst following and forecast accuracy''). *But see* S.L. Lambert, K. Krieger, and N. Mauck, *Analysts' Forecasts Timeliness and Accuracy Post-XBRL,* 27 Int'l. J. Account. Info. Mgmt. 151–188 (2019) (finding significant increases in frequency and speed of analyst forecast announcements, but no significant increase in analyst forecast accuracy post-XBRL).

[909] *See, e.g., A.* Lawrence, J. Ryans, and E. Sun, *Investor Demand for Sell-Side Research,* 92 Account. Rev. 123–149 (2017) (finding the ''average retail investor appears to rely on analysts to interpret financial reporting information rather than read the actual filing''); D. Bradley, J. Clarke, S. Lee, and C. Ornthanalai, *Are Analysts' Recommendations Informative? Intraday Evidence on the Impact of Time Stamp Delays,* 69 J. Finance 645–673 (2014) (concluding ''analyst recommendation revisions are the most important and influential information disclosure channel examined'').

[910] For example, these costs may include the revelation of trade secrets, the disclosure of profitable customers and markets, or the exposure of operating weakness to competing firms, unions, regulators, investors, customers or suppliers. These costs are commonly referred to as ''proprietary costs.''

[911] See Paperwork Reduction Act, Public Law 104–13, 109 Stat 163 (1995) (codified at 44 U.S.C. 3501 *et seq.*). *See infra* Section V.

[912] The following estimates are applicable to registrants filing form 10–K that have no existing climate-related disclosure processes or expertise. All estimates are rounded to the nearest $5,000.

operational efficiency, and competition within the market for relevant services.

One commenter provided cost estimates for their services in assisting client companies prepare TCFD-aligned disclosures.[913] For companies that have no prior experience in GHG analysis or climate-related disclosures, the commenter estimates initial costs to range from $150,000 to $200,000 to prepare TCFD-aligned disclosures.[914] Companies that have already calculated their carbon footprints and only need assistance with TCFD reporting may expect costs of $50,000 to $200,000, with the average cost of approximately $100,000. Ongoing costs for their services are expected to be zero conditional upon the TCFD requirements remaining unchanged,[915] however the reporting company may still incur internal costs in preparing these disclosures on an annual basis.

Another source presents survey results of climate-related disclosure costs for three unnamed companies, which consist of a European-based multinational large-cap financial institution, a US-based large-cap industrial manufacturing company, and a US-based mid-cap waste management company.[916] The survey reports that each firm has ''already established robust in-house climate disclosure systems that can easily be leveraged to comply with any new disclosure rule,'' as evidenced by their concurrent reporting under multiple climate disclosure frameworks (*e.g.,* TCFD, CDP, SASB, GRI, etc.). The respondents indicate that anticipated incremental costs of a mandatory climate disclosure rule are therefore expected to be minimal.[917] All respondents disclose Scopes 1, 2, and 3 emissions, while none of them obtain third-party assurance for their climate-related disclosures.

The mid-cap waste management company estimates that the cost of producing their first TCFD report was less than $10,000. The company's reported annual costs consist of employee costs ($12,600) [918] and third-party costs ($60,000 to $160,000).[919] However, the reported annual costs may be less applicable to potential compliance costs as they combine additional costs associated with several other activities not necessarily required in the proposed rules, including its adherence to multiple climate disclosure frameworks (*e.g.,* TCFD, GRI, SASB, and CDP) and designing its annual sustainability report and associated web page.[920] Overall, the company reports that its total costs related to producing climate-related disclosures across these multiple frameworks are less than 5% of its total SEC compliance-related costs.

The large-cap industrial manufacturing company reports that the costs of preparing its first CDP questionnaire was no more than $50,000. Additionally, the combined costs of producing its first TCFD, SASB, and GRI disclosures were between $200,000 and $350,000. Reported annual costs include internal costs (between $200,000 and $350,000) [921] and the cost for auditors and consultants ($400,000).[922] These cost estimates, however, may overestimate potential compliance costs to the extent that they include disclosure items or activities not required in the proposed rules. The company reports that their annual costs of producing its voluntary climate-related disclosures are less than 0.1% of their revenues.

The multinational financial institution reports that the cost of producing its first TCFD report, SASB report, and CDP questionnaire were each less than $100,000 given that such information overlaps with what the company already discloses under the EU's Prospectus Regulation (Regulation (EU) 2017/1129). The company estimates annual costs ranging from $250,000 and $500,000 to produce these disclosures, but as before, this range may combine the costs of activities that are not required in the proposed rules.[923] Similar to the industrial manufacturing company, this company also notes that the annual costs of producing its voluntary climate-related disclosures are less than 0.1% of their revenues.

Some commenters also provided estimates of climate-related disclosure costs for individual firms. One commenter provided a breakdown of such costs for seven unnamed large cap firms across six different industries.[924] Headcount requirements ranged from two to 20 full-time equivalent employees. One large-cap firm in the energy industry reported that its TCFD reporting process involved 40 employees and six months of nearly full-time participation by 20 core team members. Employee hours spent on climate reporting ranged from 7,500 to 10,000 annually. Fees for external advisory services ranged from $50,000 to $1.35 million annually, which generally included legal counsel and consulting services related to environmental engineering, emissions, climate science, modeling, or sustainability reporting. Another commenter, a Fortune 500 energy infrastructure firm, reported that it employs a full-time, management level director that spends about 25% of his time developing sustainability reports and other ESG initiatives. This commenter also reported that it pays a third-party consulting firm more than

[913] *See* memorandum, dated Feb. 4, 2022, concerning staff meeting with representatives of S&P Global.

[914] This cost range pertains to clients' use of the commenter's ''TCFD Suite'', which consists of the following modules: Benchmarking/gap assessment, management interviews, physical risk assessment, and various transition risk assessments, including policy risk analysis, market risk assessment, technology risk assessment, and reputation risk assessment. This cost range excludes the cost of additional services, such as target-setting ($20,000 to $30,000) and calculating GHG footprints ($75,000 to $125,000 for Scopes 1, 2, and 3), the latter of which is discussed in further detail in the following subsection.

[915] The commenter reports that should the TCFD requirements change based on new science, projections, and business changes, costs of the TCFD Suite in future years may range from $125,000 to $175,000.

[916] *See* L. Reiners and K. Torrent, *The Cost of Climate Disclosure: Three Case Studies on the Cost of Voluntary Climate-Related Disclosure,* Climate Risk Disclosure Lab (2021), *available at https://climatedisclosurelab.duke.edu/wp-content/uploads/2021/12/The-Cost-of-Climate-Disclosure.pdf.*

[917] Incremental costs would be minimal to the extent that the mandatory disclosure rule overlaps with their current reporting practices. The respondents acknowledge that actual incremental costs would depend on the contents of the final rule.

[918] The company allocates three employees to produce climate-related disclosures. Two employees in Legal and Compliance devote a combined 80 hours per year on this task, while one employee in Management and Administration devotes two hours per year.

[919] The company reports that approximately one-third of these third-party costs is associated with designing the annual sustainability report and associated web page, while the remaining two-thirds is associated with report writing and consulting work on the voluntary frameworks.

[920] These annual costs reflect a larger scope of climate-related disclosures (*e.g.,* multiple frameworks, sustainability report, etc.) relative to the initial cost, which is specific to TCFD reporting only. Nevertheless, because these estimates aggregate the costs of reporting under the TCFD in addition to other climate disclosure framework, these estimates can serve as an upper bound of what annual costs may be specific to TCFD reporting only.

[921] Internal costs include the cost of approximately 20 employees working part-time on climate-related disclosures from Nov. until Mar. and one full-time consultant.

[922] Auditors review data quality and data collection procedures, while consultants help prepare substantive disclosures, advise on adherence to the voluntary climate disclosure frameworks, and prepare web updates.

[923] The company notes that the bulk of its annual costs comes from producing chapter 7 of its Universal Registration Document, issued under the EU's Prospectus Regulation (Regulation (EU) 2017/1129). Chapter 7 pertains to the extra-financial performance statement of the consolidated firm.

[924] *See* Letter from Society for Corporate Governance (June 11, 2021).

$250,000 annually to assist in its ESG and sustainability report process.[925]

The UK's Department for Business, Energy & Industrial Strategy, as part of its Green Finance Strategy, has released a final stage impact assessment (the ''UK impact assessment'') of their proposed rules that would also require certain TCFD-aligned disclosures from firms and asset managers listed on UK financial markets.[926] The UK impact assessment provides a breakdown of estimated average compliance costs per affected entity. Under the assumption that affected entities have no pre-existing climate-related disclosure practices or expertise, the UK impact assessment estimates that first-year one-time costs would include familiarization costs ($17,300[927] plus $2,600 per subsidiary, as applicable) and legal review ($4,400). They also estimate recurring annual governance disclosure costs ($12,500), strategy disclosure costs ($17,900[928]), risk management disclosure costs ($14,900), metrics and targets disclosure costs ($104,400 in the first year and $80,500 in subsequent years[929]), internal audit costs ($30,300), and signposting costs ($100).[930] For companies with subsidiaries, the costs of collecting information from subsidiaries and processing this information are expected to be $4,300 for the parent company and $1,700 for each subsidiary. In total, the study estimates that a company with no pre-existing climate-related disclosure practices or expertise could incur costs of $201,800 in the first year and $177,900 in subsequent years, plus additional costs due to subsidiaries, as applicable. This cost estimation methodology is conditional upon assumptions regarding the number of required staff, the rank or title of the staff, and the required labor hours, which are then matched with local wage data to estimate final costs.

It is important to note that all of these cost estimates are conditional on specific assumptions and can vary significantly depending on firm characteristics, such as firm size, industry, business model, the complexity of the firm's corporate structure, starting level of internal expertise, etc. In addition, we note that, in certain cases, these cost estimates may represent a registrant's optimal response to investor demand, and thus may exceed the minimum cost necessary to fulfill mandatory reporting of climate-related risks. We are accordingly requesting comments regarding compliance costs, including cost data that can be used to generate more accurate, granular, and reliable cost estimates that are more representative of the full set of affected registrants.

(2) Cost Estimates Specific to Emissions

In this section, we review the available evidence, which provides some insight into the scope of the compliance costs associated with reporting GHG emissions. We are cognizant of the type of costs that registrants will incur to report GHG emissions, *e.g.* resources, systems, design and implementation of DCP, external consulting services. In light of the limited information available, however, we are unable to fully and accurately quantify these costs. Accordingly, we are requesting comments regarding cost data for GHG emissions reporting.

One commenter reports that their services in calculating client companies' GHG footprints (Scopes 1, 2, and 3 emissions) would initially cost $75,000 to $125,000 if the client company has no prior experience in this area.[931] Ongoing costs amount to approximately $40,000 assuming no material changes in Scope 3 emissions (*i.e.,* assess Scopes 1 and 2 only). If there are material changes to Scope 3 emissions, ongoing costs would range from $75,000 to $125,000 (*i.e.,* assess Scopes 1, 2, and 3).

Another commenter, a climate management and accounting platform, provided cost estimates of the measurement and reporting of emissions. This commenter's estimates are disaggregated across scopes of emissions as well as ''low maturity'' vs ''high maturity'' companies with respect to emissions reporting. Low maturity companies are defined as those that have no formal understanding of GHG emission calculations and have no related policies or programs in place. Accordingly, these companies have not organized or collected any data for such a calculation. High maturity companies are defined as those that have the aforementioned understanding, policies, programs, and data. Therefore, high maturity companies are expected to face lower incremental costs. The commenter estimates that the average first-year startup cost of assessing Scopes 1 and 2 emissions amount to $45,000 and $25,000 for companies of low and high maturity, respectively. Including the assessment of Scope 3 emissions would increase the costs by $80,000 and $25,000 for companies of low and high maturity, respectively. The commenter indicated that it expects these costs to decrease over time as software solutions simplify the process and reduce the burden on companies.

Additional cost estimates are provided by another commenter, which is an organization that assists companies, communities, and other organizations in accurately assessing emissions data across all scopes of emissions.[932] According to their pricing structure, initial one-time costs amount to $10,000, which includes identifying data input needs, developing the design and organization of user interfaces, establishing software and IT systems, and reporting emissions from prior years to the extent that historic data is available. Ongoing costs, which includes a subscription fee and data management fee, amount to $12,000 plus $1,200 per building that is covered

[925] *See* Letter from Williams Companies, Inc. (June 12, 2021).

[926] *See* U.K. Dep't for Bus., Energy, & Indus. Strategy, *Mandating Climate-Related Financial Disclosures by Publicly Quoted Companies, Large Private Companies and Limited Liability Partnerships (LLPs),* Final Stage Impact Assessment (Oct. 1, 2021), *available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1029317/climate-related-financial-disclosure-consultation-final-stage-impact-assessment.pdf* (The UK's climate-related disclosure rules would apply to Relevant Public Interest Entities (PIEs), including Premium and Standard Listed Companies with over 500 employees, UK registered companies with securities admitted to AiM with more than 500 employees, Limited Liability Partnership (LLPs) within the threshold of the ''500 test,'' and UK registered companies which are not included in the categories above and are within the threshold of the ''500 test.'').

[927] In the final stage impact assessment, the cost estimate provided for familiarization costs assumes that scenario analysis is required. Because the proposed rules do not require scenario analysis, this number references familiarization costs provided in the *initial* impact assessment, which assumes no scenario analysis. *See* U.K. Dep't for Bus., Energy, & Indus. Strategy, *Mandating Climate-Related Financial Disclosures by Publicly Quoted Companies, Large Private Companies and Limited Liability Partnerships (LLPs),* Consultation Impact Assessment (Jan. 29, 2021), *available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/972423/impact-assessment.pdf.*

[928] This number excludes the cost of scenario analysis since this is not required under the proposed rules.

[929] We note that these numbers do not include the costs of measuring and reporting Scope 3 emissions since this is not required under the UK proposed rules.

[930] These numbers have been converted from GBP based on the 2021 average exchange rate of $1.3757 USD/GBP, rounded to the nearest $100. We note that the impact assessment also provides estimates of incremental costs associated with each subsidiary; however, these costs are not included in the estimates cited above for the sake of brevity. Signposting costs refer to the ''additional annual cost to those in scope to upload the required reporting documentation and signposting to this documentation within their annual report.''

[931] *See supra* note 783. Legal and audit fees are not included in these cost estimates.

[932] *See* memorandum, dated Jan. 21, 2022, concerning staff meeting with representatives of Ledger8760, available at *https://www.sec.gov/comments/s7-10-22/s71022.htm.*

in the calculation of emissions. Another organization that offers similar services, among others, indicates that their fees for GHG accounting for Scopes 1, 2, and 3 can range from $11,800 to $118,300.[933] Their fees for applying the PCAF method on investment and lending portfolios range from $11,800 to $35,500. They note that the assessment process take approximately 1–3 months depending on the complexity and availability of data.

The EPA has also sought to quantify the costs of measuring and reporting emissions in accordance with the mandatory Greenhouse Gas Reporting Program, which generally requires facility-level reporting of emissions from large emitters and from large suppliers of certain products (*e.g.,* entities that produce gasoline that will eventually be consumed downstream by the end-user).[934] The EPA estimated that the rule would impose small expected costs on the facilities under its purview. The EPA estimated that, for most sectors, the costs represent at most 0.1% of sales.[935] For small entities,[936] the EPA estimated that the costs are on average less than 0.5% of sales. While the EPA's emissions reporting requirements, as discussed above, may elicit some of the information required under our proposed rules, given that the requirements are different, the actual compliance costs would differ accordingly.

A survey conducted by PCAF provides some estimates of the costs of assessing financed emissions.[937] Financed emissions, which can be one component of Scope 3 emissions for certain financial institutions, can be described as the emissions generated by companies in which a financial institution invests or to which it otherwise has exposure. The PCAF survey of 18 unnamed financial institutions [938] found that typical staff time ranged between 50 and 100 days and the costs for contracting external support was less than $20,000 for the majority of respondents. These estimates may provide some sense of the costs that may be incurred by those financial institutions that would be required to report Scope 3 emissions under the proposed rules.

(3) Cost Estimates of Assurance for Scopes 1 and 2 Emissions Disclosures

Registrants that are accelerated filers and large accelerated filers will incur additional costs in obtaining assurance of Scopes 1 and 2 emissions disclosures. The Commission estimates these costs starting with data on these filers' median audit fees in fiscal year 2020, which is $989,566 and $2,781,962 for accelerated filers and large accelerated filers, respectively.[939] Next, an academic study suggests that assurance costs for sustainability reports (which serve as a common location for climate-related information, in addition to other non-financial topics) may range from 5% to 10% of total audit fees.[940] We take the minimum, median, and maximum percentages (5%, 7.5%, and 10%, respectively) and apply further adjustments based on (i) emissions disclosures typically compromising only a portion of CSR reports, (ii) the potential fee premium related to attestation report included in SEC filings, and (iii) the average pricing difference between limited and reasonable assurance. For limited assurance, we estimate that accelerated filers will incur costs ranging from $30,000 to $60,000 (with a median of $45,000), while large accelerated filers will incur costs ranging from $75,000 to $145,000 (with a median of $110,000). For reasonable assurance, we estimate that accelerated filers will incur costs ranging from $50,000 to $100,000 (with a median of $75,000), while large accelerated filers will incur costs ranging from $115,000 to $235,000 (with a median of $175,000).

On the one hand, these estimates may underestimate actual costs as they are based on relative costs of assurance for financial statements, and assurance on emissions may differ in important ways. On the other hand, the costs may be lower in the future to the extent that the market for assurance services matures with respect to institutional knowledge, procedural efficiency, and overall competition. We request additional data that may assist in accurately assessing the costs of obtaining assurance over emissions disclosures.

(4) Factors That Affect Direct Costs

Incremental compliance costs may be relatively lower for registrants that already meet some of the disclosure and tagging requirements. For instance, registrants that are currently subject to the EPA's Greenhouse Gas Reporting Program would face lower incremental costs in reporting certain scopes of emissions relative to a firm that has no emissions measurement systems in place.[941] Similarly, registrants that already provide extensive qualitative disclosures on climate-related risks, which tend to be large accelerated filers and registrants in high emission industries,[942] may face lower incremental costs in meeting certain disclosure requirements. As discussed in Section IV.A.5.a, the Commission's staff reviewed 6,644 recent annual reports (Forms 10–K, 40–F, and 20–F) and found that 33% of them contained disclosures related to climate change, the majority of which discussed information related to business impact, emissions, international climate accords, and physical risks. Registrants with operations in foreign jurisdictions [943] where disclosure requirements are based on the TCFD's framework for climate-related financial reporting, would also face lower incremental costs.[944] Moreover, costs may also be mitigated by the proposed transition period, which would allow firms to more gradually transition to the new reporting regime.

Several industry reports also document how a sizeable portion of U.S.

[933] *See* memorandum, dated Jan. 14, 2022, concerning staff meeting with representatives of South Pole. These numbers have been converted from EUR based on the 2021 average exchange rate of $1.183 USD/EUR, rounded to the nearest $100.

[934] *See* Section IV.A.3 for more information on the EPA mandatory Greenhouse Gas Reporting Program.

[935] *See* EPA, *Regulatory Impact Analysis for the Mandatory Reporting of Greenhouse Gas Emissions* (Sept. 2009), *available at https://www.epa.gov/sites/default/files/2015-07/documents/regulatoryimpactanalysisghg.pdf.* The EPA notes that several facility types do not currently report emissions (or the existence of such disclosure practices cannot be confirmed), therefore the cost estimates for these facility types reflect full start-up costs to meet the reporting requirements.

[936] The EPA defines a small entity as (1) a small business, as defined by SBA's regulations at 13 CFR part 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; or (3) a small organization that is any not-for-profit enterprise that is independently owned and operated and is not dominant in its field.

[937] *See* Letter from PCAF (Dec. 21, 2021).

[938] The 18 survey respondents consist of 2 insurance companies, 13 banks (commercial, investment, or development), 1 asset owner, and 2 asset managers. Respondents' asset size ranges from less than a $1bn USD to $500bn USD. The average assets covered by this disclosure activity was approximately $5–20bn USD.

[939] Data on audit fees is from Audit Analytics, which provides all fee data disclosed by SEC registrants in electronic filings since Jan. 1, 2000.

[940] *See* R.J. Casey and J.H. Grenier, *Understanding and Contributing to the Enigma of Corporate Social Responsibility (CSR) Assurance in the United States,* 97 Auditing: A Journal of Practice & Theory 130 (2015).

[941] *See* Section IV.C.1.e for more information on how the proposed rules compare to the EPA's emissions reporting requirements.

[942] *See* Section IV.A.5.a.

[943] E.g., Morningstar reports that over 35% of S&P 500 revenues came from foreign markets, while this percentage is around 20% for the revenues coming from companies belonging to the Russell 2000 index. See, *https://www.morningstar.com/articles/918437/your-us-equity-fund-is-more-global-than-you-think.*

[944] See Section IV.A.4 for a discussion on International Disclosure Requirements.

companies report climate-related information under one or more third-party frameworks that are either fully or partially aligned with the TCFD disclosure elements. For example, the CCMC survey (G&A study) reports that among their sample of U.S. public companies, 44% (53%) use the SASB, 31% (52%) use the GRI, 29% (30%) use the TCFD, and 24% (40%) use the CDP. Moody's analytics provides a detailed view for a sample of 659 U.S. companies of the existing disclosure rate across the different TCFD disclosure elements that range from a high of 45% disclosure rate for Risks and Opportunities—Strategy (a), to a low of 5% for Risks and Opportunities—Strategy (c) (see Table 4). Since the proposed rules are broadly consistent with the TCFD framework, we would expect lower incremental compliance costs for registrants that provide most or all disclosures according to the TCFD or related frameworks, including the CDP, which has fully integrated the TCFD disclosure elements into its disclosure questionnaire, and other frameworks and/or standards partly aligned with the TCFD recommendations.

Similarly, registrants in the insurance industry may also face lower incremental costs due to their existing disclosure practices. As discussed in Section IV.A.3, a large subset of insurance firms are required to disclose their climate-related risk assessment and strategy via the NAIC Climate Risk Disclosure Survey. A comment by a state insurance commissioner stated that because this survey overlaps extensively with the TCFD recommendations, these firms should be able to easily switch to reporting via the TCFD disclosure framework.[945] This is because the proposed rules are broadly consistent with the TCFD. We expect that registrants in the insurance industry may be able to adapt more easily to providing disclosure under these rules.

Section IV.A.5.e reports survey evidence on the frequency with which firms obtain assurance in sustainability reports. This evidence suggests that a significant fraction of large companies already obtain some form, albeit limited, of assurance. To the extent that large accelerated filers and accelerated filers already voluntarily obtain some form of assurance over their GHG emissions, these registrants would face lower incremental costs associated with complying with the proposed rules' assurance requirements. These registrants tend to bear proportionately lower compliance costs than smaller issuers due to the fixed cost components of such compliance.[946] Additionally, as the market for assurance matures, the Commission staff expects these costs to decrease over time.

Incremental costs may be higher for smaller firms considering that they are less likely to have climate-related disclosure systems and processes already in place.[947] If smaller firms were to face higher proportional fixed costs in meeting the disclosure requirements, this may potentially put them at a competitive disadvantage to larger firms.[948] Conversely, incremental costs for smaller firms may be lower to the extent that they have less complexity with respect to their assets and operations, which may allow them to assess climate-risk exposures or measure emissions at lower cost.

With respect to the Inline XBRL tagging requirements, various preparation solutions have been developed and used by operating companies to fulfill their structuring requirements, and some evidence suggests that, for smaller companies, XBRL compliance costs have decreased over time.[949] The incremental compliance costs associated with Inline XBRL tagging of climate-related disclosures would also be mitigated by the fact that filers that would be subject to the proposed requirements would also be subject to other Inline XBRL requirements for other disclosures in Commission filings, including financial statement and cover page disclosures in certain periodic reports and registration statements.[950] As such, the proposal would not impose Inline XBRL compliance requirements on filers that would otherwise not be subject to such requirements, and filers may be able to leverage existing Inline XBRL preparation processes and/or expertise in complying with the proposed climate-related disclosure tagging requirements.

We expect that the number of registrants committed to preparing climate-related disclosures will increase in the future, independently from our proposed rules. As discussed in Section IV.B.1, a sizeable and growing portion of global investors consider climate change as the leading issue driving their engagements with companies and is demanding robust disclosure around its impacts and the plan to mitigate climate-related risks. Consistent with this increasing demand for climate-related information, recent trends showed an uptick in climate-related disclosures, particularly within samples of larger firms, though not necessarily through their regulatory filings.[951] Furthermore, the market for related services (*e.g.,* GHG accounting services, auditors, and other consultants, etc.) may become more competitive, driving down costs. To the extent that these trends continue in the future, we would expect that the incremental costs for complying with the proposed rules would become lower for an increasing number of firms.

b. Indirect Costs

In addition to the direct costs of preparing climate-related disclosures, the proposed rules could also lead to indirect costs. For example, the proposed rules may result in additional litigation risk since the proposed climate-related disclosures may be new

[945] *See* Letter from Mike Kreidler, Office of the Insurance Commissioner, State of Washington (June 14, 2021).

[946] For example, during fiscal year 2020, median audit fees as percentage of revenue for large accelerated filers and accelerated filers was 0.16%, while the corresponding figure for non-accelerated filers was 1.1%.

[947] *See supra* note 760. *See also* discussion of the Commission staff's review using climate-related keyword searches in Section IV.A.5.a.

[948] Because higher proportional fixed costs for smaller firms may be particularly acute with respect to assessing Scope 3 emissions, the proposed rules exempt SRCs from providing Scope 3 emissions disclosures. Since SRCs are a small fraction of the market, the overall benefit to investors would not be as large as for non-SRCs, while avoiding high fixed costs that could put them at a potential competitive disadvantage.

[949] An AICPA survey of 1,032 reporting companies with $75 million or less in market capitalization in 2018 found an average cost of $5,850 per year, a median cost of $2,500 per year, and a maximum cost of $51,500 per year for fully outsourced XBRL creation and filing, representing a 45% decline in average cost and a 69% decline in median cost since 2014. *See* M. Cohn, *AICPA Sees 45% Drop in XBRL Costs for Small Companies, Accounting Today* (Aug. 15, 2018) (stating that a 2018 NASDAQ survey of 151 listed registrants found an average XBRL compliance cost of $20,000 per quarter, a median XBRL compliance cost of $7,500 per quarter, and a maximum, XBRL compliance cost of $350,000 per quarter in XBRL costs per quarter), *available at https://www.accountingtoday.com/news/aicpa-sees-45-drop-in-xbrl-costs-for-small-reporting-companies (retrieved from Factiva database). See also* Letter from Nasdaq, Inc., Mar. 21, 2019 to the Request for Comment on Earnings Releases and Quarterly Reports; Release No. 33–10588 (Dec. 18, 2018) 83 FR 65601 (Dec. 21, 2018).

[950] *See* 17 CFR 229.601(b)(101); 17 CFR 232.405 (for requirements related to tagging financial statements (including footnotes and schedules) in Inline XBRL). *See* also 17 CFR 229.601(b)(104); 17 CFR 232.406 for requirements related to tagging cover page disclosures in Inline XBRL. Beginning in 2024, filers of most fee-bearing forms will also be required to structure filing fee information in Inline XBRL, although the Commission will provide an optional web tool that will allow filers to provide those tagged disclosures without the use of Inline XBRL compliance services or software. *See* 17 CFR 229.601(b)(108) and 17 CFR 232.408; Filing Fee Disclosure and Payment Methods Modernization, Release No. 33–10997 (Oct. 13, 2021), 86 FR 70166 (Dec. 9, 2021).

[951] *See* Section IV.A.5.

and unfamiliar to many registrants.[952] The proposed rules would significantly expand the type and amount of information registrants are required to provide about climate-related risks. Registrants unfamiliar preparing these disclosures may face significant uncertainty and novel compliance challenges. To the extent this leads to inadvertent non-compliance, registrants may face additional exposure to litigation or enforcement action.

However, certain factors may mitigate this concern. First, existing and proposed safe harbors [953] would provide protection from liability for certain statements by registrants, including projections regarding future impacts of climate-related risks on a registrant's consolidated financial statements and climate-related targets and goals. Second, the proposed rules would include phase-in periods after the effective date to provide registrants with sufficient time to become familiar with and meet the proposed disclosure requirements.[954]

Another potential indirect cost is the possibility that certain provisions of the proposed rules may force registrants to disclose proprietary information.[955] Under the proposed rules, registrants would be required to disclose a wide range of climate-related information, including potential impacts on its business operations or production processes, types and locations of its operations, products or services, supply chain and/or value chain. Registrants would be further required to disclose whether they have emissions-related targets and metrics or an internal carbon price, and if they do, what they are. To the extent that a registrant's business model or strategy relies on the confidentiality of such information, the required disclosures may put the registrant at a competitive disadvantage.

c. Other Cost Considerations

Although the proposed rules may impose significant compliance costs, we expect these costs to decrease over time, both from firm-specific and market-wide contexts. From the firm-specific context, registrant disclosing climate-related information for the first time is likely to incur initial fixed costs to develop and implement the necessary processes and controls.[956] Once the firm invests in the institutional knowledge and systems to prepare the disclosures, the procedural efficiency of these processes and controls should subsequently improve, leading to lower costs in following years.[957]

Establishing a framework for standardized climate-related disclosures could also reduce uncertainty for registrants over the specific content to disclose and could mitigate disclosure burdens to the extent that it reduces information requests from third parties. Before registrants can take any tangible steps toward preparing climate-related disclosures, they must first determine which specific climate-related discussions, metrics, and analyses are most appropriate to disclose—a process that, under the current regime, can involve significant uncertainty. Furthermore, the uncertain, complex, and multidimensional nature unique to climate-related risks, combined with the unpredictability of investor responses to such disclosures,[958] can also make it costly for management to determine the risks which meet the materiality threshold.

By implementing a standardized climate disclosure framework, the proposed rules could potentially reduce the burden that registrants may face in the environment of diverging voluntary frameworks and help clarify for registrants what they should disclose, where and when to make their disclosures, and what structure or methodology to use.[959] While a more principles-based approach would provide additional flexibility for registrants, it also may impose certain costs if they are unsure of what climate-related measures are needed to satisfy legal requirements. Such an approach could entail additional judgment on the part of management, or result in registrants erring on the side of caution in complex matters such as climate-related disclosures. This could ultimately translate into spending more resources to determine appropriate compliance with the Commission's applicable reporting standards. The proposed rules should provide legal certainty around climate-related disclosure and therefore mitigate the compliance burdens associated with the existing regulatory framework.

Furthermore, some registrants currently receive multiple, diverse requests for climate-related information from different parties, such as investors, asset managers, and data service providers. Responding to such third-party request can be costly and inefficient [960] and may put significant and sometimes competing demands on registrants.[961] A standardized climate disclosure framework could potentially reduce information requests from third parties to the extent that such requests overlap with the disclosures required under the proposed rules. We acknowledge, however, that registrants that currently use third-party frameworks to disclose climate-related information may incur certain costs of switching from their existing practice to our proposed disclosure framework.

From a market-wide context, mandated climate disclosures may heighten demand for certain data or third-party services related to preparing the required disclosures, including assistance with the reporting of emissions data. In the short term, there could be a potential increase in the prices of such services to extent that the initial growth in demand exceeds the supply. In the long term, however, this heightened demand is expected to spur competition, innovation, and other economies of scale that could over time lower associated costs for such services and data and improve their availability. Moreover, the aggregate accumulation of institutional knowledge may lead to a broad convergence of disclosure-related best practices, which could further reduce the costs of the proposed disclosures.

Overall, the market effects deriving from competition and innovation could enhance the efficiency and availability of relevant data and services, thereby

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[952] *See supra* note 841.

[953] As previously noted, registrants would be able to use the existing safe harbors for forward-looking statements that were added to the Securities Act and Exchange Act pursuant to the PSLRA assuming all conditions of those safe harbor provisions are met. *See supra* note 219.

[954] Compliance would be required in a registrant's fiscal year ending no earlier than two years after the effective date of any adopted rules. An additional one year phase-in would be provided for registrants that are not large accelerated filers, while complying with Scope 3 emissions reporting would also be provided with an additional one year phase-in.

[955] Proprietary costs are generally relevant for reporting that involves information about a firms' business operations or production processes and disclosures that are specific, detailed and process-oriented. *See, e.g.,* C. Leuz, A. Triantis, and T.Y. Wang, *Why Do Firms Go Dark? Causes and Economic Consequences of Voluntary SEC Deregistrations,* 45(2) Journal of Accounting and Economics 181–208 (2008); D.A. Bens, P. G. Berger, and S.J. Monahan, *Discretionary Disclosure in Financial Reporting: An Examination Comparing Internal Firm Data to Externally Reported Segment Data,* 86 (2) The Accounting Review 417–449 (2011).

[956] *See* Letter from Financial Executives International's (FEI) Committee on Corporate Reporting (CCR) (June 10, 2021).

[957] The assumption that first year's costs are greater than subsequent years' is consistent with the cost estimation models of the EPA's Greenhouse Gas Reporting Program and the UK's proposal of mandatory TCFD-aligned disclosure.

[958] *See* Section IV.B.2.a.(4).

[959] *See supra* note 806.

[960] *Id.*

[961] TCFD, *Status Report: Task Force on Climate-related Financial Disclosures,* (June 2019), *available at https://www.fsb-tcfd.org/wp-content/uploads/2019/06/2019-TCFD-Status-Report-FINAL-053119.pdf.*

lowering costs. These positive externalities from standard reporting practices can provide additional market-wide cost savings to the extent that they reduce duplicative effort in the production and acquisition of information.[962]

D. Anticipated Effects on Efficiency, Competition, and Capital Formation

1. Efficiency

As discussed in Section IV.B.2, the complexity, uncertainty, and long-term nature of climate risks make it unlikely that voluntary disclosure of such risks would be fully revealing. Therefore, as detailed in Section IV.C.1, mandating that climate-related disclosures be presented in a comparable and consistent manner and in a machine-readable language (Inline XBRL) is likely to enhance the information environment for investors. In doing so, the proposed rules are expected to improve market efficiency and price discovery by enabling climate-related information to be more fully incorporated into asset prices. Improved efficiency could inform the flow of capital and allow climate-related risks to be borne by those who are most willing and able to bear them.[963]

These expected improvements in market efficiency are broadly consistent with empirical research. If climate-related information is relevant for asset prices, and therefore market efficiency, then the effective disclosure of climate-related information would be expected to cause differential asset price/financing cost responses across firms and settings. Empirical evidence is largely consistent with this expectation. Academic studies have found evidence that among firms that voluntarily report emissions via the CDP questionnaire, those with higher emissions (relative to their size and industry peers) pay higher loan spreads.[964] A recent report from Lazard Ltd. also found a significant relationship between carbon dioxide emissions and a company's price-to-earnings ratio.[965] Even in settings with mandatory disclosure, evidence is consistent with abnormally positive stock returns on announcement date for low-emitters and negative returns for high-emitters.[966]

While the disclosure of climate-related information can improve market efficiency, investor response to such disclosures can vary depending on specific circumstances, thereby highlighting the limitations of the aforementioned studies.[967] For example, if increased disclosure causes investors to realize that their portfolios are more exposed to climate risk than previously known, valuations may fall and costs of capital may increase as investors reallocate capital to balance this risk. Further, aggregate pricing effects could also be due to a better understanding of future regulatory risks firms face.[968] Studies find, however, that cumulative abnormal stock returns around the announcement date are negatively correlated with firms' mandatorily disclosed emission levels. This consistent with mandatory reporting of climate-related information improving price discovery and market efficiency.

Empirical research has also documented evidence of market inefficiencies with respect to climate-related risks. For example, one study finds that stock prices of food companies (*i.e.* food processing and agricultural companies) may exhibit mispricing with respect to drought exposure.[969] The study documents that drought-exposed firms report reduced future profitability, indicating that drought exposure is a financial risk. In an efficient market, this risk should result in trading activity that decreases the current stock price and increases the expected return (to compensate investors for bearing this risk). The study, however, finds that drought-exposed firms deliver *lower* future returns relative to firms with less exposure, suggesting that the market initially under-reacts to drought exposure. In other words, the market may fail to sufficiently incorporate the risk of drought exposure into the current stock price, resulting in investors holding mispriced assets and bearing risk for which they are not appropriately compensated. Another study finds, through similar reasoning, that stock prices may exhibit mispricing with respect to temperature changes induced by climate change.[970] According to survey evidence of global institutional investors, respondents believe that equity valuations do not fully reflect climate-related risks.[971] Mandatory disclosures may help address these inefficiencies as it would provide investors with the information necessary to better incorporate climate-related risks into asset prices.

These capital market benefits can be further strengthened by the requirement to tag the climate-related disclosures in Inline XBRL, as XBRL requirements have been observed to reduce informational advantages of informed traders, increase stock liquidity, and reduce cost of capital.[972] These benefits

[962] *See supra* note 841.

[963] A recent study by McKinsey found that 85% of investors either agreed or strongly agreed that ''more standardization of sustainability reporting'' would help them allocate capital more effectively, and 83% either agreed or strongly agreed that it would help them manage risk more effectively. *See* Sara Bernow et al., *More Than Values: The Value-Based Sustainability Reporting That Investors Want,* McKinsey & Company (Aug. 7, 2019), *available at https://www.mckinsey.com/~/media/McKinsey/Business%20Functions/Sustainability/Our%20Insights/More%20than%20values%20The%20value%20based%20sustainability%20reporting%20that%20investors%20want/More%20than%20values-VF.pdf.*

[964] *See* S. Kleimeier, and M. Viehs, Carbon Disclosure, Emission Levels, and the Cost of Debt, Emission Levels, and the Cost of Debt, SSRN (2018), *available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2719665.*

[965] *See* Lazard Climate Center (2021), *available at https://www.lazard.com/media/451920/lazard-climate-center-presentation-december-2021.pdf.* The report examined more than 16,000 companies from 2016 through 2020 and found that investors are actively and directly pricing some transition risk into valuations, however the effects vary significantly across different types of GHGs, market cap, and sectors. Large cap companies (≤$50 billion) experience greater valuation discounts, while big emitters, such as energy companies, showed the starkest correlation. On average, a 10% decrease in a large U.S. energy company's emissions corresponded with a 3.9% increase in its price-to-earnings ratio.

[966] *See supra* note 850 (Jouvenout and Kruger, 2021).

[967] *Id. See also* J. Grewal, E.J. Riedl, and G. Serafeim, Market Reaction to Mandatory Nonfinancial Disclosure, 65 (7) *Management Science* 3061–3084 (2019); *See supra* note 850 (Bolton and Kacperczyk, 2020). The first paper in particular finds a negative aggregate stock market response to the passage of a mandatory ESG disclosure rules in the EU. These results, however, should be interpreted with caution. For one, the empirical design is based on matching, but there are reasons to believe that the treatment and control groups differ along important dimensions. Further, there is no event study plot, and results are not shown for cumulative abnormal returns after controlling for common risk factors like the Fama-French 3-factor model. It is therefore difficult to discern whether the passage of the disclosure rules is actually driving the aggregate market response.

[968] For example, the passage of disclosure rules may signal more stringent enforcement of emissions rules going forward, leading to an increase in the risk of regulation. Therefore, it is difficult to disentangle the pure effect of disclosure rules on stock performance and the cost of capital.

[969] *See* H. Hong, F.W. Li, J. Xu. *Climate Risks And Market Efficiency,* 208.1 Journal of Econometrics 265–28 (2019).

[970] *See, e.g.,* K. Alok, W. Xin, C. Zhang, *Climate Sensitivity And Predictable Returns, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3331872.*

[971] *See* P. Krueger, Z. Sautner, L.T. Starks, *The Importance of Climate Risks for Institutional Investors,* 33(3) The Review of Financial Studies, 1067–1111 (2020).

[972] *See, e.g.,* N. Bhattacharya, Y.J. Cho, J.B. Kim, *Leveling the Playing Field Between Large and Small Institutions: Evidence from the SEC's XBRL Mandate,* 93(5) The Accounting Review 51–71 (2018); B. Li, Z. Liu, W. Qiang, and B. Zhang, *The Impact of XBRL Adoption on Local Bias: Evidence from Mandated U.S. Filers,* 39(6) Journal of Accounting and Public Policy (2020); W. Sassi, H. Ben Othman, and K. Hussainey, *The Impact of Mandatory Adoption of XBRL on Firm's Stock Liquidity: A Cross-Country Study,* 19(2) Journal of Financial Reporting and Accounting 299–324

Continued

may also have valuation implications. The discounted cash flow model illustrates how, all else equal, a drop in the cost of capital leads to a boost in equity valuation, which can further benefit investors.

There are also important efficiency implications in relation to systemic risks.[973] The increasing frequency and severity of climate events can potentially lead to destabilizing losses for insurance companies,[974] banks,[975] and other financial intermediaries with direct and indirect exposures to different affected industries and assets. Some commentators state that, in addition to physical risks, the financial system could be destabilized also by potentially rapid and unexpected losses to carbon-intensive assets caused by a disorderly transition to a low-carbon economy or a shift in the market's perception of climate risks.[976] With insufficient and inconsistent disclosures, asset prices may not fully reflect climate-related risks. Consequently, market participants may inadvertently accumulate large exposures to such risks, leaving them vulnerable to considerable unexpected and potentially sudden losses.[977]

In the face of such losses, financial intermediaries may be forced to sell off assets at fire-sale prices to generate enough cash to pay claims or to otherwise meet the time-sensitive cash demands of creditors and counterparties. This fire-sale dynamic could push down asset prices as well as the value of firms holding similar assets due to mark-to-market losses, potentially increasing risk premia and correlations across asset classes.[978] Stress from large, complex, and interconnected financial institutions, or correlated stress across smaller market participants, could be transmitted and propagate through the financial system,[979] causing disruptions in the provision of financial services.[980] A more efficient allocation of capital brought about the disclosure required by the proposed rules could reduce the probability and magnitude of disorderly price corrections or dislocations, thereby strengthening financial system resilience.[981]

2. Competition

The provisions included in the proposed rules are expected to increase comparability among registrants by demanding climate-related information in a consistent manner and with machine-readable data language (Inline XBRL). More standardized climate reporting could improve competition among registrants as it could reduce their costs for both producing such information due to enhanced efficiencies of scale across the economy and the cost for acquiring and processing said information by investors.

As discussed in Section IV.C.2, positive externalities from standard reporting practices can provide market-wide cost savings to registrants in the long-term, to the extent that they reduce duplicative effort in registrants' production and acquisition of information (*e.g.* certain data or third-party services related to preparing the required disclosures, including the reporting of emissions data, may become cheaper in the long run as the heightened demand spur competition, innovation, and other economies of scale). These cost savings could be particularly helpful for smaller registrants, or those that are capital constrained, which otherwise may not be able to provide the same amount, or level of detail, of climate-related disclosures as registrants with greater resources.

More standardized reporting should also reduce investors' costs for acquiring and processing climate-related information by facilitating investors' analysis of a registrant's disclosure and assessing its climate-related risks against those of its competitors. The placement of climate-related information in SEC filings with machine-readable data language (Inline XBRL), rather than external reports or company websites, should also make it easier for investors to find and compare this information.

Overall, we expect that by standardizing reporting practices, the proposed rules would level the playing field among firms, making it easier for investors to assess the climate-related risks of a registrant against those of its competitors. The effects of peer benchmarking can contribute to increased competition for companies in search for capital both across and within industries, whereby firms can be more easily assessed and compared by investors against alternative options.

Failure to implement the proposed rules could lead to an informational gap between U.S. registrants and companies

(2021); C. Ra and H. Lee, *XBRL Adoption, Information Asymmetry, Cost of Capital, and Reporting Lags,* 10 IBusiness, 93–118 (2018); S.C. Lai, Y.S. Lin, Y.H. Lin, and H.W. Huang, XBRL *Adoption and Cost of Debt,* International Journal of Accounting & Information Management (2015); Y. Cong, J. Hao, and L. Zou, *The Impact of XBRL Reporting on Market Efficiency,* 28(2) Journal of Information Systems 181–207 (2014).

[973] Systemic risk refers to the risk of a breakdown of an entire system, rather than simply the failure of individual parts. In a financial context, systematic risk denotes the risk of a cascading failure in the financial sector, caused by linkages within the financial system, resulting in a severe economic downturn.

[974] *See Facts + Statistics: Global Catastrophes,* Insurance Information Institute, *available at https://www.iii.org/fact-statistic/facts-statistics-global-catastrophes.*

[975] The Office of the Comptroller of the Currency (OCC) recently requested feedback on draft principles designed to support the identification and management of climate-related financial risks at OCC-regulated institutions with more than $100 billion in total consolidated assets. *See Principles for Climate-Related Financial Risk Management for Large Banks,* Office of the Comptroller of the Currency (2021), *available at https://occ.gov/news-issuances/news-releases/2021/nr-occ-2021-138.html?source=email.*

[976] Gregg Gelzinis and Graham Steele, *Climate Change Threatens the Stability of the Financial System,* Center for American Progress (Nov. 21, 2019, 12:01 a.m.), *available at https://www.americanprogress.org/issues/economy/reports/2019/11/21/477190/climate-change-threatens-stability-financial-system.*

[977] *See The Availability Of Data with Which to Monitor and Assess Climate-Related Risks to Financial Stability,* The Financial Stability Board (''FSB'') (July 7, 2021) (stating that the availability of data with which to monitor and assess climate-related risks to financial stability), *available at https://www.fsb.org/2021/07/the-availability-of-data-with-which-to-monitor-and-assess-climate-related-risks-to-financial-stability/.*

[978] *The Implications of Climate Change for Financial Stability,* FSB, *available at https://www.iii.org/fact-statistic/facts-statistics-global-catastrophes* (2021).

[979] Physical risks can have immediate and direct effects on asset values, but they also present long-term indirect risks. By damaging assets that serve as collateral for loans or that underpin other investments, reducing property values, increasing insurance premiums or decreasing insurance coverage, diminishing agricultural capacity, and causing labor forces to migrate, the physical consequences of climate change could have profound and long term effects on financial markets more generally. *See* Jonathan Woetzel et al., *Climate Risk and Response: Physical Hazards and Socioeconomic Impacts,* McKinsey Global Institute (Jan. 2020), *available at https://www.mckinsey.com/business-functions/sustainability/our-insights/climate-risk-and-response-physical-hazards-and-socioeconomic-impacts.*

[980] A recent report by an advisory committee to the Commodity Futures Trading Commission (CFTC) concluded that ''climate change poses a major risk to the stability of the U.S. financial system and to its ability to sustain the American economy.'' See Report of the Climate-Related Market Risk Subcommittee, Market Risk Advisory Committee of the U.S. Commodity Futures Trading Commission, Managing Climate Risk in the U.S. Financial System (2020). The Office of the Comptroller of the Currency (OCC) has identified the effects of climate change and the transition to a low carbon economy as presenting emerging risks to banks and the financial system. *See, e.g.,* Semiannual Risk Perspective, 2–4 (Fall 2021), *available at https://www.occ.treas.gov/publications-and-resources/publications/semiannual-risk-perspective/files/pub-semiannual-risk-perspective-fall-2021.pdf.*

[981] *See The Availability Of Data with Which to Monitor and Assess Climate-Related Risks to Financial Stability,* (July 7, 2021) (stating that the availability of data with which to monitor and assess climate-related risks to financial stability), *available at https://www.fsb.org/2021/07/the-availability-of-data-with-which-to-monitor-and-assess-climate-related-risks-to-financial-stability/.*

operating in foreign jurisdictions which require climate-related disclosures. For example, such a gap may increase investors' uncertainty when assessing climate-related risks of U.S. registrants vis-à-vis foreign competitors and place U.S. registrants at a competitive disadvantage, with the potential to deter investments and hence increase U.S. registrants' cost of capital. This informational gap may also pose obstacles to U.S. companies transacting with counterparts and businesses in their supply-chain operating in foreign jurisdictions which require Scope 3 emission disclosures. According to Morningstar, more than 35% of S&P 500 firms' total revenues came from foreign markets, while this percentage is around 20% for the revenues of Russell 2000 firms.[982] Lack of standardized disclosures around Scope 1 and 2 GHG emission by U.S. companies, which may in part be due to the aforementioned impediments to voluntary disclosure,[983] may obstruct foreign counterparts from accurately assessing their Scope 3 GHG emissions, thus putting U.S. registrants at a competitive disadvantage over other foreign companies which may be publicly disclosing such information.

3. Capital Formation

More consistent, comparable, and reliable disclosures could lead to capital-market benefits in the form of improved liquidity, lower costs of capital, and higher asset prices (or firm valuations).[984] Enhanced disclosures (*e.g.,* accurate GHG emissions disclosures) can reduce the time necessary for processing registrant's relevant information, thus increasing efficiency for registrants in their access to capital and allowing the market to more efficiently assess its cost. These benefits would stem from reductions in information asymmetries brought about by the required disclosure of climate-related information. More comparable, consistent, and reliable climate-related disclosures could reduce information asymmetries, both among investors and between firms and their investors.

In the first case, less information asymmetry among investors could mitigate adverse selection problems by reducing the informational advantage of informed traders.[985] This is likely to improve stock liquidity (*i.e.,* narrower bid-ask spreads), which could attract more investors and reduce the cost of capital. In the second case, less information asymmetry between firms and their investors could allow investors to better estimate future cash flows, which could reduce investors' uncertainty, as well as the risk premium they demand, thus lowering the costs of capital.[986]

Recent studies provide some supporting empirical evidence of these effects within the context of ESG- or climate-related disclosure. These studies have found that, when firms voluntarily provide material sustainability disclosures, they also experience improvements in liquidity (*e.g.* smaller bid-ask spreads).[987] In addition, firms that choose to disclose emissions have lower costs of equity and loan spreads.[988] While firms' decisions about whether and when to disclose emissions data may be correlated with other factors as well asset prices/financing costs, this would be consistent with such disclosures reducing the costs of capital for firms (to the extent that some of these effects are driven by the disclosures themselves).

E. Other Economic Effects

The proposed rules may have some effects on firm behavior. Prior empirical evidence supports the notion that, in response to mandatory ESG-related disclosure rules, firms tend to report actions that appear more ''favorable'' with respect to the corresponding disclosures. These decisions would be made by a firm's management with the goal of maximizing firm value in response to the new disclosure mandate. To the extent that these actions reduce firms' exposures to physical and transition risks, this could lower the return that investors require for investing in these firms, hence facilitating capital formation. This could reduce volatility of stock returns due to enhanced resiliency against such risks.

Empirical evidence shows that mandatory reporting of GHG emissions results in reduced aggregate reported emissions among affected firms.[989] Academic research shows that mandatory ESG-related disclosure often contributes, not only to increased monitoring by investors or other stakeholders, but also to enhanced peer benchmarking by firms as they can more easily compare themselves with their competitors.[990] These changes may reflect market responses by companies and investors to the newly disclosed information. Accordingly, registrants may change their behavior in response to the proposed disclosure requirements by reducing exposures to certain physical or transition risks. However, this could also come with the potential cost of lower productivity, profitability, or market share in the short-term.

Registrants might respond to the proposed disclosures by devoting more resources to climate-related governance and risk management in an effort to address indirect effects on their business arising from the disclosures. For example, the proposed rules require disclosure of members of the board or management that have prior climate expertise. Some registrants may respond by giving more weight to climate expertise when searching for directors, which may lead them to deviate from the board composition that would have been in place absent the proposed rules. Similarly, the proposed rules would require disclosure on how climate-related risks can impact registrants' consolidated financial statements, among others. Registrants may respond by taking measures to minimize

[982] See, *https://www.morningstar.com/articles/918437/your-us-equity-fund-is-more-global-than-you-think.*

[983] *See* Section IV.B.2.

[984] *See* D.W. Diamond and R.E. Verrecchia, Disclosure, Liquidity, and the Cost of Capital, 46 *J. Fin.*1325 (1991) (this study finds that revealing public information to reduce information asymmetry can reduce a firm's cost of capital through increased liquidity); See also C. Leuz and R.E. Verrecchia, The Economic Consequences of Increased Disclosure, 38 *J. Acct. Res.* 91 (2000). Several studies provide both theoretical and empirical evidence of the link between information asymmetry and cost of capital. *See, e.g.,* T.E. Copeland and D. Galai, *Information Effects on the Bid-Ask Spread,* 38 J. Fin. 1457 (1983) (proposing a theory of information effects on the bid-ask spread); D. Easley and M. O'Hara, *Information and the Cost of Capital,* 59 J. Fin. 1553 (2004) (This study shows that differences in the composition of information between public and private information affect the cost of capital, with investors demanding a higher return to hold stocks with greater private information.).

[985] *See* R.E. Verrecchia, *Essays on Disclosure,* 32(1–3) Journal of Accounting and Economics 97–180 (2001).

[986] *See supra* note 841*; See also* D.W. Diamond and R.E. Verrecchia, *Disclosure, Liquidity, and the Cost of Capital,* 46(4) The Journal of Finance 1325–1359 (1991).

[987] *See* J. Grewal, C. Hauptmann, and G. Serafeim, *Material Sustainability Information and Stock Price Informativeness,* Journal of Business Ethics 1–32 (2020); M.E. Barth, S.F. Cahan, L. Chen, and E.R. Venter, *Integrated Report Quality: Share Price Informativeness and Proprietary Costs,* Socially Responsible Investment eJournal (2021).

[988] *See* D.S. Dhaliwal et al., *Voluntary Nonfinancial Disclosure and the Cost of Equity Capital: The Initiation of Corporate Social Responsibility Reporting,* 86.1 The Accounting Review 59–100 (2011; S. Kleimeier, and M. Viehs, *Carbon Disclosure, Emission Levels, and the Cost of Debt, Emission Levels, and the Cost of Debt* (2018); E.M. Matsumura, R. Prakash, and S.C. Vera-Munoz. *Climate Risk Materiality and Firm Risk, available at* SSRN 2983977 (2020).

[989] *See* B. Downar, J. Ernstberger, S. Reichelstein, S. Schwenen, and A. Zaklan, *The Impact of Carbon Disclosure Mandates on Emissions and Financial Operating Performance,* Review of Accounting Studies 1–39 (2021); S. Tomar, *Greenhouse Gas Disclosure and Emissions Benchmarking* (Working Paper) (2021), *available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3448904; See supra* note 850 (Jouvenout and Kruger, 2021).

[990] *See supra* note 841.

negative impacts in order to put forth more favorable metrics. For example, registrants may move assets or operations away from geographic areas with higher physical risk exposures or may seek to decrease GHG emissions.

The provision on GHG Emissions would also require scope 1, 2, and 3 (if material or the registrant has a set a target or goal for scope 3) emission disclosures. These emission disclosures may induce firms to use peer benchmarking to decide whether to investigate and reevaluate their energy usage [991] or otherwise reduce emissions based on anticipated market reactions to the disclosed information. This process may provide certain registrants with incentives to search for alternative energy sources or find different suppliers, which could increase costs. Conversely, it could also prompt certain firms to reduce nonessential activities and improve operational efficiency, which could lead to lower operating costs.

The provision requiring assurance of GHG Scopes 1 and 2 emissions disclosures would only apply to accelerated filers. Non-accelerated filers would, instead, be required only to state whether any of their GHG emissions disclosures were subject to third-party assurance, and if so, at what level. By asking all registrants, including non-accelerated filers, to disclose climate-related information within SEC filings, however, the proposed rules may motivate more non-accelerated filers to voluntarily seek assurance over these types of disclosures, than if the same information had been disclosed on companies' websites or sustainability reports. Certain non-accelerated filers may also voluntarily decide to attain assurance over their GHG emission disclosures in order to enhance their reliability and prevent these disclosures from being perceived by investors as less reliable compared to those provided by accelerated filers.

As another example, the proposed rules would require the disclosure of the location (via ZIP code) of firm assets or operations, which could allow investors to assess firms' exposures to physical risk at a more granular level. This may allow investors to more easily diversify these geographic-driven risks or expose themselves to such risks, if they choose to, more deliberately. This may cause some firms to relocate assets or operations to geographical areas less exposed to physical risks and/or give preferences to such areas for future business activity. It may also cause some firms with higher geographic exposures to physical risks to alter overall operational risk and strategies.

The proposed rules might also affect the networks firms choose to operate in. For example, a firm may choose to change some suppliers or disengage with certain clients due to the effect that they may have on the firm's Scope 3 emissions. This may be particularly relevant for certain financial institutions that are impacted by their portfolio firms' emissions or climate-related risks. These financial institutions may be less willing to extend credit to firms for which it is difficult to measure climate risk exposure information, potentially increasing the cost of capital for these firms.

However, there are certain factors that may mitigate this effect. First, the proposed rules establish a phase-in period, which is intended to give financial institutions and their prospective borrowers sufficient time to prepare the required disclosures. Second, analytical tools, data, and related methodologies (such as those related to measuring/reporting GHG emissions) are developing rapidly and increasing in availability. Finally, frameworks like the PCAF to measure financed emissions would allow financial institutions to compute proxies for the emissions of their clients in a systematic and comparable manner even in the absence of actual emissions data.

The proposed rules could also cause some firms to pursue avoidance strategies. The provision on Targets and Goals would require a registrant to disclose whether it has set any climate-related targets or goals and the specific plans in place to achieve those objectives and metrics to monitor progress. This may disincentivize certain firms from making such commitments and providing the associated disclosures in SEC filings. Risk of litigation or enforcement actions, could result in registrants being more cautious in their decision to set climate-related targets. Other firms, however, may find the existence of mandatory disclosures around climate-related targets and goals to be beneficial for signaling credible value-enhancing commitments to investors. More credible and standardized disclosures on climate-related targets and goals could make registrants' communication more effective and facilitate investors' understanding of related progress, hence providing additional incentives for making such commitments.

More generally, if compliance costs with the proposed rules are high, this could influence the marginal firm's decision to exit public markets or refrain from going public in the first place in order to circumvent the disclosure requirements. Firms may choose this strategy if they believe the potential compliance costs from the proposed rules outweigh the benefits of being registered public company. Uptake of this avoidance strategy may widen the transparency gap between public and private firms, negatively affecting capital markets' information efficiency, and potentially reduce the size of the stock market. However, it is unlikely that a significant number of firms would pursue this avoidance strategy given that it would come with significant disadvantages, such as higher costs of capital, limited access to capital markets, and limits to their growth potential. Moreover, recent trends in private markets indicate that industry's top leaders are working toward a standard set of metrics for tracking their portfolio companies' ESG progress. The pressure on private companies to disclose information on climate-related risks is rapidly escalating within the private industry, hence diminishing the potential incentive for registrants to go private in order to avoid climate-related disclosure requirements. For example, since its launch in September 2021, the ESG Data Convergence Project, which seeks to standardize ESG metrics and provide a mechanism for comparative reporting for the private market industry, has announced a milestone commitment of over 100 leading general partners and limited partners to its partnership representing $8.7 trillion USD in AUM and over 1,400 underlying portfolio companies across the globe. The initial data for the project includes, among others, greenhouse gas emissions and renewable energy metrics.[992]

F. Reasonable Alternatives

1. Requirements Limited to Only Certain Classes of Filers

One alternative would be to require the proposed disclosures only from larger registrants, such as large accelerated filers or non-SRCs. While the proposed rules already provide certain exemptions for SRCs (*e.g.,* Scope 3 emissions disclosures and assurance requirements), this alternative would exempt smaller registrants from the entirety of the proposed rules. The main benefit of this alternative is that it

[991] *See supra* note 841.

[992] *See* Carlyle, Private Equity Industry's First-Ever ESG Data Convergence Project Announces Milestone Commitment of Over 100 LPs and GPs (Jan. 28, 2022), *available at https://www.carlyle.com/media-room/news-release-archive/private-equity-industrys-first-ever-esg-data-convergence-project-announces-over-100-lps-gps.*

would avoid imposing potentially significant compliance costs on smaller registrants, which are more likely to be resource-constrained. However, considering that SRCs make up approximately 50% of registrants (and registrants that are not large accelerated filers make up approximately 70%), this alternative would also considerably undermine one of the primary objectives of the proposed rules, which is to achieve consistent, comparable, and reliable disclosures of climate-related information. Furthermore, climate-related risks are impacting or are expected to impact every sector of the economy,[993] further highlighting the need for enhanced disclosures from all registrants. In an effort to arrive at an appropriate balance between these costs and benefits, the proposed rules exempt SRCs from some, but not all, disclosure requirements.

2. Require Scenario Analysis

Another alternative would be to require registrants to conduct scenario analysis and include the related information in their disclosures. Consistent, comparable, and reliable disclosures of scenario analysis could inform investors with respect to the resilience of registrants' business strategies and operations across a range of plausible future climate scenarios. Disclosure of scenario analysis could deliver informational benefits to investors beyond that which would be provided under the proposed rules. It could help investors assess issues that have high uncertainty by evaluating the impact on and the resiliency of the registrant under multiple plausible future scenarios, such as a temperature increase of 1.5°C, 2°C, and 3°C above pre-industrial levels. It could also allow investors to proactively manage risk as they would be better able to assess the range of potential threats and opportunities, evaluate different management actions, and adapt accordingly. Furthermore, since some climate-related risks may only manifest over longer horizons, scenario analysis could assist investors in determining whether registrants have incorporated such risks into their long-term strategy. Investors could subsequently incorporate this information into asset prices, thereby more accurately pricing climate-related risks and contributing to market efficiency.

Both scenario analysis methodologies and climate science, however, continue to advance and develop, which may pose significant challenges for some registrants. Specifically, the required data may be unavailable or costly to obtain. Furthermore, some registrants may lack the necessary expertise, requiring them to hire external consultants to conduct the analysis. These challenges may pose undue burdens with respect to difficulty and/or costs to some registrants, such as smaller companies and those that otherwise have no prior experience in scenario analysis. For these reasons, the Commission is not proposing to mandate scenario analysis and related disclosure at this time.

3. Require Specific External Protocol for GHG Emissions Disclosure

Another alternative would be to require registrants to follow an external protocol (*e.g.,* GHG protocol) for reporting emissions. Requiring a specific protocol may potentially benefit investors by providing a more consistent and comparable framework in reporting emissions, thus facilitating investors' information processing. However, there also may be certain drawbacks.

First, the organizational boundaries adopted by external protocols may create inconsistencies with the way companies would report information about their GHG emissions vis-à-vis the rest of their financial statements. The GHG Protocol, for example, requires that a company base its organizational boundaries on either an equity share approach or a control approach, which may differ from the way registrants set their scope for the purpose of reporting information in their financial statements. The proposed rules would require a registrant to set the organizational boundaries for its GHG emissions disclosure using the same scope of entities, operations, assets, and other holdings as those included in its consolidated financial statements. Requiring a consistent scope of consolidation and reporting between financial data and GHG emissions data should help avoid potential investor confusion about the reporting scope used in determining a registrant's GHG emissions and the reporting scope used for the financial statement metrics.

Furthermore, requiring companies to follow a specific external protocol might limit flexibility for registrants and thus reduce their ability to report emissions in a manner that is tailored to their specific circumstances. For example, registrants following an existing but different protocol, which nevertheless provides relevant emissions information, would be required to switch protocols, incurring additional cost.

Requiring compliance with a specific protocol could also reduce the scope for innovation in driving the most appropriate forms of disclosure within these overarching guidelines (*e.g.,* the methodologies pertaining to the measurement of GHG emissions, particularly Scope 3 emissions, are still evolving). Additionally, requiring compliance with a specific external protocol as of the date of the adoption of any final rules may become problematic in the future to the extent that the external protocol's methodologies shift or evolve such that the version incorporated by reference into the final rules becomes outdated or inconsistent with improving methodologies. While we expect that many registrants will choose to follow many of the standards and guidance provided by the GHG Protocol when calculating their GHG emissions, not requiring compliance with the GHG Protocol would provide some flexibility to the Commission's climate-related disclosure regime and enable registrants to follow new and potentially less costly methodologies as they emerge.

4. Permit GHG Emissions Disclosures To Be ''Furnished'' Instead of ''Filed''

Another alternative would be to permit Scopes 1, 2, and 3 emissions disclosures to be considered ''furnished'' instead of ''filed,'' which may limit the incremental risk of being held liable under Section 18 of the Exchange Act for these disclosures. This may also benefit some registrants as their Scopes 1 and 2 emissions disclosures would not be automatically incorporated into Securities Act registration statements and thereby not be subject to Section 11 liability. We note that this could have a lower incremental impact on Scope 3 emissions disclosures since Scope 3 emissions disclosures are covered under a proposed safe harbor provision and hence already afforded other liability protections. However, reduced liability in general may lead to the applicable disclosures being perceived as less reliable by investors, which could have adverse effects on registrants' stock liquidity or costs of capital. For these reasons, the Commission is not proposing to permit emissions disclosures to be furnished at this time.

5. Do Not Require Scope 3 Emissions for Registrants With a Target or Goal Related to Scope 3

Another alternative would be to not require Scope 3 emissions disclosures if

[993] SASB research shows climate risk is nearly ubiquitous but highly differentiated across 77 industries. *See SASB Publishes Updated Climate Risk Technical Bulletin* (Apr. 13, 2021), available at *https://www.globenewswire.com/news-release/2021/04/13/2208855/0/en/SASB-Publishes-Updated-Climate-Risk-Technical-Bulletin.html.*

such emissions are part of a target or goal from any registrant. This would allow certain registrants to avoid the potentially significant costs and difficulties associated with measuring and reporting Scope 3 emissions. This could potentially deprive investors of important information necessary to assess registrants' exposures to certain risks associated with trying to achieve targets or transition plans. Scope 3 emissions can provide investors with a more complete picture of how targets or transition plans might impact risks (*e.g.,* future regulations restricting emissions or changes in market conditions that disfavor high emissions products or services) of the registrant through the value chain. This can be particularly important considering that Scope 3 emissions can make up the vast majority of total emissions for many registrants.[994] Furthermore, some firms can give the appearance of low (direct) emissions by shifting high-emission activities elsewhere in their value chain.[995] Mandatory disclosure of Scope 3 emissions for registrants with a target or goal related to Scope 3 emissions can help prevent such misrepresentation.

6. Exempt EGCs From Scope 3 Emissions Disclosure Requirements

Another alternative would be to retain the exemption for SRCs, as currently proposed, but also extend it to EGCs. EGCs may similarly face resource constraints related to company size or age, hence this alternative would allow EGCs to avoid the costs of Scope 3 emissions measurement and reporting. Given that the designations of SRC and EGC are not mutually exclusive, however, EGCs that are also SRCs would be covered under the exemption as currently proposed. Conversely, EGCs that are *not* SRCs are relatively less resource-constrained since they, by definition, have greater revenues and/or public float, and therefore may be better positioned to provide Scope 3 emissions disclosures.

7. Eliminate Exemption for SRCs From Scope 3 Reporting

Another alternative would be to eliminate the exemption for SRCs. Because SRCs make up approximately half of domestic filers in terms of numbers (though considerably less in terms of market cap), this alternative could address data gaps with respect to Scope 3 emissions, with the potential to benefit all investors. As discussed in Section II.G.3, however, this alternative may pose fixed costs (*e.g.* data gathering and verification), that would fall disproportionately on SRCs. Also, because SRCs are a small fraction of the market, the overall benefit to investors would be limited.

8. Remove Safe Harbor for Scope 3 Emissions Disclosures

The proposed rules provide a safe harbor for Scope 3 emissions disclosures. An alternative would be to remove this safe harbor for Scope 3 emissions disclosures. This alternative would strengthen accountability for Scope 3 emissions disclosures. It also would significantly increase registrants' exposure to litigation over the accuracy of such disclosures. While rigorous liability in many contexts can provide incentives that promote reliable disclosures, an accommodation may be warranted for Scope 3 emissions due to the challenges associated with their measurement and disclosure.[996]

9. Require Large Accelerated Filers and Accelerated Filers To Provide a Management Assessment and To Obtain an Attestation Report Covering the Effectiveness of Controls Over GHG Emissions Disclosures

The proposed rules would require assurance over Scopes 1 and 2 emissions disclosure from large accelerated filers and accelerated filers. In addition to such assurance, we could require these filers to also obtain either a separate assessment by management and disclosure on the effectiveness of controls over GHG emissions disclosures or an attestation report specifically covering the effectiveness of controls over GHG emissions disclosures, or both. Specifically, management could be required to include a statement in the annual report on their responsibility for the design and evaluation of controls over GHG emission disclosures, as well as to disclose their conclusion regarding the effectiveness of controls over GHG emissions disclosures, in addition to the existing DCP evaluation and disclosure. In addition, we could require a GHG emissions attestation provider to obtain reasonable assurance on whether material weaknesses exist regarding management's assessment of the effectiveness of controls over GHG emissions disclosures as of the measurement date. The GHG emissions attestation provider could also be required to issue an attestation report on the effectiveness of controls over GHG emissions disclosures.[997]

By requiring GHG emissions attestation providers to assess not just the disclosures, but also the controls over GHG emissions disclosures (*i.e.,* the underlying mechanisms, rules, and procedures associated with generating such disclosures), this alternative could further strengthen the integrity of the disclosed information. In the context of emissions, GHG emissions attestation providers may evaluate and test the effectiveness of registrants' controls related to the collection, calculation, estimation, and validation of GHG emissions data and disclosure. These processes could strengthen disclosure credibility as they reduce the likelihood of errors or fraud and their ensuing misstatements.[998] Investors would benefit from any resulting improvement in disclosure reliability for reasons discussed in prior sections: It would allow investors to make better-informed investment decisions, allow applicable information to be better incorporated into asset prices, and contribute to a more efficient allocation of capital. Registrants may also benefit via reduced costs of capital and increased stock liquidity.

However, this alternative would also impose additional assurance costs.[999] Given that GHG emissions measurement and disclosure are developing areas, it is unclear what exact controls are or would be in effect, making it difficult to anticipate precisely what such attestation would entail. These uncertainties pose further difficulties in obtaining informative cost estimates and, accordingly, accurate assessments of how burdensome such a requirement would be to registrants. This leaves the

[994] *See supra,* note 888.

[995] *See supra,* note 893.

[996] *See* Section II.G.3

[997] *See* AICPA, AU–C 940, *An Audit of Internal Control Over Financial Reporting That Is Integrated With an Audit of Financial Statements* (2021), *available at https://www.aicpa.org/content/dam/aicpa/research/standards/auditattest/downloadabledocuments/au-c-00940.pdf.*

[998] Potentially consistent with this, though in a different setting, academic evidence surrounding Section 404 of the Sarbanes-Oxley Act (SOX) finds lower accruals and discretionary accruals for small firms whose 2002 float (prior to when firms could have known and therefore tried to alter their float to avoid the regulation) made them likely to be just above the requirements for compliance, relative to those just below. Iliev, Peter (2010). The effect of SOX Section 404: Cost, earnings quality and stock prices. Journal of Finance, 65, 1163–1196.

[999] Also potentially consistent with this, prior academic studies of Section 404 of SOX find significantly higher auditing fees, negative stock returns, and reduced innovation, though no clear evidence of a decline in investment, for marginally complying small firms near the float requirement threshold. *See* Iliev, Peter (2010). The effect of SOX Section 404: Cost, earnings quality and stock prices. Journal of Finance, 65, 1163–1196; Gao, Huasheng, and Jin Zhang (2019). SOX Section 404 and corporate innovation. Journal of Financial and Quantitative Analysis 54(2): 759–787; Albuquerque, Ana and Julie Lei Zhu (2019). Has Section 404 of the Sarbanes-Oxley Act discouraged corporate investment? New evidence from a natural experiment. Management Science 65(7): 3423–3446.

possibility that the costs could outweigh the incremental benefits given that the proposed rules already require assurance for Scopes 1 and 2 emissions disclosures for applicable registrants. For these reasons, the Commission is not proposing at this time to require an attestation report on the effectiveness of controls over GHG emissions disclosures.

10. Require Reasonable Assurance for Scopes 1 and 2 Emissions Disclosures From All Registrants

Another alternative would be to require reasonable assurance for Scopes 1 and 2 emissions disclosures from all registrants. As described above, requiring assurance can benefit investors in several ways, including enhanced reliability of disclosures, which would allow investors to make better-informed investment decisions

However, because costs increase with the level of assurance, requiring reasonable assurance may be particularly burdensome for affected registrants (*i.e.,* smaller firms) as they would be more likely to incur proportionately higher compliance costs due to the fixed cost components of such compliance, regardless of whether or not there is a transition period before this requirement takes effect. While the benefits of assurance could be approximately proportional to registrant's market value, the costs are not. In an effort to arrive at an appropriate balance between these factors, the proposed rules would require reasonable assurance (after a specified transition period) only from large accelerated filers and accelerated filers because the benefits to investors are more likely to justify the costs for these firms.

11. Require Limited, Not Reasonable, Assurance for Large Accelerated Filers and/or Accelerated Filers and/or Other Filers

Obtaining reasonable assurance generally costs more than obtaining limited assurance. Current market practice appears to favor obtaining limited assurance over sustainability reports, if assurance is obtained at all. Experimental evidence suggests assurance (relative to none) may increase perceived reliability of sustainability reports, but is yet to provide evidence that reasonable assurance increases perceived reliability of sustainability reports relative to limited assurance.[1000] We acknowledge, however, that experimental findings from lab settings may not necessarily reflect the behavior or preferences of experienced investors in actual financial markets. Furthermore, other research often exhibits a selection bias (*i.e.,* companies that voluntarily decide to obtain a higher-than-required level of assurance are systematically different across several dimensions), making it difficult to determine the causal effect of the different levels of assurance.[1001]

One possibility to mitigate the additional costs of reasonable assurance would be to maintain the requirement that large accelerated filers obtain reasonable assurance, but allow accelerated filers to obtain limited assurance without any scaling up to a reasonable assurance. Another possibility would be to require limited assurance, but expand the assurance requirement to a broader scope of registrants including non-accelerated filers and smaller reporting companies. However, these possibilities have the disadvantage of lack of consistency, which could lead to confusion among investors.

12. In Lieu of Requiring Assurance, Require Disclosure About Any Assurance Obtained Over GHG Emissions Disclosures

Another alternative would be to require all registrants to disclose what type of assurance they are receiving, if any, in lieu of requiring assurance. This would potentially allow affected registrants to avoid the costs of obtaining limited assurance and/or reasonable assurance.[1002] Additionally, registrants would have the flexibility to choose any level of assurance (*i.e.,* none, limited, or reasonable assurance) but still be required to disclose their choice for transparency. This alternative, however, may reduce the reliability and comparability of these disclosures relative to the standardized assurance requirements within the proposed rules. In addition, as it does not set any minimum requirements for the assurance, this alternative would not address the fragmentation and selective disclosure issues that characterize the current, voluntary reporting regime.

13. Permit Host Country Disclosure Frameworks

Another alternative would be to permit alternative compliance using host country disclosure frameworks that the Commission deems suitable. Such an alternative would be beneficial for registrants that already comply with another country's disclosure requirements since they could avoid incurring additional costs to comply with the Commission's rules. This flexibility, however, may fail to address or may even exacerbate growing concerns from investors that climate-related disclosures lack comparability and consistency. While it might be individually optimal for a given firm to use their existing host country disclosure frameworks, the potential lack of consistency and comparability of the disclosure between these firms and other registrant might impose costs on investors. Investors might not able to compare across firms using different disclosure presentations, or may have to incur additional costs in order to do so.

14. Alternative Tagging Requirements

With respect to Inline XBRL tagging, one alternative is to change the scope of disclosures required to be tagged. We could, for example, remove the tagging requirements for climate-related disclosures for all or a subset of registrants (such as smaller reporting companies). As another example, we could require only a subset of proposed climate-related disclosures, such as the quantitative climate-related metrics, to be tagged in Inline XBRL. Narrowing the scope of climate-related disclosures to be tagged could provide some incremental cost savings for registrants compared to the proposal, because incrementally less time would be required to select and review the particular tags to apply to the climate-related disclosures.

We expect this incremental cost savings to be low because all affected registrants are or in the near future will be required to tag certain of their disclosures (including both quantitative and qualitative disclosures) in Inline XBRL.[1003] Moreover, narrowing the scope of tagging requirements would

[1000] *See, e.g.,* K. Hodge, K., N. Subramaniam, and J. Stewart, *Assurance of Sustainability Reports: Impact on Report Users' Confidence and Perceptions of Information Credibility,* 19 Australian Accounting Review 178–194 (2009), *available at https://doi.org/10.1111/j.1835-2561.2009.00056.x;* Mark Sheldon, *User Perceptions of CSR Disclosure Credibility with Reasonable, Limited and Hybrid Assurances* (Dissertation) (2016) *available at https://vtechworks.lib.vt.edu/bitstream/handle/10919/65158/Sheldon_MD_D_2016.pdf.*

[1001] *See* C.H. Cho, G. Michelon, D.M. Patten, and R.W. Roberts, *CSR report assurance in the USA: An empirical investigation of determinants and effects,* 5 (2) Sustainability Accounting, Management and Policy Journal 130, 130–148 (2014), *available at https://doi.org/10.1108/SAMPJ-01-2014-0003.*

[1002] *See* Section IV.C.2.(3) for cost estimates of assurance over emissions disclosures.

[1003] Inline XBRL requirements for business development companies will take effect beginning Aug. 1, 2022 (for seasoned issuers) and Feb. 1, 2023 (for all other issuers). If the proposed Inline XBRL requirements are adopted in the interim, they will not apply to business development companies prior to the aforementioned effectiveness dates. *See supra* note 706.

diminish the extent of informational benefits that would accrue to investors by reducing the volume of climate-related information that would become less costly to process and easier to compare across time and registrants. For example, an alternative whereby only quantitative climate-related disclosures would be tagged would inhibit investors from efficiently extracting/searching climate-related disclosures about registrants' governance; strategy, business model, and outlook; risk management; and targets and goals, thus creating the need to manually run searches for these disclosures through entire documents.[1004] Such an alternative would also inhibit the automatic comparison/redlining of these disclosures against prior periods, and the performance of targeted artificial intelligence or machine learning assessments (tonality, sentiment, risk words, etc.) of specific narrative climate-related disclosures outside the financial statements rather than the entire unstructured document.

G. Request for Comment

We request comment on all aspects of our economic analysis, including the potential costs and benefits of the proposed rules and alternatives thereto, and whether the proposed rules, if adopted, would promote efficiency, competition, and capital formation or have an impact on investor protection. In addition, we also seek comment on alternative approaches to the proposed rules and the associated costs and benefits of these approaches. Commenters are requested to provide empirical data, estimation methodologies, and other factual support for their views, in particular, on costs and benefits estimates. Specifically, we seek comment with respect to the following questions:

- Are there any costs and benefits to any entity that are not identified or misidentified in the above analysis?
- Are there any effects on efficiency, competition, and capital formation that are not identified or misidentified in the above analysis?
- Are there any other alternative approaches to improving climate-related disclosure that we should consider? If so, what are they and what would be the associated costs or benefits of these alternative approaches? For example, what would be the costs and benefits of implementing a new, comprehensive system, for reporting and transferring GHG emissions across corporate supply and distribution chains, as described by Kaplan and Ramanna (2021)? [1005]
- Are there any sources of data that could provide a more precise estimation of the potential compliance costs that registrants may incur if the proposed rules are adopted?
- Have we accurately estimated the costs of disclosing Scope 1 and 2 emissions? If not, please provide alternative estimates of these costs.
- Have we accurately estimated the costs of disclosing Scope 3? If not, please provide alternative estimates of these costs.
- Are there any additional sources of information to estimate the costs of complying with the Scopes 1, 2, and 3 GHG emissions disclosure requirements and the costs of obtaining limited and reasonable assurance for these disclosures?
- Would any data sources allow these compliance cost estimates to be apportioned to separate provisions of the proposed rules? Furthermore, how would these cost estimates vary across time horizons? For example, the first year of implementation may come with higher start-up costs while subsequent years may come with lower costs.
- Have we accurately characterized the cost of limited assurance and reasonable assurance over Scopes 1 and 2 emissions? If not, please provide an estimate of these costs. Similarly, is there data that can show how the costs of limited assurance and reasonable assurance differ for large accelerated, accelerated and non-accelerated filers?
- How are the costs of obtaining limited assurance and reasonable assurance likely to change over time (*e.g.,* over the five years following adoption or compliance with a specified level of assurance)? What would be the costs and benefits of providing a longer transition period for obtaining assurance over Scopes 1 and 2 emissions disclosures?

V. Paperwork Reduction Act

A. Summary of the Collections of Information

Certain provisions of our rules and forms that would be affected by the proposed amendments contain ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995 (''PRA'').[1006] The Commission is submitting the proposal to the Office of Management and Budget (''OMB'') for review in accordance with the PRA.[1007] The hours and costs associated with preparing and filing the forms and reports constitute reporting and cost burdens imposed by each collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information requirement unless it displays a currently valid OMB control number. Compliance with the information collections is mandatory. Responses to the information collections are not kept confidential and there is no mandatory retention period for the information disclosed. The titles for the affected collections of information are:

- Form S–1 (OMB Control No. 3235–0065);
- Form F–1 (OMB Control No. 3235–0258);
- Form S–4 (OMB Control No. 3235–0324);
- Form F–4 (OMB Control No. 3235–0325);
- Form S–11 (OMB Control No. 3235–0067);
- Form 10 (OMB Control No. 3235–0064);
- Form 10–K (OMB Control No. 3235–0063);
- Form 10–Q (OMB Control No. 3235–0070);
- Form 20–F (OMB Control No. 3235–0288); and
- Form 6–K (OMB Control No. 3235–0116).[1008]

The proposed amendments would require U.S. registrants filing Securities Act registration statements on Forms S–1, S–4, and S–11 to include the climate-related disclosures required under proposed subpart 1500 of Regulation S–K and proposed Article 14 of Regulation S–X. The proposed amendments would also require foreign private issuers to include the proposed climate-related disclosures when filing Securities Act registration statements on Forms F–1 and F–4. The proposed amendments would further require U.S. registrants and foreign private issuers to include

[1004] To illustrate, using a search string such as ''climate change'' or ''greenhouse gas'' to search through the text of all filings from a particular filer population so as to determine the trends in narrative climate-related disclosure among that population over time, could return many narrative disclosures outside of the climate-related disclosures. Examples of this would be a description of pending environmental litigation, existing government regulations and agency names, and broader regulatory risk factors.

[1005] *See* R. Kaplan and K. Ramanna, *How to Fix ESG Reporting* (2021), *available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3900146.*

[1006] *See* 44 U.S.C. 3501 *et seq.*

[1007] 44 U.S.C. 3507(d) and 5 CFR 1320.11.

[1008] The proposed amendments would also indirectly affect Forms S–3 and F–3. Registrants filing Forms S–3 and F–3 are able to incorporate by reference their annual reports filed on Forms 10–K or 20–F. Because the proposed amendments would affect Forms 10–K and 20–F, and are not expected to affect Forms S–3 and F–3 except when Forms 10–K and 20–F are incorporated by reference into those Securities Act forms, we are not separately accounting for the PRA burden related to Forms S–3 and F–3.

the proposed climate-related disclosures in their Exchange Act annual reports filed, respectively, on Forms 10–K and 20–F and in Exchange Act registration statements filed, respectively, on Forms 10 and 20–F. Registrants would be required to include the climate-related information required under proposed subpart 1500 in a part of the registration statement or annual report that is separately captioned as *Climate-Related Disclosure.* Registrants would be required to include the climate information required under Article 14 in a note to the financial statements, which would be subject to audit. Further, as described below, accelerated filers and large accelerated filers would be required to include an attestation report covering their Scopes 1 and 2 emissions disclosure, subject to phase-ins. In addition, U.S. registrants and foreign private issuers would be required to report material changes to the climate information disclosed in their Exchange Act reports on, respectively, Forms 10–Q and 6–K. A description of the proposed amendments, including the need for the climate information and its proposed use, as well as a description of the likely respondents, can be found in Section II above, and a discussion of the economic effects of the proposed amendments can be found in Section IV above.

B. Summary of the Proposed Amendments' Effects on the Collections of Information

Our estimates of the paperwork burden associated with the proposed amendments are based primarily on climate-related reporting cost estimates from six sources: A comment letter from the Society for Corporate Governance (''Society'') that provided some hour and cost estimates for climate reporting by large-cap companies; [1009] a report by the Climate Risk Disclosure Lab at Duke University School of Law's Global Financial Markets Center that presents survey results of climate-related disclosure costs for three unnamed companies; [1010] an impact assessment conducted by the United Kingdom's Department for Business, Energy, and Industrial Strategy for a rule that, similar to the Commission's proposed rules, would require TCFD-aligned disclosures from all listed firms; [1011] two cost estimates from a data analytics firm—one that covered primarily risk assessment and analysis pursuant to the TCFD framework, and the other for calculating GHG emissions; [1012] and cost estimates for GHG emissions measurement and reporting from two climate management firms.[1013]

In response to Acting Chair Lee's request for public input about climate disclosures,[1014] Society submitted the results of a survey it had conducted on a small number of public large-cap companies about the costs of their current climate reporting. According to this commenter, two companies estimated that the number of employee hours spent on climate reporting ranged from 7,500 to 10,000 annually, while a third company estimated the number of annual employee hours spent on climate reporting to be 2,940 hours.[1015] The average annual employee hours spent on climate reporting for these large-cap companies was 6,813 hours.[1016]

The Climate Risk Disclosure Lab's report presents the results of its survey of one European large-cap financial institution, one US large-cap industrial manufacturing company, and one US mid-cap waste management company about their climate-related disclosure costs.[1017] The European financial institution reported annual climate-related disclosure costs ranging from $250,000 to $500,000, which averages to $375,000 annually.[1018] For PRA purposes, we have converted this dollar cost average to 6,818 burden hours using a metric of $55/hour.[1019] The US industrial manufacturing company disclosed annual climate-related disclosure costs for its employees and one full-time consultant ranging from $200,000 to $350,000, which averages to $275,000 annually. We have similarly converted this dollar cost average to 5,000 burden hours.[1020] The US waste management company reported that its employees spent 82 hours annually to produce its climate-related disclosures. The average annual internal burden hours spent on climate reporting for these three companies comes to 3,967 hours.[1021]

The UK Impact Assessment estimated on an ongoing, annual basis the number of hours and costs that it would take in-house personnel [1022] to gather data and prepare and provide disclosure for each of the following TCFD-aligned topics: Governance, strategy, risk management, and metrics and targets.[1023] The impact assessment also estimated on an annual, ongoing basis the number of hours and costs that it would take a parent company's personnel to collect and process climate-related data from its subsidiaries.[1024] The impact assessment further estimated on a one-time basis the number of hours and costs that it would take in-house personnel to become familiar with and review the new climate-related reporting requirements and related guidance.[1025]

[1009] *See* letter from Society for Corporate Governance.

[1010] *See* Climate Risk Disclosure Lab *The Cost of Climate Disclosure: Three Case Studies on the Cost of Voluntary Climate-Related Disclosure* (Dec. 2021), *available at https://climatedisclosurelab.duke.edu/wp-content/uploads/2021/12/The-Cost-of-Climate-Disclosure.pdf.*

[1011] *See* UK Department for Business, Energy, and Industrial Strategy, Final Stage Impact Assessment (Oct. 1, 2021), available at *https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1029317/climate-related-financial-disclosure-consultation-final-stage-impact-assessment.pdf; see also* UK Department for Business, Energy, and Industrial Strategy, Initial Impact Assessment (Jan. 29, 2021), available at *https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/972423/impact-assessment.pdf* . The scope of the impact assessment included companies listed on the London Stock Exchange with over 500 employees, UK registered companies admitted to AIM with over 500 employees, and certain other companies.

[1012] *See* memorandum, dated Feb. 4, 2022, concerning staff meeting with representatives of S&P Global. This and the other staff memoranda referenced below are available at *https://www-draft.sec.gov/comments/s7-10-22/s71022.htm.*

[1013] *See* memorandum, dated Nov. 30, 2021, concerning staff meeting with representatives of Persefoni; and memorandum, dated Jan. 14, 2022, concerning staff meeting with representatives of South Pole.

[1014] *See supra* Section I.B.

[1015] *See* letter from Society for Corporate Governance. This commenter also stated that fees for external climate advisory services ranged from $50,000 to $1.35 million annually.

[1016] 7,500 hrs. + 10,000 hrs. + 2,940 hrs. = 20,440 hrs.; 20,440/3 = 6,813 hrs.

[1017] *See supra* Section IV.C.2 for a more detailed discussion of these reported costs.

[1018] $250,000 + $500,000 = $750,000. $750,000/2 = $375,000.

[1019] This metric is based on a reported national annual average salary for a climate specialist of $114,463. *See* glassdoor, *How much does a Climate Change Specialist make?* (Dec. 2021), available at *https://www.glassdoor.com/Salaries/climate-change-specialist-salary-SRCH_KO0,25.htm.* $114,463/2080 hrs. = $55/hr. $375,000/$55/hr. = 6,818 hrs. (rounded to nearest dollar).

[1020] $200,000 + $350,000 = $550,000. $550,000/2 = $275,000. $275,000/$55/hr. = 5,000 hrs.

[1021] 6,818 hrs. + 5,000 hrs. + 82 hrs. = 11,900 hrs.; 11,900 hrs./3 = 3,967 hrs.

[1022] Unlike this PRA analysis, which assumes that some of the paperwork burden will be borne by in-house personnel and some by outside professionals, the UK Impact Assessment assumed that all of the work would be done by in-house personnel.

[1023] The UK Impact Assessment's estimated number of hours for each TCFD-aligned disclosure topic per company was: 225 hrs. for governance; 295 hrs. for strategy; 245 hrs. for risk management; and (in Year 1) 2,227 hrs. for metrics and targets, which included one in-house climate-related expert working full-time.

[1024] This estimate was 85 hrs.

[1025] The primary difference between the Initial Impact Assessment and Final Impact Assessment concerned the estimated ''familiarization'' costs. The Final Impact Assessment assumed that the rule would require scenario analysis and added additional hours for in-house personnel to become familiar with scenario analysis methodology.

Continued

The total number of hours that the Impact Assessment estimated it would take a company to comply with the TCFD-aligned disclosure requirements in the first year came to 3,447 hours, of which 977.5 hours pertained to qualitative, TCFD-aligned disclosure and 2,469.5 hours pertained to GHG emissions metrics and targets disclosure.[1026]

We also have considered cost estimates from S&P Global, a data analytics firm that provides ESG consulting services, including climate-related data collection and analysis, among other services. This firm provided one cost estimate for preparing TCFD-aligned disclosures primarily covering physical risk and transition risk assessment and analysis, which, for a company lacking any experience in climate reporting, ranged from $150,000 to $200,000 (an average of $175,000) in the first year of reporting.[1027] For a company with prior experience in GHG emissions reporting but requiring assistance with TCFD-aligned reporting, the firm estimated average costs of $100,000.[1028] This results in an average cost estimate for all companies for TCFD-aligned disclosures, excluding GHG emissions calculation and reporting, of $137,500 in the first year of TCFD-aligned reporting.[1029] For PRA purposes, we have converted this dollar cost average to 2,500 burden hours.[1030]

This data analytics firm provided a separate cost estimate for calculating a company's Scopes 1, 2, and 3 emissions.[1031] For the initial calculation of a company's GHG emissions, including all three scopes, the cost estimate ranged from $75,000 to $125,000 (an average of $100,000).[1032] The firm also estimated that the setting and reporting of GHG emissions targets would on average add an additional $25,000, resulting in an average first-year cost estimate for GHG emissions metrics and targets of $125,000.[1033] For PRA purposes, we have converted this dollar cost average to 2,273 burden hours.[1034] This results in a total incremental burden increase (for both TCFD-aligned disclosures and GHG emissions calculation) in the first year of climate-related reporting of 4,773 burden hours.[1035]

We also considered the cost estimates for GHG emissions measurement and reporting provided by two climate management firms, Persefoni and South Pole. Persefoni estimated that, depending on the maturity of a company's emissions reporting program, a company's average first-year costs for measuring and reporting Scopes 1, 2, and 3 emissions ranged from $50,000 to $125,000, which averages to $87,500, or 1,591 hours.[1036] South Pole estimated annual costs for measuring and reporting Scopes 1, 2 and 3 emissions as ranging from $11,800 to $118,300, which averages to $65,050, or 1,183 hours.[1037]

The UK Impact Assessment estimated that the calculation and reporting of GHG emissions metrics and related targets would take the greatest amount of time, constituting approximately 72 percent of the total incremental burden.[1038] The data analytics firm, however, estimated that GHG emissions metrics and targets would constitute approximately 48 percent of the total incremental burden.[1039] The burden estimates provided by the above-referenced commenter and Climate Lab did not allocate between GHG emissions and non-GHG emissions climate reporting. For purposes of the PRA, we have allocated the burden estimates from the commenter and Climate Lab equally between the qualitative TCFD-aligned disclosure and the GHG emissions metrics and targets disclosure.[1040]

Based on the above sources, we estimate that the proposed qualitative TCFD-aligned disclosures would result in an average incremental burden hour increase of 2,217 hrs. for each affected collection of information for the first year of climate reporting.[1041] We estimate that the proposed GHG emissions metrics and targets disclosure would result in an average incremental burden hour increase of 2,151 hours for each affected collection of information for the first year of reporting.[1042]

In addition to GHG emissions metrics, the proposed rules would require the disclosure of certain climate-related financial statement metrics. Although the TCFD recommends the disclosure of metrics pertaining to the financial impacts of climate-related events and conditions, it is unclear whether the above sources' burden estimates for TCFD-aligned disclosure would include financial statement metrics. Based on staff experience reviewing financial statements, we estimate that preparation of the financial statements to present the proposed financial statement metrics would require 70 additional burden hours per filing. To ensure that our PRA estimates cover the burden associated with the proposed climate-related financial statement metrics, we have included this amount, in addition to the burden estimate for GHG emissions metrics and targets, in the estimated overall PRA burden of the proposed rules.

The proposed rules would require a registrant to present the climate-related financial statement metrics and associated disclosures in a note to its

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Because our proposed rules do not require scenario analysis, we are using the familiarization estimate of the Initial Impact Assessment (323 hrs.) when totaling the estimated hours required to comply with the UK's proposed climate disclosure rules. We have added to the familiarization estimate the number of hours (77 hrs.) that the Final Impact Assessment estimated for the one-time legal review of the new climate disclosure requirements by in-house personnel.

[1026] 400 hrs. (familiarization and review) + 195 hrs. (governance) + 295 hrs. (strategy) + 245 hrs. (risk management) + 2,227 hrs. (metrics and targets) + 85 hrs. (parent co. processing) = 3,447 hrs. For purposes of the PRA, we have allocated approximately half of the hours pertaining to familiarization and review and parent company processing between the qualitative TCFD-aligned disclosure and the GHG emissions metrics and targets disclosure. This results in 977.5 hrs. allocated to the qualitative TCFD-aligned disclosure and 2,469.5 hrs. allocated to the GHG emissions metrics and targets disclosure.

[1027] *See* memorandum concerning staff meeting with representatives of S&P Global. $150,000 + $200,000 = $350,000; $350,000/2 = $175,000.

[1028] *See id.*

[1029] $175,000 + $100,000 = $275,000; $275,000/2 = $137,500.

[1030] $137,500/$55/hr. = 2,500 hrs.

[1031] *See* memorandum concerning staff meeting with representatives of S&P Global. Although the proposed rules would require the disclosure of a registrant's Scope 3 emissions only if they are material, this cost estimate is relevant for determining the upper bound of the proposed rules' estimated PRA burden.

[1032] $75,000 + $125,000 = $200,000; $200,000/2 = $100,000.

[1033] Although the proposed rules would not require a registrant to set GHG emissions targets, they would require certain disclosures if the registrant does set targets. We have therefore included S&P Global's cost estimate for targets for purposes of determining the upper bound of the proposed rules' estimated PRA burden. However, because setting targets would be voluntary under the proposed rules, the estimated PRA burden may overstate the potential burden.

[1034] $125,000/$55/hr. = 2,273 hrs.

[1035] 2,500 hrs. + 2,273 hrs. = 4,773 hrs.

[1036] *See* memorandum concerning staff meeting with representatives of Persefoni. $50,000 + $125,000 = $175,000; $175,000/2 = $87,500; $87,500/$55/hr. = 1,591 hrs.

[1037] *See* memorandum concerning staff meeting with representatives of South Pole. $11,800 + $118,300 = $130,100; $130,100/2 = $65,050; $65,050/$55/hr. = 1,183 hrs.

[1038] *See supra* note 1033 (2,469.5 hrs./3,447 hrs. = 72 percent).

[1039] *See supra* note 1042 (2,273 hrs./4,773 hrs. = 48 percent).

[1040] For the Society for Corporate Governance-derived estimate, this results in 3,406.5 hrs. for each of the qualitative TCFD-aligned disclosure and the GHG emissions metrics and targets disclosure. For the Climate Lab-derived burden estimate, this results in 1,983.5 burden hrs. for each of the qualitative and quantitative disclosures.

[1041] 3,406.5 hrs. (Society) + 1,983.5 hrs. (Climate Lab) + 977.5 hrs. (UK) +2,500 hrs. (S&P Global) = 8,867.5 hrs.; 8,867.5/4 = 2,217 hrs. (rounded to the nearest whole number).

[1042] 3,406.5 hrs. (Society) + 1,983.5 hrs. (Climate Lab) + 2,469.5 hrs. (UK) + 2,273 hrs. (S&P Global) + 1,591 hrs. (Persefoni) + 1,183 hrs. (South Pole) = 12,906.5 hrs.; 12,906.5 hrs./6 = 2,151 hrs.

financial statements, which would be audited. Because the audit of such information would be part of the registrant's overall audit of its financial statements, we expect the incremental audit costs associated with these climate-related financial statement metrics and disclosures to be modest.[1043] We are conservatively estimating that auditing the note pertaining to the climate-related financial statement metrics and associated disclosures would add audit fees of $15,000 to the overall costs associated with the audit of the registrant's financial statements. We derived this estimate by first estimating costs as an average percentage of total audit fees (1.5%) [1044] and then applying that percentage to median audit fees of $690,000,[1045] which results in $10,350. To be conservative, we have increased this amount to $15,000 for estimated audit fees. We believe that this estimate represents the average cost of the incremental efforts that may be incurred, taking into consideration factors such as the scale and complexity of different registrants and the extent of impact by climate-related events (*e.g.,* location of operations, nature of business). This cost also takes into consideration the need to understand and evaluate the registrants' processes and internal controls associated with the reporting of the climate-related financial statement metrics and associated disclosures.

The proposed rules would require a registrant that is a large accelerated filer [1046] or an accelerated filer [1047] to include, in the relevant filing, an attestation report covering the disclosure of its Scope 1 and Scope 2 emissions and to provide certain related disclosures. Following a one-year phase-in period in which no attestation report would be required, for filings made for the second and third fiscal years following the compliance date for the GHG emissions disclosure requirement, large accelerated filers would be required to obtain an attestation report for their Scopes 1 and 2 emissions disclosure, at minimum, at a limited assurance level. We estimate the cost of a limited assurance attestation report covering a large accelerated filer's Scopes 1 and 2 emissions to be $110,000.[1048] Commencing with the fourth fiscal year following the compliance date and thereafter, a large accelerated filer would be required to obtain an attestation report covering its Scopes 1 and 2 emissions disclosure at a reasonable assurance level. We estimate the cost for such a reasonable assurance attestation report to be $175,000.[1049] This results in an initial six-year average [1050] assurance cost for a large accelerated filer's Scopes 1 and 2 emissions of $124,167.[1051]

Following a one-year phase-in period in which no attestation report would be required, for filings made for the second and third fiscal years following the compliance date for the GHG emissions disclosure requirement, accelerated filers would be required to obtain an attestation report for their Scopes 1 and 2 emissions disclosure, at minimum, at a limited assurance level. We estimate the cost of a limited assurance attestation report covering an accelerated filer's Scopes 1 and 2 emissions to be $45,000.[1052] Commencing with the fourth fiscal year following the compliance date and thereafter, an accelerated filer would be required to obtain an attestation report covering its Scopes 1 and 2 emissions disclosure at a reasonable assurance level. We estimate the cost for such a reasonable assurance attestation report to be $75,000.[1053] This results in an initial six-year average assurance cost for an accelerated filer's Scopes 1 and 2 emissions of $52,500.[1054]

The proposed rules would require a registrant that is not required to include a GHG emissions attestation report to state whether any of the registrant's GHG emissions disclosures were subject to third-party attestation or verification. If so, the registrant would be required to identify the provider of assurance or verification and disclose certain additional information, such as the level and scope of assurance or verification provided, among other matters.[1055] The burden and costs for this disclosure are encompassed within the estimated overall internal burden and costs for the proposed GHG emissions disclosure.

The UK Impact Assessment assumed a 25 percent reduction in hour and cost estimates for the work required to comply with the GHG emissions metrics and targets disclosure requirement in Year 2 compared to Year 1 because initial implementation of the metrics and targets framework would not need to be repeated. We believe this assumption is reasonable and have made a similar reduction after the first year of compliance when calculating the four-year average for the estimated paperwork burden hour effect of the proposed rules. We also have assumed a 10 percent reduction in the hour and cost estimates for preparing and providing the disclosures for the other TCFD-aligned topics in Years 2 through 6 compared to Year 1. We believe that this assumption is reasonable because the burden hours and costs associated with becoming familiar with the other TCFD disclosure topics would not need to be repeated.[1056] We believe that the reduction in the compliance burden and costs for the metrics and targets disclosure requirement would be greater

[1043] This belief is based on post-implementation review observations and activities from accounting standards that provided further disaggregation of information and that are analogous to the proposed financial statement metrics requirements, as discussed *supra* Section II.F.2.a (*e.g.,* segment reporting and disaggregation of revenue). *See* FASB's post-implementation review report on FASB Statement No. 131, Disclosures about Segments of an Enterprise and Related Information (Dec. 2012), 11, (''Preparers' incremental costs to implement and comply with Statement 131 generally were not significant and were in line with expectations''), *available at https://www.accountingfoundation.org/cs/Satellite?c=Document_C&cid=1176160621900&pagename=Foundation%2FDocument_C%2FDocumentPage.* *See also* FASB's Board Meeting Handout, post-implementation review of Topic 606, Revenue with Contracts with Customers Our (July 28, 2021) (While the post-implementation review is still ongoing, most users agreed that the disaggregated [revenue] disclosure is helpful (par. 16) and users noted that although they incurred costs to become familiar with the new standard, update models, or maintain dual models during the transition period, most of those costs were nonrecurring. For users that are generalists or that cover sectors that did not have significant changes to revenue recognition measurement or timing under Topic 606, the costs were not significant. (par. 20), *available at https://www.fasb.org/cs/ContentServer?c=Document_C&cid=1176176976563&d=&pagename=FASB%2FDocument_C%2FDocumentPage.*

[1044] The staff estimated a range of 0.5% to 2.5%, which averages to 1.5%.

[1045] This is based on staff review of Audit Analytics data for 2020.

[1046] Based on staff review of filings made in 2020, large accelerated filers filed approximately 31% of domestic forms and approximately 37% of Form 20–Fs in 2020. For PRA purposes, we have used 37% as a proxy for the percentage of all foreign private issuer forms filed by large accelerated filers in 2020.

[1047] Based on staff review of filings made in 2020, accelerated filers filed approximately 11% of domestic forms and 15% of Form 20–Fs in 2020.

[1048] *See supra* Section IV.C.2.a.3. for the basis of this limited assurance cost estimate.

[1049] *See id.*

[1050] In order to capture three years of the cost of a reasonable assurance attestation report required for accelerated filers and large accelerated filers, which requirement does not commence until the fourth fiscal year following the proposed rules' compliance date, we have used a six-year average when calculating the estimated paperwork burden effects of the proposed rules.

[1051] 0 + $110,000 + $110,000 + $175,000 + $175,000 + $175,000 = $745,000; $745,000/6 = $124,167.

[1052] *See supra* Section IV.C.2.a.3. for the basis of this limited assurance cost estimate.

[1053] *See id.*

[1054] 0 + $45,000 + $45,000 + $75,000 + $75,000 + $75,000 = $315,000; $315,000/6 = $52,500.

[1055] *See* proposed 17 CFR 229.1505(e).

[1056] S&P Global estimated a similar reduction in costs in subsequent years, the magnitude of which depends on the extent of material changes to the TCFD-aligned disclosure and the GHG emissions metrics.

than the reduction for the other TCFD-aligned disclosure topics because the initial work to implement a climate data collection and reporting framework to comply with the metrics and targets requirement would be greater than the initial framework required for the other disclosure requirements.

SRCs, which comprise 50 percent of domestic filers, and 45 percent of total affected registrants,[1057] would bear a lesser compliance burden because those registrants would not be subject to the proposed disclosure requirement pertaining to Scope 3 emissions, which, of the three types of GHG emissions, poses the greatest challenge to calculate and report. We accordingly estimate that the increase in the PRA burden pertaining to the GHG emissions requirement for SRCs filing on domestic forms would be approximately 50% less than the increased burden for the GHG emissions requirement for non-SRC registrants.[1058] Smaller foreign private issuers that file on the foreign private issuer forms would not be eligible for this adjustment because those foreign private issuers are excluded from the definition of, and therefore cannot be, SRCs.[1059]

In addition to requiring the annual climate disclosures, the proposed rules would require a registrant to disclose any material change to its climate-related disclosures reported in its annual Exchange Act annual report (Form 10–K or 20–F) on a Form 10–Q (if a domestic filer) or a Form 6–K (if a foreign private issuer filer). We would not expect a registrant to report such a material change until its second year of compliance, at the earliest. Based on the staff's assessment of the amount of time it would take to determine that there has been a material change in the previously reported climate disclosure, particularly concerning its GHG emissions metrics, and to prepare disclosures regarding the material change, if any, we estimate a burden hour increase of 40 hours per form, or an initial six-year average of 33 hours per form.[1060]

The following table summarizes the estimated paperwork burden effects of the proposed amendments for non-SRC and SRC registrants associated with the affected collections of information.

[1057] In 2020, there were 6,220 domestic filers + 740 foreign private issuer (fpi) filers = 6,960 affected filers. 3,110 domestic filers + 740 fpi filers = 3,850 non-SRC filers. 3,850/6,960 = 55%. 3,110 filers were SRCs in 2020. 3,110/6,960 = 45%. *See supra* Section IV.B.

[1058] This is generally consistent with some of the cost estimates obtained for calculating and reporting Scopes 1, 2, and 3 emissions. For example, Persefoni indicated that the annual GHG emissions costs for a company having experience calculating and reporting GHG emissions would double if it included Scope 3 emissions after calculating Scopes 1 and 2 emissions. *See supra* note 1020. In addition, S&P Global indicated that a company's annual ongoing reporting costs of Scopes 1 and 2 emissions would, at a minimum, increase from $40,000 to $75,000 if it included Scope 3 emissions. *See supra* note 1019.

[1059] *See, e.g.,* Instruction 2 to the definition of smaller reporting company under 17 CFR 230.405.

[1060] 0 + (40 hrs. × 5) = 200 hrs.; 200 hrs./6 = 33 hrs. (rounded to nearest whole number).

PRA TABLE 1—ESTIMATED PAPERWORK BURDEN EFFECTS OF THE PROPOSED AMENDMENTS FOR NON-SRC AND SRC REGISTRANTS [1]

Collections of information	Proposed disclosure item	Estimated PRA burden hour effect for non-SRC registrants (year 1) (hrs)	Estimated PRA burden hour effect for SRC registrants (year 1) (hrs)	Estimated PRA burden hour effect for non-SRC registrants (for each year 2 through 6) (hrs)	Estimated PRA burden hour effect for SRC registrants (for each year 2 through 6) (hrs)	Estimated PRA burden hour effect for non-SRC registrants (6 year average) (hrs)	Estimated PRA burden hour effect for SRC registrants (6 year average) (hrs)	Estimated average annual assurance costs for climate-related financial statement metrics (6 year average)	Estimated average annual assurance costs for Scopes 1 and 2 emissions disclosure by AFs [2] (6 year average)	Estimated average annual assurance costs for Scopes 1 and 2 emissions disclosure by LAFs [3] (6 year average)
Forms S–1,S–4, S–11,10, and 10–K.	Climate-related disclosures regarding governance, strategy, and risk management.	+2,217	+2,217	+1,995	+1,995	+2,032	+2,032	+$15,000	+$52,500	$124,167
	Financial statement metrics	+70	+70	+63	+63	+64	+64			
	GHG emissions metrics and targets.	+2,151	+1,076	+1,613	+807	+1,703 +852				
Total		+4,438	+3,363	+3,671	+2,865	+3,799	+2,948	+$15,000	+$52,500	$124,167
Forms F–1, F–4, and 20–F.	Climate-related disclosures regarding governance, strategy, and risk management.	+2,217 +70 +2,151	NA	+1,995 +63 +1,613	NA.	+2,032 +64 +1,703	NA	+$15,000	+$52,500	$124,167
	Financial statement metrics GHG emissions metrics and targets.									
	Financial statement metrics	+70		+63		+64				
	GHG emissions metrics and targets.	+2,151		+1,613		+1,703				
Total		+4,438		+3,671		+3,799		+$15,000	+$52,500	$124,167
Forms 10–Q and 6–K.	Material change to 10–K/20–F.	0		+40		+33		0	0	0

[1] All numbers rounded to nearest whole number.
[2] Accelerated Filers.
[3] Large Accelerated Filers.

C. Incremental and Aggregate Burden and Cost Estimates for the Proposed Amendments

Below we estimate the incremental and aggregate increase in paperwork burden resulting from the proposed amendments. These estimates represent the average burden for all issuers, both large and small. In deriving our estimates, we recognize that the burdens will likely vary among individual registrants based on a number of factors, including the nature of their business, the size and complexity of their operations, and whether they are subject to similar climate-related disclosure requirements in other jurisdictions or already preparing similar disclosures on a voluntary basis. For purposes of the PRA, the burden is to be allocated between internal burden hours and outside professional costs. The table below sets forth the percentage estimates we typically use for the burden allocation for each affected collection of information. We also estimate that the average cost of retaining outside professionals is $400 per hour.[1061]

PRA TABLE 2—STANDARD ESTIMATED BURDEN ALLOCATION FOR SPECIFIED COLLECTIONS OF INFORMATION

Collection of information	Internal (%)	Outside professionals (%)
Forms S–1, F–1, S–4, F–4, S–11, 10, and 20–F	25	75
Forms 10–K, 10–Q, and 6–K	75	25

We estimate that the proposed amendments would change the burden per response, but not the frequency, of the existing collections of information. The burden increase estimates for each collection of information were calculated by multiplying the number of responses by the increased estimated average amount of time it would take to prepare and review the disclosure required under the affected collection of information (using the estimated three-year average increase). Since 50 percent of the domestic filers in 2020 were non-SRCs and 50 percent were SRCs, we assume for purposes of our PRA estimates that 50 percent of each domestic collection of information was filed by non-SRCs and 50 percent by SRCs. The table below illustrates the incremental change to the annual compliance burden of the affected collections of information, in hours and costs.

[1061] We recognize that the costs of retaining outside professionals may vary depending on the nature of the professional services, but for purposes of this PRA analysis, we estimate that such costs would be an average of $400 per hour.

PRA TABLE 3—CALCULATION OF THE INCREMENTAL CHANGE IN BURDEN ESTIMATES OF CURRENT RESPONSES RESULTING FROM THE PROPOSED AMENDMENTS[1]

Collection of information	Filed by	Number of estimated affected respondents (A)	Burden hour annual increase per affected respondent (B)	Increase in burden hours for affected respondents (C) = (A) × (B)	Increase in internal burden hours for affected respondents (D) = (C) × 0.25 or 0.75	Increase in professional hours for affected respondents (E) = (C) × 0.75 or 0.25	Climate-related financial statement metrics assurance costs for affected respondents[2] (F) = (A) × $15,000	GHG emissions assurance costs for AFs[3] (G) = (A) × 0.11 or 0.15 × $52,500	GHG emissions assurance costs for LAFs[4] (H) = (A) × 0.31 or 0.37 × $124,167	Increase in professional costs for affected respondents (I) = (E) × $400 + (F) + (G) + (H)
S–1	Non-SRCs	447	3,799	1,698,153						
S–1	SRCs	447	2,948	1,317,756						
S–1 (Total)		894		3,015,909	753,977	2,261,932	$13,410,000	$5,145,000	$34,394,259	$957,722,059
S–4	Non-SRCs	294	3,799	1,116,906						
S–4	SRCs	294	2,948	866,712						
S–4 (Total)		588		1,983,618	495,905	1,487,714	8,820,000	3,412,500	22,598,394	629,916,494
S–11	Non-SRCs	34	3,799	129,166						
S–11	SRCs	33	2,948	97,284						
S–11 (Total)		67		226,450	56,613	169,838	1,005,000	367,500	2,607,507	71,915,207
10	Non-SRCs	108	3,799	410,292						
10	SRCs	108	2,948	318,384						
10 (Total)		216		728,676	182,169	546,507	3,240,000	1,260,000	8,319,189	231,421,989
10–K	Non-SRCs	4,146	3,799	15,750,654						
10–K	SRCs	4,146	2,948	12,222,408						
10–K (Total)		8,292		27,973,062	20,979,797	6,993,266	124,380,000	47,880,000	319,233,357	3,288,799,757
10–Q	Non-SRCs	11,463	33	378,279						
10–Q	SRCs	11,462	33	378,246						
10–Q (Total).		22,925		756,525	567,394	189,131	0	0	0	75,652,400
F–1	Both	66	3,799	250,734	62,684	188,051	990,000	525,000	2,980,008	79,715,408
F–4	Both	39	3,799	148,161	37,040	111,121	585,000	315,000	1,738,338	47,086,738
20–F	Both	729	3,799	2,769,471	692,368	2,077,103	10,935,000	5,722,500	33,525,090	881,023,790
6–K	Both	34,794	33	1,148,202	861,152	287,051	0	0	0	114,820,400

[1] All numbers rounded to nearest whole number.
[2] We have not assumed assurance costs for Form 10–Q or Form 6–K because these forms typically have only marginal assurance costs. We expect these forms to be filed in the 2nd year, at the earliest.
[3] AFs filed 11% of domestic forms and 15% of foreign private issuer forms in 2020.
[4] LAFs filed 31% of domestic forms and 37% of foreign private issuer forms in 2020.

The table below illustrates the program change expected to result from the proposed rule amendments together with the total requested change in reporting burden and costs.

PRA TABLE 4—REQUESTED PAPERWORK BURDEN UNDER THE PROPOSED AMENDMENTS

Collection of Information	Current burden			Program change			Requested change in burden		
	Current annual responses	Current internal burden hours	Current external cost burden	Number of affected responses	Change in internal burden hours	Change in external costs	Annual responses	Internal burden hours	External cost burden
	(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H) = (B) + (E)	(I) = (C) + (F)
S–1	894	146,067	$178,922,043	894	753,977	$957,722,059	894	900,044	$1,134,929,102
S–4	588	562,362	677,255,579	588	495,905	629,916,494	588	1,058,267	1,306,034,573
S–11	67	12,229	14,943,768	67	56,613	71,915,207	67	68,842	86,736,475
10	216	11,855	14,091,488	216	182,169	231,421,989	216	194,024	245,093,477
10–K	8,292	14,188,040	1,893,793,119	8,292	20,979,797	3,288,799,757	8,292	35,167,837	5,166,632,876
10–Q	22,925	3,182,333	421,490,754	22,925	567,394	75,652,400	22,925	3,749,727	497,143,154
F–1	66	26,707	32,293,375	66	62,684	79,715,408	66	89,391	111,833,783
F–4	39	14,049	17,073,825	39	37,040	47,086,738	39	51,089	64,055,563
20–F	729	479,261	576,824,025	729	692,368	881,023,790	729	1,171,629	1,455,940,315
6–K	34,794	227,031	30,270,780	34,794	861,152	114,820,400	34,794	1,088,183	145,091,180
Total	.....	18,849,934	3,856,958,756	.....	24,689,099	6,378,073,242	.....	43,539,033	10,235,031,998

D. Request for Comment

We request comment in order to:

- Evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information would have practical utility;
- Evaluate the accuracy of our estimate of the burden of the proposed collections of information, including any assumptions used;
- Determine whether there are ways to enhance the quality, utility, and clarity of the information to be collected;
- Evaluate whether there are ways to minimize the burden of the collections of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology; and
- Evaluate whether the proposed amendments would have any effects on any other collections of information not previously identified in this section.[1062]

Any member of the public may direct to us any comments about the accuracy of these burden estimates and any suggestions for reducing these burdens. Persons submitting comments on the collection of information requirements should direct the comments to the Office of Management and Budget, Attention: Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Washington, DC 20503, and should send a copy to Vanessa A. Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090, with reference to File No. S7–10–22. Requests for materials submitted to OMB by the Commission with regard to these collections of information should be in writing, refer to File No. S7–10–22, and be submitted to the Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736. OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this release. Consequently, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication.

VI. Initial Regulatory Flexibility Act Analysis

This Initial Regulatory Flexibility Act Analysis (''IRFA'') has been prepared, and made available for public comment, in accordance with the Regulatory Flexibility Act (''RFA'').[1063] It relates to the proposal to add new subpart 1500 to Regulation S–K and new Article 14 to Regulation S–X, which would require registrants to provide certain climate-related disclosures in their Securities Act and Exchange Act registration statements and Exchange Act reports. As required by the RFA, this IRFA describes the impact of these proposed amendments of Regulations S–K and S–X on small entities.[1064]

A. Reasons for, and Objectives of, the Proposed Action

We are proposing to require registrants to provide certain climate-related information in their registration statements and annual reports, including certain information about climate-related financial risks and climate-related financial metrics in their financial statements. The disclosure of this information would provide consistent, comparable, and decision-useful information to investors to enable them to make informed judgments about the impact of climate-related risks on current and potential investments. Information about climate-related risks can have an impact on public companies' financial performance or position and may be material to investors in making investment or voting decisions. For this reason, many investors—including shareholders, investment advisors, and investment management companies—currently seek information about climate-related risks from companies to inform their investment decision-making. Furthermore, many companies have begun to provide some of this information voluntarily in response to investor demand and in recognition of the potential financial effects of climate-related risks on their businesses. We are concerned that the existing voluntary disclosures of climate-related risks do not adequately protect investors. For this reason, mandatory disclosures may be necessary or appropriate to improve the consistency, comparability, and reliability of this information. The reasons for, and objectives of, the proposed amendments are discussed in more detail in Section II above.

B. Legal Basis

We are proposing the amendments contained in this release under the authority set forth in Sections 7, 10, 19(a), and 28 of the Securities Act, as amended, and Sections 3(b), 12, 13, 15, 23(a), and 36 of the Exchange Act, as amended.

C. Small Entities Subject to the Proposed Rules

The proposed amendments would affect some issuers that are small entities. The RFA defines ''small entity'' to mean ''small business,'' ''small organization,'' or ''small governmental jurisdiction.'' [1065] For purposes of the RFA, under 17 CFR 240.0–10(a), an issuer, other than an investment company, is a ''small business'' or ''small organization'' if it had total assets of $5 million or less on the last day of its most recent fiscal year and, under 17 CFR 230.157, is also engaged or proposing to engage in an offering of securities that does not exceed $5 million.

The proposed rules would apply to a registrant when filing a Securities Act or Exchange Act registration statement or an Exchange Act annual or other periodic report. We estimate that there are 1,004 registrants that are small entities that would be affected by the proposed rules.

D. Reporting, Recordkeeping, and Other Compliance Requirements

The proposed amendments would require a registrant, including a small entity, to disclose certain climate-related information, including data about their GHG emissions, when filing a Securities Act or Exchange Act registration statement or Exchange Act annual or other periodic report. In particular, like larger registrants, small entities would be required to disclose information about: The oversight of their boards and management regarding climate-related risks; any material impacts of climate-related risks on their consolidated financial statements, business, strategy, and outlook; their risk management of climate-related risks; climate-related targets or goals, if any; and certain financial statement metrics. In addition, like other registrants, small entities would be required to disclose their Scopes 1 and 2 emissions. We anticipate that the nature of any benefits or costs associated with the above proposed amendments would be similar for large and small entities. Accordingly, we refer to the discussion of the proposed amendments' economic effects on all affected parties, including small entities, in Section IV.C. Consistent with that discussion, we anticipate that the economic benefits and costs likely would vary widely among small entities based on a number of factors, including the nature and conduct of their businesses, which makes it difficult to

[1062] We request comment pursuant to 44 U.S.C. 3506(c)(2)(B).

[1063] 5 U.S.C. 601 *et seq.*

[1064] 5 U.S.C. 603(a).

[1065] 5 U.S.C. 601(6).

project the economic impact on small entities with precision. However, we request comment on how the proposed amendments would affect small entities.

While small entities would not be exempt from the full scope of the proposed amendments, they would be exempt from the Scope 3 emissions disclosure requirements, which would likely impose the greatest compliance burden for registrants due to the complexity of data gathering, calculation, and assessment required for that type of emissions.[1066] Small entities would also have a longer transition period to comply with the proposed rules than other registrants.[1067] We believe that these accommodations would reduce the proposed rules' compliance burden for small entities that, compared to larger registrants with more resources, may be less able to absorb the costs associated with reporting of Scope 3 emissions and may need additional time to allocate the resources necessary to begin providing climate-related disclosures.

E. Duplicative, Overlapping, or Conflicting Federal Rules

The proposed rules do not duplicate or conflict with other existing federal rules. As discussed in Section IV, some registrants currently report certain GHG emissions via the EPA's 2009 mandatory Greenhouse Gas Reporting Program. However, as discussed above, the reporting requirements of the EPA's program and the resulting data are different and more suited to the purpose of building a national inventory of GHG emissions rather than allowing investors to assess emissions-related risks to individual registrants.

F. Significant Alternatives

The RFA directs us to consider alternatives that would accomplish our stated objectives, while minimizing any significant economic impact on small entities. In connection with the proposed amendments, we considered the following alternatives:

- Establishing different compliance or reporting requirements that take into account the resources available to small entities;
- Clarifying, consolidating, or simplifying compliance and reporting requirements under the rules for small entities;
- Using performance rather than design standards; and
- Exempting small entities from all or part of the requirements.

As discussed above, the proposed amendments would exempt small entities from certain GHG emissions disclosure requirements that would likely impose the greatest compliance burden on registrants compared to other proposed disclosure requirements. In addition, while there would be a transition period for all registrants to comply with the proposed amendments, small entities would have an additional two more years to comply with the proposed rules than large accelerated filers and an additional year compared to other registrants. We believe that this scaled and phased-in approach would help minimize the economic impact of the proposed amendments on small entities. We are not, however, proposing a complete exemption from the proposed amendments for SRCs because, due to their broad impact across industries and jurisdictions, climate-related risks may materially impact the operations and financial condition of domestic and foreign issuers, both large and small.

For similar reasons, other than the exemption for reporting Scope 3 emissions by SRCs, we are not proposing to clarify, consolidate, or simplify the proposed disclosure requirements for small entities. A key objective of the proposed amendments is to elicit consistent, comparable and reliable information about climate-related risks across registrants. Alternative compliance requirements for small entities could undermine that goal.

The proposed amendments are primarily based on performance standards with some provisions that are more like design standards. For example, while the proposed amendments include certain concepts, such as scopes, developed by the GHG Protocol, they do not require a registrant to use the GHG Protocol's methodology when calculating its GHG emissions if another methodology better suits its circumstances. Using a performance standard for calculation of GHG emissions would provide registrants with some flexibility regarding how to comply with the proposed GHG emissions requirement while still providing useful information for investors about the various scopes of emissions. Similarly, the proposed amendments would require a registrant that is a large accelerated filer or an accelerated filer to include an attestation report covering its Scopes 1 and 2 emissions that would require the report to meet certain minimum criteria while permitting the filer, at its option, to obtain additional levels of assurance. In contrast, the proposed amendments would require all registrants, including small entities, to express their GHG emissions both disaggregated by each constituent greenhouse gas and in the aggregate, expressed in terms of carbon dioxide equivalent (CO_2e). Using a design standard for the expression of a registrant's GHG emissions would enhance the comparability of this disclosure for investors.

Request for Comment

We encourage the submission of comments with respect to any aspect of this IRFA. In particular, we request comments regarding:

- How the proposed rule and form amendments can achieve their objective while lowering the burden on small entities;
- The number of small entity companies that may be affected by the proposed rule and form amendments;
- The existence or nature of the potential effects of the proposed amendments on small entity companies discussed in the analysis;
- How to quantify the effects of the proposed amendments; and
- Whether there are any federal rules that duplicate, overlap, or conflict with the proposed amendments.

Commenters are asked to describe the nature of any effect and provide empirical data supporting the extent of that effect. Comments will be considered in the preparation of the Final Regulatory Flexibility Analysis, if the proposed rules are adopted, and will be placed in the same public file as comments on the proposed rules themselves.

VII. Small Business Regulatory Enforcement Fairness Act

For purposes of the Small Business Regulatory Enforcement Fairness Act of 1996 (''SBREFA''),[1068] the Commission must advise OMB as to whether the proposed amendments constitute a ''major'' rule. Under SBREFA, a rule is considered ''major'' where, if adopted, it results in or is likely to result in:

- An annual effect on the U.S. economy of $100 million or more;
- A major increase in costs or prices for consumers or individual industries; or
- Significant adverse effects on competition, investment, or innovation.

We request comment on whether our proposal would be a ''major rule'' for purposes of SBREFA. In particular, we request comment and empirical data on:

[1066] *See supra* Section II.G.3 and II.L (discussing the proposed exemption from Scope 3 emissions disclosure for smaller reporting companies).

[1067] *See supra* Section II.L (discussing the proposed additional two years for smaller reporting companies to comply with the proposed rules compared to large accelerated filers).

[1068] 5 U.S.C. 801 *et seq.*

- The potential effect on the U.S. economy on an annual basis;
- Any potential increase in costs or prices for consumers or individual industries; and
- Any potential adverse effect on competition, investment, or innovation.

VIII. Statutory Authority

The amendments contained in this release are being proposed under the authority set forth in Sections 7, 10, 19(a), and 28 of the Securities Act, as amended, and Sections 3(b), 12, 13, 15, 23(a), and 36 of the Exchange Act, as amended.

List of Subjects in 17 CFR Parts 210, 229, 232, 239, and 249

Accountants; Accounting; Administrative practice and procedure, Reporting and recordkeeping requirements, Securities.

For the reasons set out in the preamble, the Commission is proposing to amend title 17, chapter II of the Code of Federal Regulations as follows:

PART 210—FORM AND CONTENT OF AND REQUIREMENTS FOR FINANCIAL STATEMENTS, SECURITIES ACT OF 1933, SECURITIES EXCHANGE ACT OF 1934, INVESTMENT COMPANY ACT OF 1940, INVESTMENT ADVISERS ACT OF 1940, AND ENERGY POLICY AND CONSERVATION ACT OF 1975

■ 1. The authority citation for part 210 continues to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 77z–2, 77z–3, 77aa(25), 77aa(26), 77nn(25), 77nn(26), 78c, 78j–1, 78*l,* 78m, 78n, 78o(d), 78q, 78u-5, 78w, 78ll, 78mm, 80a–8, 80a20, 80a–29, 80a–30, 80a–31, 80a–37(a), 80b–3, 80b–11, 7202 and 7262, and sec. 102(c), Pub. L. 112–106, 126 Stat. 310 (2012), unless otherwise noted.

■ 2. Amend § 210.8–01 by revising paragraph (b) to read as follows:

§ 210.8–01 General requirements for Article 8.

* * * * *

(b) Smaller reporting companies electing to prepare their financial statements with the form and content required in Article 8 need not apply the other form and content requirements in 17 CFR part 210 (Regulation S–X) with the exception of the following:

(1) The report and qualifications of the independent accountant shall comply with the requirements of §§ 210.2–01 through 210.2–07 (Article 2); and

(2) The description of accounting policies shall comply with § 210.4–08(n);

(3) Smaller reporting companies engaged in oil and gas producing activities shall follow the financial accounting and reporting standards specified in § 210.4–10 with respect to such activities; and

(4) Sections 210.14–01 and 210.14–02 (Article 14).

* * * * *

■ 3. Add an undesignated center heading and §§ 210.14–01 and 210.14–02 to read as follows:

Article 14—Climate-Related Disclosure

§ 210.14–01 Climate-related disclosure instructions.

(a) *General.* A registrant must include disclosure pursuant to § 210.14–02 in any filing that is required to include disclosure pursuant to subpart 229.1500 of this chapter and that also requires the registrant to include its audited financial statements. The disclosure pursuant to § 210.14–02 must be included in a note to the financial statements included in such filing.

(b) *Definitions.* The definitions in § 229.1500 (Item 1500 of Regulation S–K) apply to this Article 14 of Regulation S–X.

(c) *Basis of calculation.* When calculating the metrics in this Article 14, except where otherwise indicated, a registrant must:

(1) Use financial information that is consistent with the scope of the rest of its consolidated financial statements included in the filing; and

(2) Whenever applicable, apply the same accounting principles that it is required to apply in preparation of the rest of its consolidated financial statements included in the filing.

(d) *Historical periods.* Disclosure must be provided for the registrant's most recently completed fiscal year, and for the historical fiscal year(s) included in the consolidated financial statements in the filing (*e.g.,* a registrant that is required to include balance sheets as of the end of its two most recent fiscal years and income statements and cash flow statements as of the end of its three most recent fiscal years would be required to disclose two years of the climate-related metrics that correspond to balance sheet line items and three years of the climate-related metrics that correspond to income statement or cash flow statement line items).

§ 210.14–02 Climate-related metrics.

(a) *Contextual information.* Provide contextual information, describing how each specified metric was derived, including a description of significant inputs and assumptions used, and, if applicable, policy decisions made by the registrant to calculate the specified metrics.

(b) *Disclosure thresholds.* (1) Disclosure of the financial impact on a line item in the registrant's consolidated financial statements pursuant to paragraphs (c) and (d) of this section (including any impacts included pursuant to paragraphs (i) and (j) of this section) is not required if the sum of the absolute values of all the impacts on the line item is less than one percent of the total line item for the relevant fiscal year.

(2) Disclosure of the aggregate amount of expenditure expensed or the aggregate amount of capitalized costs incurred pursuant to paragraphs (e) and (f) of this section (including any impacts included pursuant to paragraphs (i) and (j) of this section) is not required if such amount is less than one percent of the total expenditure expensed or total capitalized costs incurred, respectively, for the relevant fiscal year.

(c) *Financial impacts of severe weather events and other natural conditions.* Disclose the impact of severe weather events and other natural conditions, such as flooding, drought, wildfires, extreme temperatures, and sea level rise on any relevant line items in the registrant's consolidated financial statements during the fiscal years presented. Disclosure must be presented, at a minimum, on an aggregated line-by-line basis for all negative impacts and, separately, at a minimum, on an aggregated line-by-line basis for all positive impacts. Impacts may include, for example:

(1) Changes to revenues or costs from disruptions to business operations or supply chains;

(2) Impairment charges and changes to the carrying amount of assets (such as inventory, intangibles, and property, plant and equipment) due to the assets being exposed to severe weather, flooding, drought, wildfires, extreme temperatures, and sea level rise;

(3) Changes to loss contingencies or reserves (such as environmental reserves or loan loss allowances) due to impact from severe weather events; and

(4) Changes to total expected insured losses due to flooding or wildfire patterns.

(d) *Financial impacts related to transition activities.* Disclose the impact of any efforts to reduce GHG emissions or otherwise mitigate exposure to transition risks on any relevant line items in the registrant's consolidated financial statements during the fiscal years presented. Disclosure must be presented, at a minimum, on an aggregated line-by-line basis for all negative impacts and, separately, at a minimum, on an aggregated line-by-line

basis for all positive impacts. Impacts may include, for example:

(1) Changes to revenue or cost due to new emissions pricing or regulations resulting in the loss of a sales contract;

(2) Changes to operating, investing, or financing cash flow from changes in upstream costs, such as transportation of raw materials;

(3) Changes to the carrying amount of assets (such as intangibles and property, plant, and equipment) due to, among other things, a reduction of the asset's useful life or a change in the asset's salvage value by being exposed to transition activities; and

(4) Changes to interest expense driven by financing instruments such as climate-linked bonds issued where the interest rate increases if certain climate-related targets are not met.

(e) *Expenditure to mitigate risks of severe weather events and other natural conditions.* Disclose separately the aggregate amount of expenditure expensed and the aggregate amount of capitalized costs incurred during the fiscal years presented to mitigate the risks from severe weather events and other natural conditions, such as flooding, drought, wildfires, extreme temperatures, and sea level rise. For example, a registrant may be required to disclose the amount of expense or capitalized costs, as applicable, to increase the resilience of assets or operations, retire or shorten the estimated useful lives of impacted assets, relocate assets or operations at risk, or otherwise reduce the future impact of severe weather events and other natural conditions on business operations.

(f) *Expenditure related to transition activities.* Disclose separately the aggregate amount of expenditure expensed and the aggregate amount of capitalized costs incurred during the fiscal years presented to reduce GHG emissions or otherwise mitigate exposure to transition risks. For example, a registrant may be required to disclose the amount of expense or capitalized costs, as applicable, related to research and development of new technologies, purchase of assets, infrastructure, or products that are intended to reduce GHG emissions, increase energy efficiency, offset emissions (purchase of energy credits), or improve other resource efficiency. A registrant that has disclosed GHG emissions reduction targets or other climate-related commitments must disclose the expenditures and costs related to meeting its targets, commitments, and goals, if any, in the fiscal years presented.

(g) *Financial estimates and assumptions impacted by severe weather events and other natural conditions.* Disclose whether the estimates and assumptions the registrant used to produce the consolidated financial statements were impacted by exposures to risks and uncertainties associated with, or known impacts from, severe weather events and other natural conditions, such as flooding, drought, wildfires, extreme temperatures, and sea level rise. If yes, provide a qualitative description of how the development of such estimates and assumptions were impacted by such events.

(h) *Financial estimates and assumptions impacted by transition activities.* Disclose whether the estimates and assumptions the registrant used to produce the consolidated financial statements were impacted by risks and uncertainties associated with, or known impacts from, a potential transition to a lower carbon economy or any climate-related targets disclosed by the registrant. If yes, provide a qualitative description of how the development of such estimates and assumptions were impacted by such a potential transition or the registrant's disclosed climate-related targets.

(i) *Impact of identified climate-related risks.* A registrant must also include the impact of any climate-related risks (separately by physical risks and transition risks, as defined in § 229.1500(c) of this chapter), identified by the registrant pursuant to § 229.1502(a) of this chapter, on any of the financial statement metrics disclosed pursuant to paragraphs (c) through (h) of this section.

(j) *Impact of climate-related opportunities.* A registrant may also include the impact of any opportunities arising from severe weather events and other natural conditions, any impact of efforts to pursue climate-related opportunities associated with transition activities, and the impact of any other climate-related opportunities, including those identified by the registrant pursuant to § 229.1502(a) of this chapter, on any of the financial statement metrics disclosed pursuant to paragraphs (c) through (h) of this section. If a registrant makes a policy decision to disclose the impact of an opportunity, it must do so consistently for the fiscal years presented, including for each financial statement line item and all relevant opportunities identified by the registrant.

PART 229—STANDARD INSTRUCTIONS FOR FILING FORMS UNDER SECURITIES ACT OF 1933, SECURITIES EXCHANGE ACT OF 1934 AND ENERGY POLICY AND CONSERVATION ACT OF 1975—REGULATION S–K

■ 4. The authority citation for part 229 continues to read as follows:

Authority: 15 U.S.C. 77e, 77f, 77g, 77h, 77j, 77k, 77s, 77z–2, 77z-3, 77aa(25), 77aa(26), 77ddd, 77eee, 77ggg, 77hhh, 77iii, 77jjj, 77nnn, 77sss, 78c, 78i, 78j, 78j-3, 78l, 78m, 78n, 78n–1, 78o, 78u-5, 78w, 78ll, 78 mm, 80a–8, 80a–9, 80a–20, 80a–29, 80a–30, 80a–31(c), 80a37, 80a–38(a), 80a–39, 80b–11 and 7201 *et seq.;* 18 U.S.C. 1350; sec. 953(b), Pub. L. 111–203, 124 Stat. 1904 (2010); and sec. 102(c), Pub. L. 112–106, 126 Stat. 310 (2012).

■ 5. Add subpart 229.1500 (''Climate-Related Disclosure'') to read as follows:

Subpart 229.1500—Climate-Related Disclosure

Sec.

Subpart 229.1500—Climate-Related Disclosure

§ 229.1500 (Item 1500) Definitions.

As used in this subpart, these terms have the following meanings:

(a) *Carbon offsets* represents an emissions reduction or removal of greenhouse gases (''GHG'') in a manner calculated and traced for the purpose of offsetting an entity's GHG emissions.

(b) *Climate-related opportunities* means the actual or potential positive impacts of climate-related conditions and events on a registrant's consolidated financial statements, business operations, or value chains, as a whole.

(c) *Climate-related risks* means the actual or potential negative impacts of climate-related conditions and events on a registrant's consolidated financial statements, business operations, or value chains, as a whole. Climate-related risks include the following:

(1) *Physical risks* include both acute risks and chronic risks to the registrant's business operations or the operations of those with whom it does business.

(2) *Acute risks* are event-driven and may relate to shorter term extreme weather events, such as hurricanes, floods, and tornadoes, among other events.

(3) *Chronic risks* relate to longer term weather patterns and related effects, such as sustained higher temperatures, sea level rise, drought, and increased wildfires, as well as related effects such as decreased arability of farmland, decreased habitability of land, and decreased availability of fresh water.

(4) *Transition risks* are the actual or potential negative impacts on a registrant's consolidated financial statements, business operations, or value chains attributable to regulatory, technological, and market changes to address the mitigation of, or adaptation to, climate-related risks, such as increased costs attributable to changes in law or policy, reduced market demand for carbon-intensive products leading to decreased prices or profits for such products, the devaluation or abandonment of assets, risk of legal liability and litigation defense costs, competitive pressures associated with the adoption of new technologies, reputational impacts (including those stemming from a registrant's customers or business counterparties) that might trigger changes to market behavior, consumer preferences or behavior, and registrant behavior.

(d) *Carbon dioxide equivalent* (''CO_2e'') means the common unit of measurement to indicate the global warming potential (''GWP'') of each greenhouse gas, expressed in terms of the GWP of one unit of carbon dioxide (''CO_2'').

(e) *Emission factor* means a multiplication factor allowing actual GHG emissions to be calculated from available activity data or, if no activity data is available, economic data, to derive absolute GHG emissions. Examples of activity data include kilowatt-hours of electricity used, quantity of fuel used, output of a process, hours of operation of equipment, distance travelled, and floor area of a building.

(f) *Global warming potential* (''GWP'') means a factor describing the global warming impacts of different greenhouse gases. It is a measure of how much energy will be absorbed in the atmosphere over a specified period of time as a result of the emission of one ton of a greenhouse gas, relative to the emissions of one ton of carbon dioxide (CO_2).

(g) *Greenhouse gases* (''GHG'') means carbon dioxide (CO_2), methane (''CH_4''), nitrous oxide (''N_2O''), nitrogen trifluoride (''NF_3''), hydrofluorocarbons (''HFCs''), perfluorocarbons (''PFCs''), and sulfur hexafluoride (''SF_6'').

(h) *GHG emissions* means direct and indirect emissions of greenhouse gases expressed in metric tons of carbon dioxide equivalent (CO_2e), of which:

(1) Direct emissions are GHG emissions from sources that are owned or controlled by a registrant.

(2) Indirect emissions are GHG emissions that result from the activities of the registrant, but occur at sources not owned or controlled by the registrant.

(i) *GHG intensity* (or *carbon intensity*) means a ratio that expresses the impact of GHG emissions per unit of economic value (*e.g.,* metric tons of CO_2e per unit of total revenues, using the registrant's reporting currency) or per unit of production (*e.g.,* metric tons of CO_2e per product produced).

(j) *Internal carbon price* means an estimated cost of carbon emissions used internally within an organization.

(k) *Location* means a ZIP code or, in a jurisdiction that does not use ZIP codes, a similar subnational postal zone or geographic location.

(l) *Operational boundaries* means the boundaries that determine the direct and indirect emissions associated with the business operations owned or controlled by a registrant.

(m) *Organizational boundaries* means the boundaries that determine the operations owned or controlled by a registrant for the purpose of calculating its GHG emissions.

(n) *Renewable energy credit or certificate* (''*REC*'') means a credit or certificate representing each megawatt-hour (1 MWh or 1,000 kilowatt-hours) of renewable electricity generated and delivered to a power grid.

(o) *Scenario analysis* means a process for identifying and assessing a potential range of outcomes of various possible future climate scenarios, and how climate-related risks may impact a registrant's operations, business strategy, and consolidated financial statements over time. For example, registrants might use scenario analysis to test the resilience of their strategies under certain future climate scenarios, such as those that assume global temperature increases of 3 °C, 2 °C, and 1.5 °C above pre-industrial levels.

(p) *Scope 1 emissions* are direct GHG emissions from operations that are owned or controlled by a registrant.

(q) *Scope 2 emissions* are indirect GHG emissions from the generation of purchased or acquired electricity, steam, heat, or cooling that is consumed by operations owned or controlled by a registrant.

(r) *Scope 3 emissions* are all indirect GHG emissions not otherwise included in a registrant's Scope 2 emissions, which occur in the upstream and downstream activities of a registrant's value chain.

(1) Upstream activities in which Scope 3 emissions might occur include:

(i) A registrant's purchased goods and services;

(ii) A registrant's capital goods;

(iii) A registrant's fuel and energy related activities not included in Scope 1 or Scope 2 emissions;

(iv) Transportation and distribution of purchased goods, raw materials, and other inputs;

(v) Waste generated in a registrant's operations;

(vi) Business travel by a registrant's employees;

(vii) Employee commuting by a registrant's employees; and

(viii) A registrant's leased assets related principally to purchased or acquired goods or services.

(2) Downstream activities in which Scope 3 emissions might occur include:

(i) Transportation and distribution of a registrant's sold products, goods or other outputs;

(ii) Processing by a third party of a registrant's sold products;

(iii) Use by a third party of a registrant's sold products;

(iv) End-of-life treatment by a third party of a registrant's sold products;

(v) A registrant's leased assets related principally to the sale or disposition of goods or services;

(vi) A registrant's franchises; and

(vii) Investments by a registrant.

(s) *Transition plan* means a registrant's strategy and implementation plan to reduce climate-related risks, which may include a plan to reduce its GHG emissions in line with its own commitments or commitments of jurisdictions within which it has significant operations.

(t) *Value chain* means the upstream and downstream activities related to a registrant's operations. Upstream activities in connection with a value chain may include activities by a party other than the registrant that relate to the initial stages of a registrant's production of a good or service (*e.g.,* materials sourcing, materials processing, and supplier activities). Downstream activities in connection with a value chain may include activities by a party other than the registrant that relate to processing materials into a finished product and delivering it or providing a service to the end user (*e.g.,* transportation and distribution, processing of sold products, use of sold products, end of life treatment of sold products, and investments).

§ 229.1501 (Item 1501) Governance.

(a)(1) Describe the board of director's oversight of climate-related risks. Include the following, as applicable:

(i) The identity of any board members or board committee responsible for the oversight of climate-related risks;

(ii) Whether any member of the board of directors has expertise in climate-related risks, with disclosure in such detail as necessary to fully describe the nature of the expertise;

(iii) The processes by which the board of directors or board committee discusses climate-related risks, including how the board is informed about climate-related risks, and the frequency of such discussion;

(iv) Whether and how the board of directors or board committee considers climate-related risks as part of its business strategy, risk management, and financial oversight; and

(v) Whether and how the board of directors sets climate-related targets or goals, and how it oversees progress against those targets or goals, including the establishment of any interim targets or goals.

(2) If applicable, a registrant may also describe the board of director's oversight of climate-related opportunities.

(b)(1) Describe management's role in assessing and managing climate-related risks. Include the following, as applicable:

(i) Whether certain management positions or committees are responsible for assessing and managing climate-related risks and, if so, the identity of such positions or committees and the relevant expertise of the position holders or members in such detail as necessary to fully describe the nature of the expertise;

(ii) The processes by which such positions or committees are informed about and monitor climate-related risks; and

(iii) Whether and how frequently such positions or committees report to the board or a committee of the board on climate-related risks.

(2) If applicable, a registrant may also describe management's role in assessing and managing climate-related opportunities.

§ 229.1502 (Item 1502) Strategy, business model, and outlook.

(a) Describe any climate-related risks reasonably likely to have a material impact on the registrant, including on its business or consolidated financial statements, which may manifest over the short, medium, and long term. If applicable, a registrant may also disclose the actual and potential impacts of any climate-related opportunities when responding to any of the provisions in this section.

(1) Discuss such climate-related risks, specifying whether they are physical or transition risks and the nature of the risks presented.

(i) For physical risks, describe the nature of the risk, including if it may be categorized as an acute or chronic risk, and the location and nature of the properties, processes, or operations subject to the physical risk.

(A) If a risk concerns the flooding of buildings, plants, or properties located in flood hazard areas, disclose the percentage of those assets (square meters or acres) that are located in flood hazard areas in addition to their location.

(B) If a risk concerns the location of assets in regions of high or extremely high water stress, disclose the amount of assets (*e.g.,* book value and as a percentage of total assets) located in those regions in addition to their location. Also disclose the percentage of the registrant's total water usage from water withdrawn in those regions.

(ii) For transition risks, describe the nature of the risk, including whether it relates to regulatory, technological, market (including changing consumer, business counterparty, and investor preferences), liability, reputational, or other transition-related factors, and how those factors impact the registrant. A registrant that has significant operations in a jurisdiction that has made a GHG emissions reduction commitment may be exposed to transition risks related to the implementation of the commitment.

(2) Describe how the registrant defines short-, medium-, and long-term time horizons, including how it takes into account or reassesses the expected useful life of the registrant's assets and the time horizons for the registrant's climate-related planning processes and goals.

(b) Describe the actual and potential impacts of any climate-related risks identified in response to paragraph (a) of this section on the registrant's strategy, business model, and outlook.

(1) Include impacts on the registrant's:

(i) Business operations, including the types and locations of its operations;

(ii) Products or services;

(iii) Suppliers and other parties in its value chain;

(iv) Activities to mitigate or adapt to climate-related risks, including adoption of new technologies or processes;

(v) Expenditure for research and development; and

(vi) Any other significant changes or impacts.

(2) Include the time horizon for each described impact (*i.e.,* in the short, medium, or long term, as defined in response to paragraph (a) of this section).

(c) Discuss whether and how any impacts described in response to paragraph (b) of this section are considered as part of the registrant's business strategy, financial planning, and capital allocation. Provide both current and forward-looking disclosures that facilitate an understanding of whether the implications of the identified climate-related risks have been integrated into the registrant's business model or strategy, including how any resources are being used to mitigate climate-related risks. Include in this discussion how any of the metrics referenced in § 210.14–02 of this chapter and § 229.1504 or any of the targets referenced in § 229.1506 relate to the registrant's business model or business strategy. If applicable, include in this discussion the role that carbon offsets or RECs play in the registrant's climate-related business strategy.

(d) Provide a narrative discussion of whether and how any climate-related risks described in response to paragraph (a) of this section have affected or are reasonably likely to affect the registrant's consolidated financial statements. The discussion should include any of the climate-related metrics referenced in § 210.14–02 of this chapter that demonstrate that the identified climate-related risks have had a material impact on reported financial condition or operations.

(e)(1) If a registrant maintains an internal carbon price, disclose:

(i) The price in units of the registrant's reporting currency per metric ton of CO_2e;

(ii) The total price, including how the total price is estimated to change over time, if applicable;

(iii) The boundaries for measurement of overall CO_2e on which the total price is based if different from the GHG emission organizational boundary required pursuant to § 229.1504(e)(2); and

(iv) The rationale for selecting the internal carbon price applied.

(2) Describe how the registrant uses any internal carbon price described in response to paragraph (e)(1) of this section to evaluate and manage climate-related risks.

(3) If a registrant uses more than one internal carbon price, it must provide the disclosures required by this section for each internal carbon price, and disclose its reasons for using different prices.

(f) Describe the resilience of the registrant's business strategy in light of potential future changes in climate-related risks. Describe any analytical tools, such as scenario analysis, that the registrant uses to assess the impact of climate-related risks on its business and consolidated financial statements, and to support the resilience of its strategy and business model. If the registrant uses scenario analysis to assess the resilience of its business strategy to climate-related risks, disclose the scenarios considered (*e.g.,* an increase of no greater than 3 °C, 2 °C, or 1.5 °C above pre-industrial levels), including parameters, assumptions, and analytical choices, and the projected principal financial impacts on the registrant's business strategy under each scenario. The disclosure should include both qualitative and quantitative information.

§ 229.1503 (Item 1503) Risk management.

(a) Describe any processes the registrant has for identifying, assessing, and managing climate-related risks. If applicable, a registrant may also describe any processes for identifying, assessing, and managing climate-related opportunities when responding to any of the provisions in this section.

(1) When describing any processes for identifying and assessing climate-related risks, disclose, as applicable, how the registrant:

(i) Determines the relative significance of climate-related risks compared to other risks;

(ii) Considers existing or likely regulatory requirements or policies, such as GHG emissions limits, when identifying climate-related risks;

(iii) Considers shifts in customer or counterparty preferences, technological changes, or changes in market prices in assessing potential transition risks; and

(iv) Determines the materiality of climate-related risks, including how it assesses the potential scope and impact of an identified climate-related risk, such as the risks identified in response to § 229.1502.

(2) When describing any processes for managing climate-related risks, disclose, as applicable, how the registrant:

(i) Decides whether to mitigate, accept, or adapt to a particular risk;

(ii) Prioritizes whether to address climate-related risks; and

(iii) Determines how to mitigate any high priority risks.

(b) Disclose whether and how any processes described in response to paragraph (a) of this section are integrated into the registrant's overall risk management system or processes. If a separate board or management committee is responsible for assessing and managing climate-related risks, a registrant should disclose how that committee interacts with the registrant's board or management committee governing risks.

(c)(1) If the registrant has adopted a transition plan as part of its climate-related risk management strategy, describe the plan, including the relevant metrics and targets used to identify and manage any physical and transition risks. To allow for an understanding of the registrant's progress to meet the plan's targets or goals over time, a registrant must update its disclosure about the transition plan each fiscal year by describing the actions taken during the year to achieve the plan's targets or goals.

(2) If the registrant has adopted a transition plan, discuss, as applicable:

(i) How the registrant plans to mitigate or adapt to any identified physical risks, including but not limited to those concerning energy, land, or water use and management;

(ii) How the registrant plans to mitigate or adapt to any identified transition risks, including the following:

(A) Laws, regulations, or policies that:

(*1*) Restrict GHG emissions or products with high GHG footprints, including emissions caps; or

(*2*) Require the protection of high conservation value land or natural assets;

(B) Imposition of a carbon price; and

(C) Changing demands or preferences of consumers, investors, employees, and business counterparties.

(3) If applicable, a registrant that has adopted a transition plan as part of its climate-related risk management strategy may also describe how it plans to achieve any identified climate-related opportunities, such as:

(i) The production of products that may facilitate the transition to a lower carbon economy, such as low emission modes of transportation and supporting infrastructure;

(ii) The generation or use of renewable power;

(iii) The production or use of low waste, recycled, or other consumer products that require less carbon intensive production methods;

(iv) The setting of conservation goals and targets that would help reduce GHG emissions; and

(v) The provision of services related to any transition to a lower carbon economy.

§ 229.1504 (Item 1504) GHG emissions metrics.

(a) *General.* Disclose a registrant's GHG emissions, as defined in § 229.1500(h), for its most recently completed fiscal year, and for the historical fiscal years included in its consolidated financial statements in the filing, to the extent such historical GHG emissions data is reasonably available.

(1) For each required disclosure of a registrant's Scopes 1, 2, and 3 emissions, disclose the emissions both disaggregated by each constituent greenhouse gas, as specified in § 229.1500(g), and in the aggregate, expressed in terms of CO_2e.

(2) When disclosing a registrant's Scopes 1, 2, and 3 emissions, exclude the impact of any purchased or generated offsets.

(b) *Scopes 1 and 2 emissions.* (1) Disclose the registrant's total Scope 1 emissions and total Scope 2 emissions separately after calculating them from all sources that are included in the registrant's organizational and operational boundaries.

(2) When calculating emissions pursuant to paragraph (b)(1) of this section, a registrant may exclude emissions from investments that are not consolidated, are not proportionately consolidated, or that do not qualify for the equity method of accounting in the registrant's consolidated financial statements.

(c) *Scope 3 emissions.* (1) Disclose the registrant's total Scope 3 emissions if material. A registrant must also disclose its Scope 3 emissions if it has set a GHG emissions reduction target or goal that includes its Scope 3 emissions. Disclosure of a registrant's Scope 3 emissions must be separate from disclosure of its Scopes 1 and 2 emissions. If required to disclose Scope 3 emissions, identify the categories of upstream or downstream activities that have been included in the calculation of the Scope 3 emissions. If any category of Scope 3 emissions is significant to the registrant, identify all such categories and provide Scope 3 emissions data separately for them, together with the registrant's total Scope 3 emissions.

(2) If required to disclose Scope 3 emissions, describe the data sources used to calculate the registrant's Scope 3 emissions, including the use of any of the following:

(i) Emissions reported by parties in the registrant's value chain, and whether such reports were verified by the registrant or a third party, or unverified;

(ii) Data concerning specific activities, as reported by parties in the registrant's value chain; and

(iii) Data derived from economic studies, published databases, government statistics, industry associations, or other third-party sources outside of a registrant's value

chain, including industry averages of emissions, activities, or economic data.

(3) A smaller reporting company, as defined by §§ 229.10(f)(1), 230.405, and 240.12b–2 of this chapter, is exempt from, and need not comply with, the disclosure requirements of this paragraph (c).

(d) *GHG intensity.* (1) Using the sum of Scope 1 and 2 emissions, disclose GHG intensity in terms of metric tons of CO_2e per unit of total revenue (using the registrant's reporting currency) and per unit of production relevant to the registrant's industry for each fiscal year included in the consolidated financial statements. Disclose the basis for the unit of production used.

(2) If Scope 3 emissions are otherwise disclosed, separately disclose GHG intensity using Scope 3 emissions only.

(3) If a registrant has no revenue or unit of production for a fiscal year, it must disclose another financial measure of GHG intensity or another measure of GHG intensity per unit of economic output, as applicable, with an explanation of why the particular measure was used.

(4) A registrant may also disclose other measures of GHG intensity, in addition to metric tons of CO_2e per unit of total revenue (using the registrant's reporting currency) and per unit of production, if it includes an explanation of why a particular measure was used and why the registrant believes such measure provides useful information to investors.

(e) *Methodology and related instructions.* (1) A registrant must describe the methodology, significant inputs, and significant assumptions used to calculate its GHG emissions. The description of the registrant's methodology must include the registrant's organizational boundaries, operational boundaries (including any approach to categorization of emissions and emissions sources), calculation approach (including any emission factors used and the source of the emission factors), and any calculation tools used to calculate the GHG emissions. A registrant's description of its approach to categorization of emissions and emissions sources should explain how it determined the emissions to include as direct emissions, for the purpose of calculating its Scope 1 emissions, and indirect emissions, for the purpose of calculating its Scope 2 emissions.

(2) The organizational boundary and any determination of whether a registrant owns or controls a particular source for GHG emissions must be consistent with the scope of entities, operations, assets, and other holdings within its business organization as those included in, and based upon the same set of accounting principles applicable to, the registrant's consolidated financial statements.

(3) A registrant must use the same organizational boundaries when calculating its Scope 1 emissions and Scope 2 emissions. If required to disclose Scope 3 emissions, a registrant must also apply the same organizational boundaries used when determining its Scopes 1 and 2 emissions as an initial step in identifying the sources of indirect emissions from activities in its value chain over which it lacks ownership and control and which must be included in the calculation of its Scope 3 emissions. Once a registrant has determined its organizational and operational boundaries, a registrant must be consistent in its use of those boundaries when calculating its GHG emissions.

(4) A registrant may use reasonable estimates when disclosing its GHG emissions as long as it also describes the assumptions underlying, and its reasons for using, the estimates.

(i) When disclosing its GHG emissions for its most recently completed fiscal year, if actual reported data is not reasonably available, a registrant may use a reasonable estimate of its GHG emissions for its fourth fiscal quarter, together with actual, determined GHG emissions data for the first three fiscal quarters, as long as the registrant promptly discloses in a subsequent filing any material difference between the estimate used and the actual, determined GHG emissions data for the fourth fiscal quarter.

(ii) In addition to the use of reasonable estimates, a registrant may present its estimated Scope 3 emissions in terms of a range as long as it discloses its reasons for using the range and the underlying assumptions.

(5) A registrant must disclose, to the extent material and as applicable, any use of third-party data when calculating its GHG emissions, regardless of the particular scope of emissions. When disclosing the use of third-party data, it must identify the source of such data and the process the registrant undertook to obtain and assess such data.

(6) A registrant must disclose any material change to the methodology or assumptions underlying its GHG emissions disclosure from the previous fiscal year.

(7) A registrant must disclose, to the extent material and as applicable, any gaps in the data required to calculate its GHG emissions. A registrant's GHG emissions disclosure should provide investors with a reasonably complete understanding of the registrant's GHG emissions in each scope of emissions. If a registrant discloses any data gaps encountered when calculating its GHG emissions, it must also discuss whether it used proxy data or another method to address such gaps, and how its accounting for any data gaps has affected the accuracy or completeness of its GHG emissions disclosure.

(8) When determining whether its Scope 3 emissions are material, and when disclosing those emissions, in addition to emissions from activities in its value chain, a registrant must include GHG emissions from outsourced activities that it previously conducted as part of its own operations, as reflected in the financial statements for the periods covered in the filing.

(9) If required to disclose Scope 3 emissions, when calculating those emissions, if there was any significant overlap in the categories of activities producing the Scope 3 emissions, a registrant must describe the overlap, how it accounted for the overlap, and the effect on its disclosed total Scope 3 emissions.

(f) *Liability for Scope 3 emissions disclosures.* (1) A statement within the coverage of paragraph (f)(2) of this section that is made by or on behalf of a registrant is deemed not to be a fraudulent statement (as defined in paragraph (f)(3) of this section), unless it is shown that such statement was made or reaffirmed without a reasonable basis or was disclosed other than in good faith.

(2) This paragraph (f) applies to any statement regarding Scope 3 emissions that is disclosed pursuant to §§ 229.1500 through 229.1506 and made in a document filed with the Commission.

(3) For the purpose of this paragraph (f), the term fraudulent statement shall mean a statement that is an untrue statement of material fact, a statement false or misleading with respect to any material fact, an omission to state a material fact necessary to make a statement not misleading, or that constitutes the employment of a manipulative, deceptive, or fraudulent device, contrivance, scheme, transaction, act, practice, course of business, or an artifice to defraud as those terms are used in the Securities Act of 1933 or the Securities Exchange Act of 1934 or the rules or regulations promulgated thereunder.

§ 229.1505 Attestation of Scope 1 and Scope 2 emissions disclosure.

(a) *Attestation.* (1) A registrant that is required to provide Scope 1 and Scope 2 emissions disclosure pursuant to

§ 229.1504 and that is an accelerated filer or a large accelerated filer must include an attestation report covering such disclosure in the relevant filing. For filings made by an accelerated filer or a large accelerated filer for the second and third fiscal years after the compliance date for § 229.1504, the attestation engagement must, at a minimum, be at a limited assurance level and cover the registrant's Scope 1 and Scope 2 emissions disclosure. For filings made by an accelerated filer or large accelerated filer for the fourth fiscal year after the compliance date for § 229.1504 and thereafter, the attestation engagement must be at a reasonable assurance level and, at a minimum, cover the registrant's Scope 1 and Scope 2 emissions disclosures.

(2) Any attestation report required under this section must be provided pursuant to standards that are publicly available at no cost and are established by a body or group that has followed due process procedures, including the broad distribution of the framework for public comment. An accelerated filer or a large accelerated filer obtaining voluntary assurance prior to the first required fiscal year must comply with subparagraph (e) of this section. Voluntary assurance obtained by an accelerated filer or a large accelerated filer thereafter must follow the requirements of paragraphs (b) through (d) of this section and must use the same attestation standard as the required assurance over Scope 1 and Scope 2.

(b) *GHG emissions attestation provider.* The GHG emissions attestation report required by paragraph (a) of this section must be prepared and signed by a GHG emissions attestation provider. A GHG emissions attestation provider means a person or a firm that has all of the following characteristics:

(1) Is an expert in GHG emissions by virtue of having significant experience in measuring, analyzing, reporting, or attesting to GHG emissions. Significant experience means having sufficient competence and capabilities necessary to:

(i) Perform engagements in accordance with professional standards and applicable legal and regulatory requirements; and

(ii) Enable the service provider to issue reports that are appropriate under the circumstances.

(2) Is independent with respect to the registrant, and any of its affiliates, for whom it is providing the attestation report, during the attestation and professional engagement period.

(i) A GHG emissions attestation provider is not independent if such attestation provider is not, or a reasonable investor with knowledge of all relevant facts and circumstances would conclude that such attestation provider is not, capable of exercising objective and impartial judgment on all issues encompassed within the attestation provider's engagement.

(ii) In determining whether a GHG emissions attestation provider is independent, the Commission will consider:

(A) Whether a relationship or the provision of a service creates a mutual or conflicting interest between the attestation provider and the registrant (or any of its affiliates), places the attestation provider in the position of attesting such attestation provider's own work, results in the attestation provider acting as management or an employee of the registrant (or any of its affiliates), or places the attestation provider in a position of being an advocate for the registrant (or any of its affiliates); and

(B) All relevant circumstances, including all financial or other relationships between the attestation provider and the registrant (or any of its affiliates), and not just those relating to reports filed with the Commission.

(iii) The term ''affiliates'' as used in this section has the meaning provided in 17 CFR 210.2–01, except that references to ''audit'' are deemed to be references to the attestation services provided pursuant to this section.

(iv) The term ''attestation and professional engagement period'' as used in this section means both:

(A) The period covered by the attestation report; and

(B) The period of the engagement to attest to the registrant's GHG emissions or to prepare a report filed with the Commission (''the professional engagement period''). The professional engagement period begins when the GHG attestation service provider either signs an initial engagement letter (or other agreement to attest a registrant's GHG emissions) or begins attest procedures, whichever is earlier.

(c) *Attestation report requirements.* The GHG emissions attestation report required by paragraph (a) of this section must be included in the separately captioned ''Climate-Related Disclosure'' section in the filing. The form and content of the attestation report must follow the requirements set forth by the attestation standard (or standards) used by the GHG emissions attestation provider. Notwithstanding the foregoing, at a minimum the report must include the following:

(1) An identification or description of the subject matter or assertion being reported on, including the point in time or period of time to which the measurement or evaluation of the subject matter or assertion relates;

(2) An identification of the criteria against which the subject matter was measured or evaluated;

(3) A statement that identifies the level of assurance provided and describes the nature of the engagement;

(4) A statement that identifies the attestation standard (or standards) used;

(5) A statement that describes the registrant's responsibility to report on the subject matter or assertion being reported on;

(6) A statement that describes the attestation provider's responsibilities in connection with the preparation of the attestation report;

(7) A statement that the attestation provider is independent, as required by paragraph (a) of this section;

(8) For a limited assurance engagement, a description of the work performed as a basis for the attestation provider's conclusion;

(9) A statement that describes significant inherent limitations, if any, associated with the measurement or evaluation of the subject matter against the criteria;

(10) The GHG emissions attestation provider's conclusion or opinion, based on the applicable attestation standard(s) used;

(11) The signature of the attestation provider (whether by an individual or a person signing on behalf of the attestation provider's firm);

(12) The city and state where the attestation report has been issued; and

(13) The date of the report.

(d) *Additional disclosures by the registrant.* In addition to including the GHG emissions attestation report required by paragraph (a) of this section, a large accelerated filer and an accelerated filer must disclose the following information within the separately captioned ''Climate-Related Disclosure'' section in the filing, after requesting relevant information from any GHG emissions attestation provider as necessary:

(1) Whether the attestation provider has a license from any licensing or accreditation body to provide assurance, and if so, identify the licensing or accreditation body, and whether the attestation provider is a member in good standing of that licensing or accreditation body;

(2) Whether the GHG emissions attestation engagement is subject to any oversight inspection program, and if so, which program (or programs); and

(3) Whether the attestation provider is subject to record-keeping requirements with respect to the work performed for

the GHG emissions attestation engagement and, if so, identify the record-keeping requirements and the duration of those requirements.

(e) *Disclosure of voluntary attestation.* A registrant that is not required to include a GHG emissions attestation report pursuant to paragraph (a) of this section must disclose within the separately captioned ''Climate-Related Disclosure'' section in the filing the following information if the registrant's GHG emissions disclosures were subject to third-party attestation or verification:

(1) Identify the provider of such attestation or verification;

(2) Describe the attestation or verification standard used;

(3) Describe the level and scope of attestation or verification provided;

(4) Briefly describe the results of the attestation or verification;

(5) Disclose whether the third-party service provider has any other business relationships with or has provided any other professional services to the registrant that may lead to an impairment of the service provider's independence with respect to the registrant; and

(6) Disclose any oversight inspection program to which the service provider is subject (*e.g.,* the AICPA's peer review program).

§ 229.1506 (Item 1506) Targets and goals.

(a)(1) A registrant must provide disclosure pursuant to this section if it has set any targets or goals related to the reduction of GHG emissions, or any other climate-related target or goal (*e.g.,* regarding energy usage, water usage, conservation or ecosystem restoration, or revenues from low-carbon products) such as actual or anticipated regulatory requirements, market constraints, or other goals established by a climate-related treaty, law, regulation, policy, or organization.

(2) A registrant may provide the disclosure required by this section as part of its disclosure in response to § 229.1502 or § 229.1503.

(b) If the registrant has set climate-related targets or goals, disclose the targets or goals, including, as applicable, a description of:

(1) The scope of activities and emissions included in the target;

(2) The unit of measurement, including whether the target is absolute or intensity based;

(3) The defined time horizon by which the target is intended to be achieved, and whether the time horizon is consistent with one or more goals established by a climate-related treaty, law, regulation, policy, or organization;

(4) The defined baseline time period and baseline emissions against which progress will be tracked with a consistent base year set for multiple targets;

(5) Any interim targets set by the registrant; and

(6) How the registrant intends to meet its climate-related targets or goals. For example, for a target or goal regarding net GHG emissions reduction, the discussion could include a strategy to increase energy efficiency, transition to lower carbon products, purchase carbon offsets or RECs, or engage in carbon removal and carbon storage.

(c) Disclose relevant data to indicate whether the registrant is making progress toward meeting the target or goal and how such progress has been achieved. A registrant must update this disclosure each fiscal year by describing the actions taken during the year to achieve its targets or goals.

(d) If carbon offsets or RECs have been used as part of a registrant's plan to achieve climate-related targets or goals, disclose the amount of carbon reduction represented by the offsets or the amount of generated renewable energy represented by the RECS, the source of the offsets or RECs, a description and location of the underlying projects, any registries or other authentication of the offsets or RECs, and the cost of the offsets or RECs.

§ 229.1507 (Item 1507) Interactive data requirement.

Provide the disclosure required by this Subpart 1500 in an Interactive Data File as required by § 232.405 of this chapter (Rule 405 of Regulation S–T) in accordance with the EDGAR Filer Manual.

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 6. The general authority citation for part 232 continues to read as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78*l,* 78m, 78n, 78o(d), 78w(a), 78*ll,* 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, 7201 *et seq.;* and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 7. Amend § 232.405 by adding paragraphs (b)(1)(iii), (b)(3)(i)(C), and (b)(4) as follows:

§ 232.405 Interactive Data File submissions.

* * * * *

(b) * * *

(1) * * *

(iii) As applicable, the disclosure set forth in paragraph (4) of this section.

* * * * *

(3) * * *

(i) * * *

(C) The disclosure set forth in paragraph (4) of this section.

(4) An Interactive Data File must consist of the disclosure provided under 17 CFR 229 (Regulation S–K) and related provisions that is required to be tagged, including, as applicable:

(i) The climate-related information required by Subpart 1500 of Regulation S–K (§§ 229.1500 through 229.1507 of this chapter).

* * * * *

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

■ 8. The general authority citation for part 239 continues to read as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s, 77z–2, 77z–3, 77sss, 78c, 78*l,* 78m,78n, 78o(d), 78o-7 note, 78u-5, 78w(a), 78*ll,* 78mm, 80a–2(a), 80a–3, 80a–8, 80a–9, 80a–10, 80a–13, 80a–24, 80a–26, 80a–29, 80a–30, and 80a–37; and sec. 107, Pub. L. 112–106, 126 Stat. 312, unless otherwise noted.

* * * * *

■ 9. Amend Form S–1 (referenced in § 239.11) by adding Item 11(o) to Part I to read as follows:

Note: The text of Form S–1 does not, and these amendments will not, appear in the Code of Federal Regulations.

FORM S–1

* * * * *

PART I—INFORMATION REQUIRED IN PROSPECTUS

* * * * *

Item 11. Information With Respect to the Registrant.

* * * * *

(o) Information required by Subpart 1500 of Regulation S–K (17 CFR 229.1500 through 229.1507), in a part of the registration statement that is separately captioned as *Climate-Related Disclosure.* Pursuant to Rule 411 (17 CFR 230.411) and General Instruction VII of this form, a registrant may incorporate by reference disclosure from other parts of the registration statement (*e.g.,* Risk Factors, Business, Management's Discussion and Analysis, or the financial statements) or from a separately filed annual report or other periodic report into the Climate-Related Disclosure item if it is responsive to the topics specified in Items 1500 through 1507 of Regulation S–K.

* * * * *

■ 10. Amend Form S–11 (referenced in § 239.18) by adding Item 9 to Part I to read as follows:

Note: The text of Form S–11 does not, and these amendments will not, appear in the Code of Federal Regulations.

FORM S–11

* * * * *

PART I. INFORMATION REQUIRED IN PROSPECTUS

* * * * *

Item 9. Climate-related disclosure. Provide the information required by Subpart 1500 of Regulation S–K (17 CFR 229.1500 through 229.1507), in a part of the registration statement that is separately captioned as *Climate-Related Disclosure.* Pursuant to Rule 411 (17 CFR 230.411) and General Instruction H of this form, a registrant may incorporate by reference disclosure from other parts of the registration statement (*e.g.,* Risk Factors, Management's Discussion and Analysis, or the financial statements) or from a separately filed annual report or other periodic report into the Climate-Related Disclosure item if it is responsive to the topics specified in Items 1500 through 1507 of Regulation S–K.

* * * * *

■ 11. Amend Form S–4 (referenced in § 239.25) by:

■ a. Adding paragraph (k) to Item 14 to Part I; and

■ b. Adding paragraph (b)(11) to Item 17 to Part I.

The additions read as follows:

Note: The text of Form S–4 does not, and these amendments will not, appear in the Code of Federal Regulations.

FORM S–4

* * * * *

PART I

INFORMATION REQUIRED IN THE PROSPECTUS

* * * * *

Item 14. Information With Respect to Registrants Other Than S–3 Registrants.

* * * * *

(k) Information required by Subpart 1500 of Regulation S–K (17 CFR 229.1500 through 229.1507), in a part of the registration statement that is separately captioned as *Climate-Related Disclosure.* Pursuant to Rule 411 (17 CFR 230.411) a registrant may incorporate by reference disclosure from other parts of the registration statement (*e.g.,* Risk Factors, Description of Business, Management's Discussion and Analysis, or the financial statements) into the Climate-Related Disclosure item if it is responsive to the topics specified in Items 1500 through 1507 of Regulation S–K.

* * * * *

Item 17. Information With Respect to Companies Other Than S–3 Companies.

* * * * *

(b) * * *

(11) Information required by Items 1500–1507 of Regulation S–K (17 CFR 229.1500 through § 229.1507), in a part of the registration statement that is separately captioned as *Climate-Related Disclosure of Company Being Acquired.*

* * * * *

■ 12. Amend Form F–4 (referenced in § 239.34) by:

■ a. Adding paragraph (k) to Item 14 to Part I; and

■ b. Amending paragraph (3) to Item 17(b) to Part I.

The additions read as follows:

Note: The text of Form F–4 does not, and these amendments will not, appear in the Code of Federal Regulations.

FORM F–4

* * * * *

PART I

INFORMATION REQUIRED IN THE PROSPECTUS

* * * * *

Item 14. Information With Respect to Foreign Registrants Other Than F–3 Registrants.

* * * * *

(k) Item 3.E of Form 20–F, climate-related disclosure.

* * * * *

Item 17. Information With Respect to Foreign Companies Other Than F–3 Companies.

* * * * *

(b) * * *

(3) Item 3.E of Form 20–F, climate-related disclosure;

* * * * *

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

■ 13. The authority citation for part 249 continues to read as follows:

Authority: 15 U.S.C. 78a *et seq.* and 7201 *et seq.;* 12 U.S.C. 5461 *et seq.;* 18 U.S.C. 1350; Sec. 953(b) Pub. L. 111–203, 124 Stat. 1904; Sec. 102(a)(3) Pub. L. 112–106, 126 Stat. 309 (2012), Sec. 107 Pub. L. 112–106, 126 Stat. 313 (2012), Sec. 72001 Pub. L. 114–94, 129 Stat. 1312 (2015), and secs. 2 and 3 Pub. L. 116–222, 134 Stat. 1063 (2020), unless otherwise noted.

* * * * *

Section 249.220f is also issued under secs. 3(a), 202, 208, 302, 306(a), 401(a), 401(b), 406 and 407, Pub. L. 107–204, 116 Stat. 745, and secs. 2 and 3, Pub. L. 116–222, 134 Stat. 1063.

Section 249.308a is also issued under secs. 3(a) and 302, Pub. L. 107–204, 116 Stat. 745.

* * * * *

Section 249.310 is also issued under secs. 3(a), 202, 208, 302, 406 and 407, Pub. L. 107–204, 116 Stat. 745.

* * * * *

■ 14. Amend Form 10 (referenced in § 249.210) by adding Item 3.A (''Climate-Related Disclosure'') to read as follows:

Note: The text of Form 10 does not, and these amendments will not, appear in the Code of Federal Regulations.

FORM 10

* * * * *

Item 3.A Climate-Related Disclosure. Provide the information required by Subpart 1500 of Regulation S–K (17 CFR 229.1500 through 229.1507), in a part of the registration statement that is separately captioned as *Climate-Related Disclosure.* Pursuant to Exchange Act Rule 12b–23 (17 CFR 240.12b–23) and General Instruction F of this form, a registrant may incorporate by reference disclosure from other parts of the registration statement (*e.g.,* Risk Factors, Business, Management's Discussion and Analysis, or the financial statements) into the Climate-Related Disclosure item if it is responsive to the topics specified in Item 1500 through 1507 of Regulation S–K.

* * * * *

■ 15. Amend Form 20–F (referenced in § 249.220f) by adding Item 3.E (''Climate-related disclosure'') to Part I to read as follows:

Note: The text of Form 20–F does not, and these amendments will not, appear in the Code of Federal Regulations.

FORM 20–F

* * * * *

PART I

* * * * *

Item 3. Key Information

* * * * *

E. Climate-Related Disclosure

1. *Required disclosure.* The company must provide disclosure responsive to the topics specified in Subpart 1500 of Regulation S–K (17 CFR 229.1500 through 229.1507) in a part of the registration statement or annual report that is separately captioned as *Climate-Related Disclosure.*

2. *Incorporation by reference.* Pursuant to Rule 12b–23 (17 CFR 240.12b–23), the company may incorporate by reference disclosure from other parts of the registration statement

or annual report (*e.g.,* Risk Factors, Information on the Company, Operating and Financial Review and Prospects, or the financial statements) into the Climate-Related Disclosure item if it is responsive to the topics specified in Item 1500 through 1507 of Regulation S–K.

* * * * *

■ 16. Amend Form 6–K (referenced in § 249.306) by adding the phrase ''climate-related disclosure;'' before the phrase ''and any other information which the registrant deems of material importance to security holders.'' in the second paragraph of General Instruction B.

■ 17. Amend Form 10–Q (referenced in § 249.308a) by adding Item 1.B (''Climate-Related disclosure'') to Part II (''Other Information'') to read as follows:

Note: The text of Form 10–Q does not, and these amendments will not, appear in the Code of Federal Regulations.

FORM 10–Q

* * * * *

Item 1B. Climate-Related Disclosure. Disclose any material changes to the disclosures provided in response to Item 6 (''Climate-related disclosure'') of Part II to the registrant's Form 10–K (17 CFR 229.310).

* * * * *

■ 18. Amend Form 10–K (referenced in § 249.310) by:

■ a. Revising paragraph (1)(g) of General Instruction J (''Use of this Form by Asset-backed Issuers''); and

■ b. Adding Item 6 (''Climate-Related Disclosure'') to Part II to read as follows:

The revision and addition read as follows:

Note: The text of Form 10–K does not, and these amendments will not, appear in the Code of Federal Regulations.

FORM 10–K

* * * * *

GENERAL INSTRUCTIONS

* * * * *

J. Use of This Form by Asset-Backed Issuers.

* * * * *

(1) * * *

(g) Item 6, Climate-Related Disclosure;

* * * * *

Part II

* * * * *

Item 6. Climate-Related Disclosure

Provide the disclosure required by Subpart 1500 of Regulation S–K (17 CFR 229.1500 through 229.1507) in a part of the annual report that is separately captioned as *Climate-Related Disclosure.* Pursuant to Rule 12b–23 (17 CFR 240.12b–23) and General Instruction G of this form, a registrant may incorporate by reference disclosure from other parts of the registration statement or annual report (*e.g.,* Risk Factors, Business, Management's Discussion and Analysis, or the financial statements) into the Climate-Related Disclosure item if it is responsive to the topics specified in Item 1500 through 1507 of Regulation S–K.

* * * * *

By the Commission.

Dated: March 21, 2022.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2022–06342 Filed 4–8–22; 8:45 am]

BILLING CODE 8011–01–P

FEDERAL REGISTER

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Part IV

Federal Communications Commission

47 CFR Part 1
Establishing the Digital Opportunity Data Collection; Final Rule

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[WC Docket No. 19–195, DA–22–241; FR ID 78895]

Establishing the Digital Opportunity Data Collection

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Wireless Telecommunications Bureau (WTB), the Office of Economics and Analytics (OEA), and the Office of Engineering and Technology (OET) (collectively, the Bureau and Offices) adopt technical requirements to implement the mobile challenge, verification, and crowdsourcing processes required by the Broadband DATA Act. The Bureau and Offices adopt the proposed processes and methodology set forth in the *Broadband Data Collection (BDC) Mobile Technical Requirements Proposed Rules* for collecting challenge process data and for determining when the threshold to create a cognizable challenge has been met. Additionally, the Bureau and Offices adopt detailed processes for mobile providers to respond to challenges, for the Federal Communications Commission (Commission or FCC) to initiate a verification request to a service provider, and for providers to respond to verification requests to confirm broadband coverage in areas they claim have service. The Bureau and Offices adopt the parameters and metrics that must be collected both for on-the-ground test data to support challenge submissions, rebuttals to cognizable challenges, and responses to verification requests, and for infrastructure information to support challenge rebuttals and responses to verification requests. Government entities and third parties are required to submit verified broadband data using the same data specifications required of mobile service providers. Finally, the Bureau and Offices find the Commission's speed test app to be a reliable and efficient method for entities to use in submitting crowdsourced mobile coverage data to the Commission and describe the methodology staff will use in determining when a ''critical mass of'' crowdsourced filings suggests that a provider has submitted inaccurate or incomplete data. The measures adopted in this document to implement the mobile challenge, verification, and crowdsourcing processes will enable the Commission, Congress, other Federal and state policy makers, Tribal entities, consumers, and other third parties to verify and supplement the data collected by the Commission on the status of mobile broadband availability throughout the United States.

DATES: Effective May 11, 2022.

FOR FURTHER INFORMATION CONTACT: William Holloway at *William.Holloway@fcc.gov,* Competition & Infrastructure Policy Division, (WTB), (202) 418–2334, Jonathan McCormack at *Jonathan.McCormack@fcc.gov* (OEA), (202) 418–1065, or Martin Doczkat at *Martin.Doczkat@fcc.gov* (OET), (202) 418–2435.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Order,* DA 22–241, in WC Docket No. 19–195, adopted and released on March 9, 2022. The full text of this document, including the technical appendix is available for public inspection and can be downloaded at *https://www.fcc.gov/document/fcc-releases-bdc-mobile-technical-requirements-order.*

People With Disabilities. To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Government Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

Paperwork Reduction Act. This document does not contain new or modified information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13, as the requirements adopted in this document are statutorily exempted from the requirements of the PRA. As a result, the Order will not be submitted to the Office of Management and Budget (OMB) for review under Section 3507(d) of the PRA.

Congressional Review Act. The Commission has determined, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, concurs, that these rules are ''non-major'' under the Congressional Review Act, 5 U.S.C. 804(2). The Commission will send a copy of the Order to Congress and the Government Accountability Office pursuant to 5 U.S.C. 801(a)(1)(A).

Synopsis

1. In this document, the Bureau and Offices adopt the technical requirements to implement the mobile challenge, verification, and crowdsourcing processes required by the Broadband DATA Act as part of the FCC's ongoing BDC effort to improve the Commission's broadband availability data.

I. Discussion

A. Mobile Service Challenge Process

2. In this document, the Bureau and Offices adopt the proposals for the mobile challenge process set forth in the *BDC Mobile Technical Requirements Proposed Rules* (86 FR 40398, July 28, 2021), with certain modifications described below.

3. The Broadband DATA Act requires that the Commission ''establish a user-friendly challenge process through which consumers, [s]tate, local, and Tribal governmental entities, and other entities or individuals may submit coverage data to the Commission to challenge the accuracy of—(i) the coverage maps; (ii) any information submitted by a provider regarding the availability of broadband internet access service; or (iii) the information included in the [Broadband Serviceable Location] Fabric.'' The general requirements and framework for the mobile challenge process predate the *BDC Mobile Technical Requirements Proposed Rules,* and were set forth in either the Broadband DATA Act or prior Commission orders. We note that, to the extent commenters ask the Bureau and Offices to eliminate, modify, or otherwise revisit particular requirements established in either the Broadband DATA Act or prior Commission-level orders, we lack the legal authority to do so. In the *Third Further Notice of Proposed Rulemaking (Third Further NPRM)* (85 FR 50911, Aug. 18, 2020), the Commission proposed a challenge process that ''encourages participation to maximize the accuracy of the maps, while also accounting for the variable nature of wireless service.'' In the *Third Order* (85 FR 18124, April 7, 2021), the Commission adopted its proposals from the *Second Order* (85 FR 50886, Aug. 18, 2020) and *Third Further NPRM,* and established a framework for consumers, state, local, and Tribal governments, and other entities to submit data to challenge the mobile broadband coverage maps.

4. The Commission determined that it should enable stakeholders to challenge mobile coverage data based on both a lack of service and poor service quality (such as slow delivered user speeds). Challenges must be based upon on-the-ground speed test data taken outdoors (*i.e.,* from an in-vehicle mobile or outdoor stationary environment). The Commission adopted a requirement that consumers use a speed test application (either developed by the FCC or a third-

party app approved by OET for use in the challenge process) that automatically collects information and metrics associated with each speed test and allows for submission of information directly to the Commission from a mobile device. Consumers will be required to submit certain identifying information to deter frivolous filings. Government and other third-party entity challengers (including competing mobile service providers) may use their own software or hardware to collect data for the challenge process so long as the data contain metrics that are substantially the same as those collected by approved speed test applications. Moreover, government and other entity challengers are required to conduct on-the-ground tests using a device advertised by the challenged provider as compatible with its network.

5. The Commission adopted a requirement for providers to either submit a rebuttal to the challenge or concede the challenge within 60 days of being notified of the challenge. Rebuttals must consist of either on-the-ground test data or infrastructure data. A challenge respondent may also submit supplemental data in support of its rebuttal, either voluntarily or in response to a request for additional information from OEA. The Commission directed OEA to develop a methodology and mechanism to determine if the data submitted by a provider constitute a successful rebuttal to all or some of the challenged service area and to establish procedures to notify challengers and providers of the results of a challenge. Further, the Commission adopted a requirement that providers that concede or lose a challenge file new coverage data within 30 days depicting the challenged area that has been shown to lack service.

6. The requirements that we adopt in this document will enable the Commission to collect sufficient measurements to ensure that the challenge process is statistically valid while remaining ''user-friendly.'' In particular, we establish a methodology for determining a threshold number of mobile speed tests and the geographic boundaries within a specified area. Based on this methodology, a challenge is created by associating the locations of validated speed tests within geographical hexagons defined by the accessible, open-source H3 geospatial indexing system and analyzing those speed tests. We also adopt the parameters and metrics that speed tests must meet to be validated and used to meet the challenge thresholds. Importantly, as the Commission specified in the *Third Order,* the challenge process will remain user-friendly because all of the information a consumer needs to create a challenge will be collected and submitted by the FCC Speed Test app and any third-party mobile speed test apps approved by OET. Governmental and other entity challengers may use these apps or their own software or hardware to collect data for the challenge process. Additionally, we implement the Commission's decision to aggregate speed tests to resolve challenges ''in an efficient manner, mitigate the time and expense involved, and ensure that the mobile coverage maps are as reliable and useful as possible,'' by adopting our proposal to combine speed tests conducted by consumers, governmental agencies, and other entities to determine whether the thresholds for a cognizable challenge have been met. These requirements strike the appropriate balance between ensuring that consumers, state, local, and Tribal governments, and other entities can participate in the challenge process, on the one hand, and protecting providers from being burdened by having to respond to challenges that do not meet the cognizable challenge standard, on the other hand.

1. Creating a Challenge/Cognizable Challenges

7. *On-the-Ground Speed Test Data Parameters and Metrics.* Challenges must be supported by on-the-ground test data. We have therefore established the required testing parameters and data metrics for speed test submissions. At the outset, we will require the FCC Speed Test app and approved third-party apps to collect the name and email address of the end user and mobile phone number of the device on which the speed test was conducted, to the extent technically feasible. As discussed in further detail below, Apple iOS devices will not automatically transmit the mobile phone number associated with the device that runs a speed test. We will therefore require testers submitting tests for use in the challenge process to manually submit, through the speed test app, the phone number associated with the device on which the speed test was conducted. The Commission's rules state that consumer challengers must include ''name and contact information (*e.g.,* address, phone number, and/or email address) in their data submissions.'' We amend these rules to require that app users also submit their email address so that the Commission can notify testers of the status of their speed test(s) and any resulting challenge(s), and we also amend the rules to require app users to submit the mobile phone number of the device on which the speed test was conducted so that we may, if necessary, share this information with mobile broadband providers for use when responding to challenges. We anticipate we will only share the phone number of the device on which the speed test was conducted with mobile broadband providers in situations where a challenged provider is unable to identify a subscriber by using the timestamp that test measurement data were transmitted to the app developer's servers, as well as the source IP address and port of the device, as measured by the server, which we will also require to be included in challenge data submitted by the app, as discussed below. We will not collect the address of an end user for use in the mobile challenge process at this time in order to minimize the amount of personally identifiable information we require from end users, and because a mobile user's physical address is not currently helpful either to the Bureau and Offices when considering challenges or to providers when responding to challenges. In addition to the testing metrics adopted by the Commission in the *Third Order,* we adopt the testing parameters and updated metrics for challenge speed test data proposed in the *BDC Mobile Technical Requirements Proposed Rules,* with the modifications described below. We will require the FCC Speed Test app and approved third-party apps to collect the consumer's name, email address, and phone number of the device on which the speed test was conducted to the extent technically feasible. With the exception of different considerations pertaining to the submission of speed test data taken on iOS devices and the submission of IP address, source port, and timestamp measured by an app developer's servers by government entities and service providers in some scenarios, these parameters and metrics will apply across all testing mechanisms, not only in the challenge process but also for on-the-ground data submitted in response to verification inquiries. The information we will use in the challenge process that can be collected from Android devices, but not iOS devices, includes the signal strength, signal quality, unique identifier, and other radiofrequency (RF) metrics of each serving cell, as well as the spectrum bands used for the test and other network characteristics (*e.g.,* whether the device was roaming, as well as the identity of the provider for the connected network). As discussed in greater detail below, we will allow

government and other third-party entities to alternatively submit the International Mobile Equipment Identity (IMEI) of the device used to conduct a speed test for use in the challenge process rather than provide the source IP address, source port, and timestamp measured by an app developer's servers. We will also not require a service provider to submit either the device IMEI or the combination of source IP address, source port, and timestamp measured by an app developer's servers when submitting speed tests either in response to a challenge or in response to a verification inquiry. Individual consumer challengers must collect on-the-ground speed test data using mobile devices running either a Commission-developed app (*e.g.,* the FCC Speed Test app) or another speed test app approved by OET for the submission of challenges. The Bureau and Offices will announce the process and procedures for third-party app providers to seek approval for a speed test app to be used in submitting data for use in the challenge process. Third-party and governmental entities may, as specified in the *Third Order,* collect data using either one of these speed test apps or their own software and hardware that collects broadband availability data, consistent with the parameters and metrics set forth herein. We include ''hardware'' to capture the professional tools such as laptops, hard drives, or other hardware devices, used to collect on-the-ground data. The *Third Order* provided that government and other entity challengers submit a complete description of the methodologies used to collect the data. The Bureau and Offices will issue a public notice announcing the process and procedures for such parties to submit the necessary documentation.

8. In the *Third Order,* the Commission required consumer challengers to use a speed test app approved by OET for use in the challenge process and provided the metrics that approved apps must collect for each speed test. The Commission directed OET, in consultation with OEA and WTB, to update the FCC Speed Test app as necessary or develop a new speed test app to collect the designated metrics, so that challengers may use it in the challenge process. For government and third-party entity challengers, the Commission did not require the use of a Commission-approved speed test app but instead set forth the information that all submitted government and third-party challenger speed test data must contain and directed OEA, WTB, and OET to adopt additional testing requirements if they determine it is necessary to do so. Our *BDC Mobile Technical Requirements Proposed Rules* proposed certain testing parameters and metrics to standardize the on-the-ground test data submitted in the challenge process and to assure more reliable challenges; a number of parties agree that such consistency among the apps used for challenges and rebuttals is important. This set of standardized parameters and metrics will also ensure that we can make a meaningful comparison of tests run by different entities using different methods (*e.g.,* tests run on a speed test app versus a government's own hardware and software), and will enable us to easily combine and evaluate speed test data used in the challenge process. Accordingly, we will require that such data meet the following testing parameters set forth in the *BDC Mobile Technical Requirements Proposed Rules:* (1) A minimum test length of 5 seconds and a maximum test length of 30 seconds; (2) test measurement results that have been averaged over the duration of the test (*i.e.,* total bits received divided by total test time); and (3) a restriction that tests must be conducted between the hours of 6:00 a.m. and 10:00 p.m. local time. To avoid requiring excessive data usage for tests on particularly fast networks (*e.g.,* 5G–NR (New Radio) using high-band spectrum), we will relax the minimum test duration requirement once a download or upload test measurement has transferred at least 1,000 megabytes of data. Specifically, when a speed test transfers at least 1,000 megabytes of data, we will validate the test if it has a duration value of greater than 0 seconds and less than or equal to 30 seconds. Otherwise, a speed test must have a duration value of greater than or equal to 5 seconds and less than or equal to 30 seconds to be valid.

9. We clarify that the minimum and maximum test length parameters will apply individually to download speed, upload speed, and round-trip latency measurements, and will not include ramp up time. We disagree with the Competitive Carriers Association (CCA), Public Knowledge/New America, and Vermont Department of Public Service (Vermont DPS) that imposing a maximum test limit places an arbitrary or inferior limitation on testing. These timing requirements balance representative measurement over a stable Transmission Control Protocol (TCP) connection, on the one hand, versus data usage considerations, on the other hand—especially for consumers who may have limited data plans. The FCC Speed Test app, for example, first initiates a test server selection process, which typically takes two seconds (and a maximum of 10 seconds if servers fail to respond) then individually runs, including a warm-up time, a maximum of eight seconds for download and eight seconds for upload tests by establishing three concurrent TCP connections and summing the three resulting data rates for each test. In addition, the round-trip latency testing runs for a fixed five seconds to transmit up to 200 UDP (User Datagram Protocol) packets (*i.e.,* datagrams) to calculate the average latency of those datagrams. Hence, a typical test cycle takes approximately 23 seconds to complete, and a maximum of 31 seconds to complete.

10. We also decline to adopt CCA's request to exempt continuous network monitoring from the maximum test length. Continuous network monitoring software can monitor active users' speeds at the cell sites and other network parameters over extended periods of time. We are not persuaded that deviating from the uniform 30-second per test component maximum testing standard to accommodate continuous network monitoring will yield equal or more accurate test results. We found in the Mobility Fund Phase II challenge process that continuous network monitoring speed tests recorded significant variability within the same area and across a short time span, in some cases recording strong network performance well exceeding the minimum requirement interspersed with short seconds-long drops in performance that may have been the result of normal network conditions (*e.g.,* sector handover or network scheduling). The overall performance in these areas indicated that coverage was adequate (*i.e.,* with the average of tests in the same area over 15–20 seconds exceeding the minimum requirement), but because the test results were so variable, we are concerned that allowing the reporting of continuous speed tests could result in inaccurate results that do not reflect the typical on-the-ground customer experience, which as the results showed, may be adequate when averaged, but may not deliver consistent speeds to consumers. To the extent challengers choose to use continuous network monitoring to record challenge data, results of the speed tests should report the average speeds over a uniform time period consistent with the minimum and maximum test lengths we adopt above (*i.e.,* a minimum of 5 seconds and a maximum of 30 seconds).

11. We share Ookla's concern that averaging the number of bits received over the entire duration of a throughput

test may negatively affect the accuracy of any calculation, as that may not exclude an internet connection's known and expected ''ramp-up time.'' To account for this, we will apply the following formula: [(total bits received − ramp up bits) divided by (total test time − ramp up time)]. We consider ''ramp up bits'' to be the initial bits received during the initial warm-up time. We find that this approach will sufficiently account for ramp-up time and fully satisfy Ookla's concern, especially in light of the clarification above that the test time limits apply individually to tests' upload and download measurements.

12. We require on-the-ground speed test data to include a standardized set of metrics. Each on-the-ground speed test must include the following metrics that were previously adopted by the Commission as modified by the updates proposed in the *BDC Mobile Technical Requirements Proposed Rules:* (1) The timestamp and duration of each test metric; (2) geographic coordinates (*i.e.,* latitude/longitude) measured at the start and end of each test metric with typical Global Positioning System (GPS) Standard Positioning Service accuracy or better, along with the location accuracy (''location accuracy'' refers to a metric that GPS-enabled smartphones are able to report on the horizontal accuracy of the geographic coordinates of the location reported); (3) the consumer-grade device type(s), brand/model, and operating system used for the test; (4) the name and identity of the service provider being tested; (5) location (*e.g.,* hostname or IP address) of the test server; (6) signal strength, signal quality, unique identifier, and other RF metrics of each serving cell, where available; (7) download speed; (8) upload speed; (9) round-trip latency; (10) for an in-vehicle test, the speed the vehicle was traveling when the test was taken, where available. All on-the-ground speed tests must also include the following metrics previously adopted by the Commission: (11) Whether the test was taken in an in-vehicle mobile or outdoor, pedestrian stationary environment (government and other third-party entities must also indicate whether an in-vehicle mobile test was conducted with the antenna outside of the vehicle); (12) an indication of whether the test failed to establish a connection with a mobile network at the time and location it was initiated; and (13) the network technology (*e.g.,* 4G LTE (Long Term Evolution), 5G–NR) and spectrum bands used for the test. We adopt an additional metric that was proposed in the *BDC Mobile Technical Requirements Proposed Rules:* (14) The app name and version. We will also require all speed tests to include: (15) The timestamp that test measurement data were transmitted to the app developer's servers, as well as the source IP address and port of the device, as measured by the server. Given concerns that challengers may conduct tests after exceeding data limits, we will collect the timestamp that test measurement data were transmitted to the app developer's servers, as well as the source IP address and port of the device, as measured by the server, so that a service provider may determine if a challenger's device is subject to reduced speeds or otherwise lacks full network performance. The source port of the device is an available network port over which the device communicates with the server and is unique to a particular network connection or transmission. The IP address and source port associated with the device used in testing is attainable from devices using both iOS and Android devices. For the same reasons, we will allow government and other third-party entities to alternatively submit the IMEI of the device used to conduct the test rather than provide the source IP address, source port, and timestamp measured by an app developer's servers since such entities are allowed to use their own hardware or software to conduct speed tests. The purpose of collecting either type of data is to allow for the challenged provider to identify characteristics of the device or service plan used to conduct the test, such as whether the device was roaming or was subjected to slower service due to the subscriber's data plan. Accordingly, we will not require a service provider to submit either the device IMEI or the combination of source IP address, source port, and timestamp when submitting speed tests (either in response to a challenge or in response to a verification inquiry), as these fields are relevant only for data submitted by challengers.

13. Finally, we require on-the-ground challenge test data to include all other metrics required per the most recent specification for mobile test data adopted by OEA and WTB in accordance with 5 U.S.C. 553. Concurrent with release of this document, we are publishing the full technical and data specifications for mobile speed test data on the Commission's website at *https://www.fcc.gov/BroadbandData/resources.* The specification for speed test data includes additional fields derived from the high-level metrics defined herein, as well as other identifiers to facilitate management of the submission of such data. These fields include: a unique device installation ID; a unique test ID; the device Type Allocation Code (TAC); the Mobile Country Code (MCC) and Mobile Network Code (MNC) values measured from the network and from the device's SIM card; flags indicating whether the network is connected, is available, and/or is roaming; total bytes transferred and calculated bytes per second for download and upload tests; jitter and packets sent and received for latency tests; for each connected cell, the measured cell ID, Physical Cell Identity (PCI), cell connection status, Received Signal Strength Indication (RSSI), Reference Signal Received Power (RSRP), Reference Signal Received Quality (RSRQ), Signal to Interference and Noise Ratio (SINR), Channel Quality Indicator (CQI), spectrum band and bandwidth, and Absolute Radio-Frequency Channel Number (ARFCN); and the horizontal accuracy of GPS coordinates and speed accuracy of measured velocity for each location measurement. Third-party app developers and government or other third parties that use their own hardware or software to conduct speed tests will be required to update their processes in accordance with such updates, including, as stated in the *BDC Mobile Technical Requirements Proposed Rules,* revised specifications for mobile test data adopted by the Bureau and Office in accordance with 5 U.S.C. 553. The modified set of parameters and metrics we adopt aligns more closely with those already required of government and third-party challengers. The Commission delegated authority to the Bureau and Offices to adopt additional testing requirements for government and third-party challengers. We therefore add certain metrics to those listed in paragraph 117 of the *Third Order* and § 1.7006(f) of the Commission's rules and make clear that all challengers must collect these metrics, with the exception that consumers need not indicate whether an in-vehicle mobile test was conducted with the antenna outside of the vehicle.

14. We recognize the concerns raised by Vermont DPS, Enablers, and Public Knowledge/New America about excessive data and burdens on consumers and governments and other third-party challengers to assure that their data aligns to these standards, but we believe that such parameters and metrics are necessary to provide the Commission with complete and reliable challenge data that accurately reflect on-the-ground conditions in the challenged

area and provide the additional context necessary to efficiently and fully adjudicate challenges and thereby assure that more accurate and reliable coverage maps are made available. These data metrics are also substantially similar to those adopted by the Commission in the *Third Order,* and therefore we do not anticipate that they will create any new burdens on consumers or governmental entities and third parties beyond those in place resulting from the previously adopted requirements. Further, the challenge process will remain user-friendly because any challenger can use a readily downloadable mobile app to collect and submit data (including the FCC Speed Test app, which the FCC makes available for download at no cost), and government and third-party entities have the flexibility also to use their own software or hardware. Therefore, government and other third parties will only need to modify their software once, to the extent necessary to conform to the required testing parameters and metrics we discuss above (and subject to our adopting any new metrics in the future). The Commission will also provide technical assistance to consumers and state, local, and Tribal governmental entities with respect to the challenge process, which will be a resource for government entities that do not understand some of our data collection requirements. The Bureau and Offices will ensure that the FCC Speed Test app and other apps approved for use in the challenge process collect this information, and government and other third-party challengers will be able to submit challenge data to the Commission through such apps under the procedures adopted for consumer challenges.

15. We understand that certain technical network information and RF metrics that we would otherwise require are not currently available on Apple iOS devices. The information we will use in the challenge process that can be collected from Android devices, but not iOS devices, includes the signal strength, signal quality, unique identifier, and other RF metrics of each serving cell, as well as the spectrum bands used for the test and other network characteristics (*e.g.,* whether the device was roaming, as well as the identity of the provider for the connected network). Therefore, until such time as such information and metrics are available on iOS devices, and the Bureau and Offices indicate they will collect such information from iOS devices, government and third-party entity challenges must use a device that is able to interface with drive test software and/or runs the Android operating system. The iOS operating system, which supports iPhone and iPad hardware devices, does not disclose certain technical network information and RF metrics that are essential to the Commission's challenge and crowdsource processes. This limits the conclusions that we can draw from on-the-ground tests conducted using such devices. OET will update its guidance if future iOS software versions are released that disclose this technical network information and/or RF metrics. To ensure that the challenge process remains user-friendly and encourage public participation, including by consumers who use a device running the iOS operating system, however, we will not extend this restriction to challenges submitted by consumers, and we will still consider speed test data submitted using an iOS device towards challenges. Although iOS software does not report the complete metrics we require in this document (*e.g.,* certain technical network information and RF metrics), the Bureau and Offices will nevertheless use the remaining on-the-ground data we receive from consumers using iOS software in the challenge process. Although we may receive limited data from tests run on iOS devices, we do not anticipate that such tests will significantly impede the creation of challenges because, as mentioned, the Commission will aggregate speed tests to create cognizable challenges. iOS speed tests will be considered in combination with other speed tests that fall within the same resolution 8 hexagon. We therefore anticipate that data submitted by government and other entities, as well as consumer tests run on Android devices, will help fill in any gaps in information about the on-the-ground quality and availability of broadband coverage that may result from the limited nature of the data we receive from speed tests run on iOS devices. Our approach preserves balance and flexibility for both types of challengers, while also ensuring that the Commission gathers adequate data to adjudicate challenges. On the one hand, government and other third-party entities who can be expected to submit large amounts of speed test data may not use iOS devices but have the flexibility to use their own hardware and software. On the other hand, consumers who use iOS devices and would face a prohibitive burden if required to use a non-iOS device to submit a challenge may submit speed tests conducted using an iOS device but do not have the same flexibility as government and other entities to use non-approved software.

16. Third-party app developers and government or other entities that use their own hardware or software to conduct speed tests will be required to update their processes in accordance with updates to the full technical and data specifications for mobile speed test data, including, as stated in the *BDC Mobile Technical Requirements Proposed Rules,* revised specifications for mobile test data adopted by the Bureau and Offices. The Rural Wireless Association (RWA) asserts that adopting the proposed data metrics and parameters, including ''all other metrics required per the most-recent specification for mobile test data released by OEA and WTB'' would be an improper incorporation by reference that violates the Office of the Federal Register (OFR) regulations and the Administrative Procedure Act (APA). We disagree with RWA that this is an improper incorporation by reference that violates OFR regulations and the APA. The metrics we require are substantially similar to those already adopted by the Commission in the *Third Order,* and have been adopted after notice and comment in accordance with the APA's rulemaking requirements. Furthermore, we note that certain changes to the specifications that apply to the submission of on-the-ground test data, including for example, changing the file type to be submitted, are not substantive changes, and may be adopted without notice and comment. The Bureau and Offices have been delegated authority to adopt such procedural changes pursuant to § 1.7010 of the Commission's rules. To the extent that we may wish to make any substantive changes to testing parameters or metrics, we clarify that we would make such changes in accordance with 5 U.S.C. 553. Any future changes we make to the testing parameters or metrics will also be consistent with the Commission's Orders implementing the Broadband DATA Act. Finally, the adoption of these rules will not result in an improper incorporation by reference because we will comply with the requirements of any applicable Federal statutes and regulations governing the publication of these test parameters and metrics in the **Federal Register** and the Code of Federal Regulations.

17. *Speed Test Applications.* Pursuant to the Commission's directive in the *Third Order,* OET is currently in the process of developing updates to the FCC Speed Test app to incorporate additional functionalities that will allow for its use in submitting speed test data

as part of the BDC mobile challenge and crowdsource processes. OET recently released a technical description of the metrics and methodologies used in the current version of the FCC Speed Test app. The revised technical description document includes updated technical standards and additional modifications. While this document does not illustrate future user experience design changes to the FCC Speed Test app that will be made to implement the challenge and crowdsource functionalities, we anticipate that the fundamental measurement methodologies reflected in the recently updated technical description document will not be affected by these design updates. We note that the description includes the following about the test system architecture: ''The measurement servers, each supporting a 100 [gigabit per second] Gbps capacity, used for mobile broadband measurement are hosted by StackPath and are distributed nationally to enable a measurement client to select the host server with the least latency.'' The technical description includes data dictionaries for both Android and iOS versions of the app, but these dictionaries define data fields and formats for the current version of the app (and not the updated version of the app). To provide third-party app developers and other stakeholders with information and guidance as early in the process as possible, the Bureau and Offices have made available, contemporaneous with the release of this document, a current draft of the data specification the FCC Speed Test app will use once updated to include challenge and crowdsource data functionalities. The updated data specification aligns with the test metrics adopted in this document. The updated FCC Speed Test app with those functionalities will be available on the FCC's website and in iOS and Android app stores prior to the opening of the challenge and crowdsource process.

18. We decline to provide a further opportunity for comment on the FCC Speed Test app. Although some parties request an opportunity for public comment on both the FCC Speed Test app and third-party apps before we allow them to be used in the challenge process, we note that the Commission already sought comment on the use of the FCC Speed Test app in the challenge process as part of this rulemaking proceeding. The Commission also provided other opportunities to comment on the FCC Speed Test app because (1) the app was initially developed in coordination with the major wireless providers and trade associations several years ago; and (2) information on the data collected by the app has been publicly available on the Commission's website and has been available for comment in a rulemaking docket for several years. Additionally, the Commission specified in the *Third Order* that the challenge process use an FCC app, and, unlike some newer third-party speed test apps, the FCC Speed Test app has been in use for several years and the updates that are underway will merely implement the data specifications and requirements proposed in the *BDC Mobile Technical Requirements Proposed Rules* and adopted by this document. For these reasons, we do not believe it is necessary to seek comment on the use of the FCC Speed Test app for challenge and verification purposes.

19. CCA and RWA assert that it is unclear how the FCC Speed Test app will operate when there is inadequate connectivity to upload data or record a test. The FCC Speed Test app is designed to record and store measurements conducted in areas without internet connectivity and then to automatically transmit such failed tests once the app is opened when the device next has broadband connectivity. Moreover, third-party apps will be required to function in a similar way to be granted approval for use in the challenge process. Several commenters likewise misunderstand how the FCC Speed Test App reports ''failed'' tests or tests where mobile service is unavailable. As set forth in the 2021 technical description of the FCC Speed Test app, ''test[ ] results are transferred depending on the available connectivity at the conclusion of the test and can be stored and forwarded when connectivity is immediately unavailable.'' Failed test results are therefore uploaded to the server and included in the relevant dataset when the app user reestablishes a broadband connection. The upload and download components of a failed test will be recorded as negative if they fail to meet the minimum speeds that the mobile service provider reports as available where the test occurred. For example, if a failed test records speeds of 0 megabits per second (Mbps) upload and 0 Mbps download, both components of the test will be recorded as negative.

20. At a later date, OET will release a public notice outlining the process for collecting, reviewing, and approving applications for third-party speed test apps. In their applications, app developers will be required to describe their performance-centric speed test methodologies and how their app complies with the data collection requirements set forth in this document. Applicants will not be required to disclose any proprietary and/or confidential information that is sensitive to public inspection, such as source code, to the Commission, and we therefore decline to adopt T-Mobile's request that we require developers to submit their source code for public review. The OET public notice also will describe procedures for interested parties to submit comments and replies in response to the proposals and will publish on the Commission's website a list of approved third-party apps and any available data specifications for third-party apps.

21. We agree with commenters who recommend holding the FCC Speed Test app and third-party apps to the same technical standards. Both the FCC Speed Test app and third-party apps, as well as software used by state and local governments and other third parties, must comply with the data collection requirements set forth in this document. We also agree with commenters who recommend requiring speed test apps to use multiple servers that are geographically diverse. As to this point, CCA asserts that Ookla's speed test app is more accurate than the FCC Speed Test app due in major part to its many geographically distributed servers (with 41 servers in the U.S. and 15,019 testing servers globally), which allow users to run a test against a server that is located physically close to them reducing the likelihood of inaccurate latency measurements or artificial increases in latency distorting the download and upload speeds. As described in the most recent technical description for the FCC Speed Test app, the app currently carries out measurements against 13 servers spread out across ten locations throughout the United States and initiates a test sequence by selecting a measurement server using a latency test to identify the optimal server that has the lowest round-trip latency for performing subsequent tests. We believe that the current distribution of FCC Speed Test app servers, combined with this measurement server selection process, provides sufficient diversity to meet this geographic-diversity criterion. We also note that the number of servers used by a speed test is of less concern than the ratio of the concurrent consumers conducting tests to the total capacity of the test server hosting those tests (*i.e.,* the server utilization rate). The FCC Speed Test app's test servers are overprovisioned based upon statistics of the utilization rate and usage pattern, which are automatically monitored for the highest system

availability, to maintain the optimal connectivity rate. A utilization rate of 80% or more is classified as a critical state, and triggers the provisioning of new servers to stabilize load across the platform. Accordingly, although not as geographically diverse as Ookla's speed test app, we believe that the geographic diversity offered by the FCC Speed Test app in the United States provides sufficient capacity to support its user base and that it is sufficiently diverse to meet the required needs that rely on the test system architecture. The test system architecture for multiple redundant and meshed servers to target maximum availability of the test platform also employs load balancing for traffic to failover to other servers in which each server provides a 100 Gbps connectivity capacity. In sum, the FCC Speed Test app provides sufficient capacity to support its users and has sufficient geographic diversity to meet the required needs of the test system architecture. We also observe that latency is the principal concern raised by commenters. In this regard, we note that Commission rules require measurement of round-trip latency. As adopted and implemented in the FCC Speed Test app, the variability of latency is not entirely a function of geographical distance to the test server but also is a function of the network congestion, and so, at a minimum, servers should be distributed nationally in consideration of user base, population density, and the server utilization rate for multiple servers to be examined before the test server selection and located reasonably close to internet eXchange Points (IXPs) to accurately reflect unbiased real-world conditions. We point out that the FCC Speed Test app sufficiently considers these effects to help reduce round-trip latency.

22. *Validating Speed Tests.* As proposed in the *BDC Mobile Technical Requirements Proposed Rules,* we will validate submitted speed tests and exclude those that: (i) Are outside the scope of the challenge process, (ii) do not conform to the data specifications, or (iii) do not otherwise present reliable evidence. We will accept as valid speed tests only those tests conducted between the hours of 6:00 a.m. and 10:00 p.m. local time. Commenters do not raise concerns with our adopting a window for purposes of validating speed tests. We will compare speed tests for a particular network technology (*e.g.,* 3G, 4G LTE, or 5G–NR) to the coverage maps for the corresponding technology or higher-generation technology, to the extent the service provider claims coverage for the more than one technology in the tested location. We implement these changes so that testers are able to submit tests to be used to challenge a higher-generation technology map in situations when a mobile service provider claims multiple technologies at a location but the tester's device only connects to a lower-generation technology. We agree with Vermont DPS that our original proposal did not adequately address those situations where a device that is unable to connect to a network using a particular technology ''falls back'' to a lower-generation technology (*e.g.,* 4G LTE to 3G), which could make it impossible to challenge the higher-generation technology. We will allow, therefore, a speed test conducted using a device capable of connecting to a higher-generation technology, but that only connects to a lower-generation technology, to count as a test for the higher-generation technology. To be a valid test for the higher-generation technology, the consumer submitting the challenge must also subscribe to a service plan that is capable of connecting to the provider's network using the higher-generation technology. To prevent gaming, and as discussed further below, we will allow challenged providers to invalidate challenger speed tests with specific evidence that the challenger's device was not capable of connecting using a higher-generation technology or that the service plan to which the challenger subscribes does not allow use of the higher-generation technology. For example, a test conducted with a 4G LTE-capable device in a location where the service provider claims 4G LTE but where the challenger can only connect via the 3G network could count as both a 3G test when compared to the provider's 3G coverage map as well as a negative 4G LTE test when compared to its 4G LTE coverage map if the test did not meet the 5/1 Mbps minimum speeds; alternatively, it could count as a positive 4G test if the test met or surpassed the 5/1 Mbps minimum speeds reported for the 4G LTE map. Note that, under this approach, the 3G test may count towards the 4G LTE coverage map regardless of whether the provider claims 3G coverage at the location. This modified approach would resolve Vermont DPS's hypothetical concern that, under the proposal set forth in the *BDC Mobile Technical Requirements Proposed Rules,* a test result that ''fell back'' to a lower-generation technology would not be ''preserved.'' As discussed, such tests will be preserved and used to challenge a higher technology's maps if a service provider offers a higher-generation service in that area and the tester subscribes to a service plan that is capable of connecting to the provider's network using the higher-generation technology.

23. Similarly, if a challenger conducts a test but fails to connect to any network, we will treat that as a failed test against the provider's coverage maps for each technology to which the device is capable of connecting. These small changes to our original proposal will help prevent the scenario raised by Vermont DPS and enable more meaningful challenges in areas with marginal coverage where a device ''falls back'' to a lower-generation technology. Our updated approach also accounts for situations in which a device could alternate between, or utilize both, 4G LTE and 5G–NR over the course of a single test. Verizon agrees with the Bureau and Offices' initial proposal to compare each speed test against the relevant coverage map, and argues that ''only speed tests conducted on 3G networks should be used to challenge 3G coverage, only speed tests conducted on 4G LTE networks should be used to challenge 4G LTE coverage, and only speed tests conducted on 5G–NR networks should be used to challenge 5G–NR coverage.'' However, we are persuaded that the proposal we sought comment on in the *BDC Mobile Technical Requirements Proposed Rules* could allow for a scenario in which a tester seeking to support a challenge to a provider's 5G coverage would be prevented from submitting evidence because their phone fell back to the 4G network. Under our original proposal, in areas where a provider claims coverage for multiple technologies, a lower-generation technology could have prevented the higher-generation technology from being challenged, which in turn could isolate higher-generation technologies from legitimate challenges.

24. We will also compare speed tests conducted in a particular environment—outdoor stationary or in-vehicle mobile—to where the provider's maps report coverage for the corresponding environment (*i.e.,* outdoor stationary or in-vehicle mobile), as discussed in greater detail below. Additionally, we will also treat as invalid and exclude from the challenge process any speed tests that fall outside the boundaries of the provider's most recent coverage data for all claimed technologies and environments. This differs from our original proposal in the *BDC Mobile Technical Requirements Proposed Rules* in that the system will preserve all tests in a geographic area

where a provider claims coverage by any technology. We believe our modified approach will result in more reliable evidence for challenges because tests that may otherwise have been excluded for falling outside a provider's coverage for a specific technology under the proposed methodology in the *BDC Mobile Technical Requirements Proposed Rules* may now be counted as challenge data. This change will allow for the scenarios discussed above, in which a test conducted using a lower-generation technology could be used to challenge a provider's map for a higher-generation technology if the provider claims both types of coverage (*e.g.,* 4G LTE and 5G–NR), but a challenger's device is not connected to the higher-generation technology.

25. In response to Verizon's concerns that tests may be throttled, we will not validate, for purposes of the challenge process, speed tests conducted by customers of mobile virtual network operators (MVNOs) or tests conducted while roaming on another carrier's network, so as to avoid biasing the challenge process with speed tests that may not reflect typical network performance. MVNOs do not own any network facilities. Instead, they purchase mobile wireless service wholesale from facilities-based service providers and resell these services to consumers. Because the agreements between a facilities-based provider and MVNOs or roaming partners often include limitations on the technology and speed available to or the network prioritization of devices used by consumers of the MVNO or roaming partner, we conclude that speed tests from such devices are not reliable evidence about the performance of the facilities-based provider's network. While we anticipate that the majority of tests conducted by an MVNO subscriber or while roaming will fail our automated validations, there may be circumstances where the BDC system is unable to automatically identify these tests (*e.g.,* identifying whether an iOS device is roaming is not currently possible). We anticipate that a provider may identify whether a specific device(s) used in the testing was either roaming at the time, was an MVNO customer, or was subject to deprioritized or otherwise limited service because, as discussed, on-the-ground speed tests submitted in the challenge process will include the timestamp that test measurement data were transmitted to the app developer's servers, as well as the source IP address and port of the device, as measured by the server. We therefore do not agree with Vermont DPS's assertion that pre-paid tests in rural areas will be less accurate than speed tests run by subscribers of a typical service provider, due to the fact that pre-paid services exclude roaming in rural areas, because we will not validate any tests conducted while a subscriber is roaming. While we will allow a service provider's pre-paid customers to submit speed tests for use in the challenge process, a service provider will be able to use the timestamp that test measurement data were transmitted to the app developer's servers, as well as the source IP address, and port of the device, as measured by the server to determine if a specific speed test is run by a pre-paid subscriber that experienced limited service, and use that information when responding to a challenge. Given that these consumers may likely be subject to de-prioritization or otherwise limited service, and that the BDC system will be unable to detect whether or not a limitation in mobile service exists, we are unable to establish a reliable method for validating MVNO or roaming tests and, thus, these tests will be excluded from the challenge process. As discussed later, however, we may consider speed tests conducted by consumers of MVNOs and consumers roaming on other providers' networks when evaluating crowdsourced data.

26. *Aggregating Valid Speed Tests.* The Bureau and Offices will combine and collectively evaluate—according to the testing environment (*i.e.,* outdoor stationary or in-vehicle mobile) and technology type—valid speed tests submitted by consumer, governmental, and third-party challengers. Speed tests, including those collected through an approved speed test app and the data collected by government and other third-party entities through their own software and hardware, will be combined and collectively evaluated according to their tested environment and technology type. For example, as discussed in greater detail below, in-vehicle tests will generally be evaluated against a carrier's in-vehicle maps, and stationary tests will generally be compared against a carrier's stationary maps. We expect that in-vehicle and stationary tests will have substantially different results such that they would not provide an equal comparison and aggregating these tests would be problematic because there are fundamental characteristics of the two environments that are expected to cause noticeable signal losses for the in-vehicle mobile environment. As noted above, we do not expect iOS and Android devices to pose a similar problem. While we will receive a more complete set of datapoints from Android tests than iOS tests, we do not expect them to have substantially different results when, for example, tests using both types of devices are conducted in a pedestrian stationary environment, such that the tests would not have equal value and could not be compared and aggregated; the fact that iOS provides fewer datapoints than Android tests does not render a test run using iOS any less accurate than a test run using the Android operating system. Similarly, tests conducted with an external antenna will be considered in-vehicle, and while subtle differences between test results from those antenna placements may occur, overall those differences are considerably less significant than the differences between stationary vs. in-vehicle mobile more broadly.

27. We will combine such speed test evidence and apply a single methodology to determine whether the thresholds for a cognizable challenge (described in greater detail below) have been met and the boundaries of the challenged area. Several commenters express support for aggregating speed tests from multiple challengers, and we find that doing so will result in more accurate challenges and will further the Commission's goals of resolving challenges in an efficient manner, mitigating time and expense, and ensuring that maps are as reliable and useful as possible. We disagree with the California Public Utilities Commission's (CPUC) assertion that combining speed test data will not reduce costs or complexity in the challenge process. In fact, combining speed tests could ease the other potential burdens on an individual challenger of conducting multiple speed tests to meet the challenge thresholds. Our approach ensures that a smaller number of speed tests by one person or entity may nevertheless contribute to a challenge because the tests will be combined with other validated speed tests to meet the testing, temporal, and geographic thresholds. As a result, in many cases, no single challenger—whether a consumer, a government agency, or other entity—will be required to individually shoulder the burden of creating a challenge. While in places with low population density an individual challenger may be the only entity to submit speed tests to create a cognizable challenge, in many other cases, challengers will be able to combine efforts to submit speed tests in an area. Speed tests will be combined and used collectively—according to

testing environment (*i.e.,* outdoor stationary or in-vehicle mobile) and technology type—to meet the thresholds set forth below.

28. We will evaluate tests for a given technology against each provider map independently (one reporting stationary and one reporting in-vehicle mobile coverage) when determining whether to establish a cognizable challenge. Pursuant to the *Third Order,* tests taken on bicycles and motorcycles will be considered tests from in-vehicle mobile environments. We will consider in-motion tests taken in similar environments, such as on snowmobile or all-terrain vehicle, to be tests from in-vehicle mobile environments. By contrast, consistent with the *Third Order,* tests taken from stationary positions and tests taken at pedestrian walking speeds (such as on horseback) will be considered tests taken in outdoor pedestrian environments. We decline to exclude tests taken on other vehicles as T-Mobile requests. The Commission did not give the Bureau and Offices authority to change this accommodation; we anticipate that challengers may take speed tests on other vehicles than cars in areas with difficult or hard to reach terrain. Additionally, we will exclude stationary tests that occur outside a provider's stationary coverage map and in-vehicle mobile tests that occur outside a provider's in-vehicle mobile coverage map. Our approach differs from that which we proposed in the *BDC Mobile Technical Requirements Proposed Rules* in that we will no longer aggregate in-vehicle and stationary maps together. We find that the approach we adopt will result in more accurate challenges. To ensure that the challenge process also remains user-friendly, and because we expect performance to be better for stationary tests than for in-vehicle tests, stationary speed test results that create a cognizable challenge to an area on the stationary map will also create a cognizable challenge to the same area on the in-vehicle map if the area has overlapping coverage on both maps. On the other hand, the reverse situation will not be permitted, meaning, we will not permit a challenge to an area on the in-vehicle map to automatically create a challenge to the same area on the stationary map if the area has coverage on both maps. If, however, in an area that has coverage on both maps we find that large portions of a provider's in-vehicle mobile map have been successfully challenged, but there are very few speed tests conducted in a stationary environment, then we may use this as evidence upon which to form a credible basis for initiating a verification inquiry of a provider's stationary coverage in that area. Similarly, a provider refuting a challenge to a geographic area on the in-vehicle map would also refute a challenge to the same area on the stationary map if that challenge exists.

29. Several providers express concern about the proposal to aggregate in-vehicle mobile and outdoor stationary tests and compare them collectively against both coverage maps. As described above, we will not aggregate all stationary and in-vehicle mobile tests for comparison against both maps but will evaluate stationary tests against the stationary map and the in-vehicle mobile tests against the in-vehicle map. Rather than aggregating all tests, we will allow cognizable challenges to the stationary map to also create a challenge for the same area on the in-vehicle map and successful provider responses to the in-vehicle map to also refute a cognizable challenge of the same area on the stationary map. We find that this approach adequately addresses providers' concerns about comparing tests from different modeled environments, and promotes consistency between the maps. We thus decline to adopt the Vermont DPS's recommendation to allow challengers to submit in-motion tests to challenge stationary coverage, because we do not expect in-vehicle tests to achieve the same performance had the test been conducted in a stationary environment. If we did not allow for challenge or response comparison to both maps in the limited circumstances we adopt above, it would be easier for one map in an area to show a lack of coverage while the other map shows robust coverage—solely because of a lack of testing.

30. Data from speed tests taken after the ''as-of'' date of the initial BDC data collection will be considered as part of the challenge process upon confirmation that they meet the validation criteria set forth herein. Accordingly, once the Commission has generated maps of the data collected from providers, the BDC system will analyze all previously submitted tests to determine whether they were taken after the ''as-of'' date of the maps and to perform the data validations discussed further below, including whether they were taken within the published coverage area claimed by the applicable provider. Speed tests submitted as part of the challenge process that do not meet these qualifications will be considered crowdsourced data. Validated speed tests results will be reconsidered on a monthly basis, in conjunction with any newly validated speed test filings, to determine whether the data meet the geographic, temporal, and testing thresholds to create a cognizable challenge to an area. Such speed tests will be considered for up to one year to determine whether the data for a location subsequently meet the thresholds to be considered a cognizable challenge, and if so, the tests will be used collectively to challenge the maps that are published at that time.

31. Once the maps have been published, the BDC system will analyze all submitted tests to determine whether speed tests fall within the geographic area depicted in a provider's published coverage area. Speed tests submitted after the ''as of'' date but prior to publication of the map, as well as those submitted after the publication of the maps, will be used to challenge the maps that are published at that time, subject to the restriction that speed tests are considered valid evidence for one year from the date the test was taken. During the one-year period that they remain valid evidence, speed tests may initially be excluded from consideration in the challenge process because the speed tests fell outside of the provider's reported coverage maps but be included when the system reconsiders the challenge data every month, due to subsequent publication of maps reporting coverage in which such tests are located. For example, if a challenger submits otherwise valid speeds tests that were conducted in July in an area reported by the provider to not have coverage in its maps that are ''as of'' the previous December 31, such tests would be initially excluded. If the coverage maps submitted by the provider ''as of'' June 30 and published in September of that year do report such areas as covered however, the tests taken in July would be considered as valid evidence in favor of a challenge to the June 30 maps. Parties submitting speed tests to be used in the challenge process will be notified when their test has been submitted and that the test submitted may be used to create a challenge if such data meet the validation requirements. Thereafter, parties that have submitted speed tests to be used in the challenge process will be notified of the status of their submitted speed tests, which will include information on whether their speed test is used in the creation of a cognizable challenge.

32. *Maps That Can Be Challenged.* We clarify that speed test data will only be used to create challenges in areas where a provider reports that it has broadband service availability. We will, however, permit challenges to 3G, 4G LTE, and 5G–NR coverage maps. Some

commenters suggest that we defer consideration of challenges to 3G maps, but the Commission has classified 3G as a mobile broadband technology in previous BDC orders and has determined to allow challenges to the accuracy of mobile broadband coverage maps. Since the Commission did not delegate to the Bureau and Offices the authority to limit challenges to certain technologies, we lack the discretion to limit challenges to only 4G LTE and 5G–NR maps. Moreover, doing so could exclude certain consumers from the challenge process. For example, consumers rely on 3G in areas where 4G LTE and 5G–NR are not offered by the provider or are otherwise unreliable, and subscribers in rural areas continue to use 3G at higher concentrations than other parts of the country. We note that, when a provider retires a given mobile broadband technology such as 3G, that service would not be included on its updated coverage maps and therefore would not be available for challenges. However, until providers retire a particular broadband network technology, they will be obligated to respond to challenges to their claims of coverage for that technology.

33. Based on the record and the goals underlying the Broadband DATA Act, we adopt our proposal to exclude voice maps from the challenge process. The Broadband DATA Act requires the Commission to establish a process for challenging the accuracy of broadband coverage data, which, for mobile services, is defined as ''the coverage maps'' (*i.e.,* the broadband maps discussed in 47 U.S.C. 642 (c)(1)) and ''any information submitted by a provider regarding the availability of broadband internet access service.'' Additionally, the Commission has decided that the mobile challenge process applies only to broadband (and not voice) coverage maps. We also note that commenters raise concerns with using ''speed test'' data to verify voice coverage maps. Vermont DPS disagrees, proposing that the Bureau and Offices should set parameters for voice maps, including defining a threshold signal level of upload and download speeds that would indicate voice service is available in an area. We reject the Vermont DPS proposal. Vermont DPS was the only commenter to proffer minimum throughput parameters (*i.e.,* download and upload speeds) or signal strength values necessary to support a voice call, but these values did not receive any additional record support. Although Vermont DPS recommends that the Bureau and Offices determine threshold parameters that ''would be indicative of no mobile service,'' it does not propose specific parameters, noting only that zero would be indicative of no service and that 256 kilobits per second (kbps) download, 64 kbps upload, or a signal strength of less than −105 decibel-milliwatts (dBm) would indicate that service is likely insufficient. We therefore decline to include voice maps as part of the mobile challenge process at this time.

34. Additionally, we reject commenters' requests to allow challenges only to outdoor stationary coverage maps. CTIA—The Wireless Association, Verizon, T-Mobile, and AT&T argue that the Commission should focus first on challenges to outdoor stationary maps, and defer consideration of any challenges to in-vehicle maps until after it has ruled on CTIA's petition for reconsideration to eliminate in-vehicle coverage maps. The Commission's *Third Order* clearly directed that we collect both sets of maps, and we will not eliminate or delay the challenge process for in-vehicle maps given the importance in making the challenge process available for consumers and other entities that use mobile services in vehicles, unless the Commission determines that such maps are not necessary. CTIA, Verizon, T-Mobile, and AT&T also argue that in-vehicle maps should be excluded from the challenge process because the Commission has not established parameters for mapping in-vehicle coverage or evaluating in-vehicle challenges. Limiting the challenge process to outdoor stationary tests and maps could reduce the utility and accuracy of the challenge process, given that many consumers use mobile services in vehicles and in motion. We recognize that many states ban handset use while driving and many vehicle operators do not have passengers. We do not intend to contravene state bans on handset use while driving, nor do we advocate for consumers to run speed tests on a personal handset while operating a vehicle. It also would ignore a significant number of speed tests, especially on highways and in areas where it is not safe or convenient to conduct stationary speed tests. Moreover, the Commission has established sufficient parameters for mapping in-vehicle coverage and evaluating in-vehicle challenges. The Commission has allowed consumers to conduct speed tests in an in-vehicle mobile environment, but declined to adopt detailed testing requirements for in-vehicle consumer tests, whereas it required government and third-party challengers to submit more detailed information on tests run in in-vehicle mobile environments. We reiterate that all challengers must report whether the test was taken in an in-vehicle mobile or outdoor pedestrian environment; for in-vehicle tests, the speed the vehicle was traveling when in-vehicle tests were taken (where available); and, for government and other third-party challengers conducting in-vehicle tests, whether the test was conducted with an antenna located outside of the vehicle.

35. Finally, we decline to adopt Vermont DPS's request to change the thresholds for in-vehicle tests ''to account for the slight difference in performance of stationary and mobile tests'' because, as discussed, we will not use in-vehicle test data to form the basis of a challenge of stationary maps. Moreover, Vermont DPS has not given us any objective metric by which to adjust tests upward or downward for purposes of meeting the threshold when comparing the test against the other environment (*i.e.,* Vermont does not suggest any formula to accurately estimate actual performance (based upon, *e.g.,* signal strength) and thus, there is no way we could translate signal strength into actual speeds).

36. We also reject suggestions that we permit challenges only in rural areas. The Broadband DATA Act envisions a broad challenge process, and there is nothing in the Act that authorizes the Commission, or by extension, the Bureau and Offices, to limit the challenge process to rural areas.

37. *Grouping Valid Speed Tests by Location.* After excluding speed tests that fail our validations, we will associate the location of each valid speed test with a particular underlying hexagonal cell geography based on the H3 geospatial indexing system. The H3 system is designed with a nested structure wherein a lower resolution cell (the ''parent'' hexagon) contains approximately seven hexagonal cells at the next higher resolution (its ''children'' and each a ''child'' hexagon), which approximately fit within the ''parent'' hexagon. The lower the resolution, the larger the area of the hexagonal cell. Because of this nested structure, using the H3 system to group speed tests allows for challenges at multiple levels of granularity which, as discussed below, enables challengers in rural areas where broadband coverage may be more sporadic to contest larger areas if aggregated speed test data demonstrate a lack of coverage within a sufficient number of child hexagons. As proposed, the smallest cognizable challenge will be to a single resolution 8 hexagonal cell, which has an area of approximately 0.7 square kilometers.

38. Some commenters support the use of hexagons to evaluate challenges but recommend basing challenges on a different hexagonal cell size. While Vermont DPS generally supports the proposed use of H3 indexing, it argues that the system is not intuitive to use and asks the Commission to create and share geospatial indexing system (GIS) layers for the H3 hexagons at all resolutions it intends to employ in the coverage analysis, which we have already done. CTIA, T-Mobile, and AT&T urge us to use smaller resolution 10 hexagons instead of resolution 8, contending that hexagons at resolution 10 better match the 100-meter resolution providers must use when submitting their coverage maps. RWA and Vermont DPS, meanwhile, recommend allowing challenges to resolution 6 and 7 hexagons in rural areas, which RWA notes are often difficult to test because of a lack of accessible roads.

39. We find that resolution 8 strikes an appropriate balance as the smallest resolution for a cognizable challenge. Smaller areas (*e.g.,* resolution 9 or 10) could result in many disparate challenges that may require excessive testing by providers and, in the case of resolution 10 hexagons, may exceed the granularity of propagation maps that were not designed to provide such precision. Coverage maps must be submitted at a resolution of 100 meters (*i.e.,* 0.1 km) or better. Therefore, allowing for challenges to an area as small as a resolution 10 hexagon cell, which is smaller than the 100 meter map resolution, may instead reflect inaccuracies due to the resolution at which the provider generated its maps. Larger areas (*e.g.,* resolution 6 or 7 hexagons), on the other hand, would require significantly more testing for challengers and make it difficult to verify coverage in distinct local areas. For example, a resolution 7 hexagon would require four to seven times as many tests as a resolution 8 hexagon to create a successful challenge. The Commission directed staff to determine the requisite number of tests and define the geographic boundaries of cognizable challenges while satisfying the goals of both ''encourag[ing] consumers to participate in the challenge process and assuring that providers are not subject to the undue cost of responding to a large number of challenges to very small areas.'' We are not persuaded that allowing challenges to areas smaller than the 100-meter resolution (*i.e.,* a resolution 10 hexagon) requirement would adequately meet these goals. Using areas smaller than a resolution 8 hexagon would additionally make it difficult for consumers to reach the threshold of cognizable challenges. A challenger would need to take many more tests in the smaller hexagons to achieve the statistical significance required. Use of particularly small areas also would likely make in-motion testing for both challengers and providers impossible. In the future, we may consider using hexagonal cells at a higher resolution if it becomes necessary to correct coverage errors at a more granular level.

40. RWA and Verizon assert that the use of the H3 geospatial indexing system would present implementation issues. RWA cautions that third-party network maps, which providers may use to supplement the data used to rebut challenges, may not be compatible with the H3 geospatial indexing system. Verizon also raises concerns that providers would need to develop new tools and systems for managing speed tests and evaluating data in an H3-based environment and notes that tracking and evaluation may be complicated because child cells will not nest precisely into their parent cell. These concerns do not warrant deviations from our proposal since parties seeking to rebut challenges do not need to conform their tools or data to the H3 indexing system. The BDC system itself will overlay submitted speed test points with the H3 hexagons; providers need only submit their speed test data and the BDC system will appropriately index them (so long as the data otherwise meet the specifications and test requirements to qualify as valid on-the-ground speed test data). Moreover, H3 is an open-source indexing system, and therefore we do not anticipate it being overly expensive or burdensome for providers to access. Finally, in response to Verizon's argument that the tracking and evaluation of speed test data will be complicated because child cells will not nest precisely into their parent cell, we note that speed tests will be evaluated based on the resolution 8 hexagon within which a test falls.

41. CPUC and Public Knowledge/New America assert that submitting speed test data under the H3 system using resolution 8 hexagons would be more burdensome and expensive, and would result in fewer challenges, because challengers would need to gather statewide measurements in each resolution 8 hexagon. We disagree. First, challengers will not need to submit speed tests in every resolution 8 hexagon in a state because challenge data cannot form the basis of a cognizable challenge in areas where a provider does not claim coverage. Challengers will be aware of the areas in which a provider does not claim coverage from the publicly available mobile broadband map and can avoid the burden and expense of conducting speed tests in those areas. Second, as discussed, we will combine, according to the tested environment, valid speed tests conducted by consumers, state, local, and Tribal governments, and other entities. This likely will reduce the number of speed tests that any one challenger needs to submit to create a challenge. The number of required tests needed to meet the thresholds reflect the *total* number of speed tests needed to create a cognizable challenge, not necessarily the number of speed tests that must be submitted by an individual consumer or entity. Third, CPUC's concerns ignore our decision to allow testers to challenge larger geographic areas, such as resolution 7 hexagons or resolution 6 hexagons, when at least four of the seven child hexagons of the parent hexagon are challenged. Testers will be able to see which areas have been challenged and if, for example, four or more of the seven child-resolution 8 hexagons in a resolution 7 hexagon are challenged, then the entire resolution 7 hexagon will be considered challenged. Finally, H3 indexing will not burden testers because it will serve as an ''under the hood'' way for the Commission to group and analyze speed tests submitted by testers at various times and places.

42. We will evaluate all valid challenger speed tests that present evidence about the service of a given technology and environment within each hexagon to determine whether to create a cognizable challenge to the coverage in that area. We did not receive any comments on this proposal. We also adopt the alternative approach proposed in the *BDC Mobile Technical Requirements Proposed Rules* to evaluate the download and upload components of each speed test individually rather than evaluating them jointly. Under this approach, each component will be categorized as either ''positive'' or ''negative'' based on whether the component is consistent with the provider's modeled coverage (*i.e.,* the coverage assumptions in providers' BDC propagation maps). A positive component is one that records speeds meeting or exceeding the minimum speeds that the mobile service provider reports as available where the test occurred. A negative component is one that records speeds that fail to meet the minimum speeds that the mobile service provider reports as available where the test occurred. For each speed test, the download component will be

either positive or negative, and the upload component will be either positive or negative. The coverage map will then be evaluated for all download tests and separately for all upload tests. If a resolution 8 hexagon meets the thresholds for either upload or download tests, a challenge would be triggered. In order to rebut a challenge, a provider would need to meet the thresholds for both the upload components and download components. Speed test apps typically measure download and upload components sequentially and not simultaneously, so evaluating these components independently will better account for geographic and/or temporal variability.

43. In the case where the starting and ending locations of a test are in different hexagons (*e.g.,* because the testing device was in motion), we will associate the test with the hexagon containing the midpoint of the reported start and end coordinates for each test component. We also will use the midpoint to determine whether the test component falls within the applicable provider's coverage map. Each test component will be point-hex dependent. Therefore, a download test could be associated with a different point-hex than an upload test, and in such cases, the two tests would be treated independently. We disagree with Ookla that we should use the start location as the single point value of a test rather than associating two locations for each data point. We also disagree with Vermont DPS that we should use a single set of geographic coordinates at the start of each on-the-ground sequence, but we do agree with its alternative recommendation and will capture the timestamp and duration of each test component, as well as the geographic coordinates measured at the start and end of each test component with typical GPS Standard Positioning Service accuracy or better. Having start and end coordinates for each test will facilitate our verification of stationary maps versus mobile maps because it will enable us to capture the precise locations of drive tests.

44. We decline Verizon's request to adopt additional device- and plan-specific requirements. We recognize that some devices have limitations (*e.g.,* an older device may not connect to all spectrum bands), but find that restricting the types of devices that can be used to conduct speed tests would make the challenge process less user-friendly and less accessible to consumers and non-consumers alike. At the same time, a challenger must disclose the manufacturer and model of its device so that providers will have this information when rebutting challenges and can seek to invalidate tests from devices that are not compatible with a specific network or band. We will also allow mobile service providers to respond to a challenge with infrastructure information in situations where a mobile device used in the testing accessed the network over a data plan that could result in slower service. Finally, the methodology we adopt for aggregating speed tests and requiring challenges to meet the thresholds described below will ensure that challenges are temporally and geographically diverse and therefore reflect a robust and representative sample of user experience, regardless of device type or subscriber plan.

45. *Challenges to Larger, Lower-Resolution Hexagons.* We adopt our proposal for a ''parent'' or ''grandparent'' hexagon (*i.e.,* a hexagon at resolution 7 or 6) to be considered challenged if at least four of its child hexagons are challenged. CCA supports this proposal, while T-Mobile and Verizon argue that it could allow for challenges to very large areas even though significant portions of them have not been tested. We disagree with T-Mobile and Verizon and find that this approach will allow for the effective challenge of larger areas where an abundance of geographically diverse tests indicate a pervasive problem. Under it, a resolution 7 or 6 ''parent'' hexagon will be considered challenged only if more than half (*i.e.,* at least four of seven) of its ''child'' hexagons are challenged. The threshold can therefore be met without testing each resolution 8 hexagon, including ones that may be practically inaccessible. But each ''child'' hexagon must still meet the geographic threshold described below, which means that any challenges to larger ''parent'' hexagons will reflect that negative tests are persistent throughout the geographic area. While we decline to set the minimum size of a cognizable challenge at either resolution 7 or resolution 6 hexagons as requested by RWA, we believe that the approach we adopt herein will allow for challenges covering a significant portion of otherwise inaccessible resolution 8 hexagons. So long as challengers submit tests meeting the thresholds in at least four of the seven resolution 8 hexagons for a ''parent'' resolution 7 hexagon, the remaining hexagons would be effectively covered by the challenge to the ''parent,'' even if these resolution 8 hexagons are inaccessible. We conclude that this strikes an appropriate balance between reducing the burden on challengers while ensuring that robust evidence of a problem exists before requiring a provider to respond.

46. *Required Thresholds.* A resolution 8 hexagon will, as proposed, be challenged when tests submitted within the hexagon meet three thresholds: Geographic, temporal, and testing. We adopt the proposed geographic threshold, modified to account for our approach to evaluate each test component (*i.e.,* download and upload) separately. If the tests for a given technology in a resolution 8 hexagon meet all three thresholds we will consider that map's coverage to be challenged in that area. To satisfy the geographic threshold for a challenge, in general, at least four child hexagons (*i.e.,* ''point-hexes'') within the resolution 8 hexagon must contain two of the same test components (download or upload), one of which is a negative test, in each point-hex. The threshold must be met for one component entirely, meaning that a challenge may contain either two upload components per point-hex, one of which is negative, or two download components per point-hex, one of which is negative. Requiring at least four out of seven point-hexes to include two of the same test components and at least one negative test will ensure that more than half of the point-hexes within a resolution 8 hexagon show inadequate coverage. Requiring at least one negative test in multiple locations within the geographic area of a resolution 8 hexagon will demonstrate that negative tests are persistent throughout the hexagon.

47. Consistent with the Commission's direction to consider (among other factors) ''whether the tests were conducted in urban or rural areas'' when setting the methodology for aggregating speed test results, we will adjust the geographic thresholds to allow challenges that account for differences in areas. Specifically, we adopt a different geographic threshold depending on the road density of each resolution 8 hexagon. We will relax the geographic threshold to require tests in fewer than four point-hexes when fewer than four of the point-hexes of a resolution 8 hexagon are ''accessible.'' We define an ''accessible'' point-hex as one in which the provider reports coverage for at least 50% of the area of the point-hex in its reported coverage data and through which at least one road traverses. Using the most recent U.S. Census Bureau roadway data, a point-hex would contain a road if it overlaps any primary, secondary, or local road, which are defined as Master Address File/Topologically Integrated Geocoding and Referencing (MAF/

TIGER) Feature Class Codes S1100, S1200, or S1400, respectively. In order to account for road width, we will apply a small buffer around the U.S. Census Bureau road line data. No entities commented on this definition. We choose 50% of the area of the point-hex to be within the provider's reported coverage because we want challengers to have a high likelihood of being within the coverage map when they test. We note that challengers can still test within a point-hex that is not ''accessible'' so long as the test falls within the provider's reported coverage. We settle on this definition of ''accessible'' because without a road it becomes significantly more difficult for parties to run speed tests in a point-hex. We find that the existence of at least one road gives parties a way to access a hexagon and run speed tests. We anticipate that this approach will make it easier for challengers to establish a challenge in less densely populated areas because challengers will be permitted to show less geographic diversity among tests if there are fewer accessible point-hexes in a resolution 8 hexagon.

48. We decline to adopt Vermont DPS's proposal to eliminate the requirement that four of the seven point-hexes within a resolution 8 hexagon meet the geographic threshold. Requiring a challenge to meet the geographic threshold in four of seven point-hexes ensures geographic diversity of tests and will help identify potential coverage gaps over a sufficiently wide area. Vermont DPS does not propose any alternative geographic threshold, and the record supports our conclusion that the geographic threshold is necessary to minimize the chance of anomalous results. We also reject RWA's proposal to reduce the geographic threshold for inaccessible resolution 7 hexagons or allow for a resolution 7 hexagon with low road density to automatically trigger a challenge. We believe the two proposals we adopt—(1) to reduce the geographic threshold for resolution 8 hexagons with low road density, and (2) to allow a ''parent'' or ''grandparent'' hexagon (*i.e.,* a hexagon at resolution 7 or 6) to be challenged if at least four of its child hexagons are considered challenged—adequately address RWA's concerns. For example, a resolution 7 hexagon that does not contain any roads is comprised of seven resolution 8 hexagons that also do not contain roads. A challenger therefore would not need to meet the geographic threshold in any of the resolution 8 hexagons if none of the point-hexes contain roads. Moreover, if a challenger runs tests meeting the temporal and testing thresholds in four resolution 8 hexagons and such tests show inadequate coverage sufficient to create a challenge, then the entire resolution 7 hexagon will be considered challenged. Thus, while our proposal does require challengers to meet the temporal and testing thresholds in a resolution 8 hexagon that has no accessible point-hexes, the tests do not need to be geographically diverse within each resolution 8 hexagon. We believe such a trade-off is reasonable to challenge a large geographic area.

49. We also adopt a modified version of our proposed temporal threshold. To meet the temporal threshold under the approach we adopt, each resolution 8 hexagon cell must include a set of two negative components of the same type (upload or download) with a time-of-day at least four hours different from two other negative components of the same type as the first set, regardless of the date of the tests. In other words, if the negative tests within the hexagon were ordered chronologically, regardless of the day of the tests, the difference in time between the first two tests and the last two tests must be at least four hours. The temporal threshold is evaluated across all tests within the resolution 8 hexagon and need not be met for each point-hex within the hexagon. That is, the earliest two negative tests and the latest two negative tests can be recorded in different point-hexes and still meet the temporal threshold so long as the difference in time between the two pairs of tests is at least four hours. Accordingly, because the geographic threshold for a fully-accessible resolution 8 hexagon requires at least eight negative tests (*i.e.,* two each in four of the hexagon's point-hexes) whereas the temporal threshold could be met using only four of those tests (located in any of the point-hexes), the temporal threshold would not necessarily require the challenger(s) to conduct additional testing. This threshold is different from that which we proposed in the *BDC Mobile Technical Requirements Proposed Rules* in that we now require two sets of negative tests to be temporally diverse, rather than one negative test being temporally diverse from one other test. T-Mobile supports the adoption of the temporal threshold proposed in the *BDC Mobile Technical Requirements Proposed Rules,* and we believe our modified approach is consistent with the concepts for which T-Mobile expresses support. Verizon and AT&T generally support a temporal threshold, and agree with our determination that temporal diversity is important, but we decline to adopt their proposal to categorize tests into specific four-hour ranges. We disagree that categorizing tests into specific time ranges would ensure temporal diversity. For example, Verizon and AT&T's proposal could allow a challenger to satisfy the temporal threshold with tests that have been conducted within a very short timeframe. However, in light of Verizon's concerns with our initial proposal, we find that multiple tests separated by four hours, rather than one at each end of a minimum of a four hour period, are needed to show temporal diversity, and thus modify our approach to ensure temporal diversity across several tests.

50. We are also unpersuaded by Vermont DPS's argument that we should not adopt the temporal threshold because it would require a challenger to drive test a road twice, and by CPUC's argument that the temporal threshold would significantly increase costs on challengers. We believe that the effort required to achieve the temporal threshold is outweighed by the need to collect a representative sample of a mobile service provider's coverage, particularly since our decision to combine challenge data from consumers, governments, and other entities in a given area will help minimize burdens on challengers and limit the number of drive tests any one challenger will need to conduct. We conclude that our approach is a reasonable solution that will ensure challengers demonstrate persistent inadequate coverage while accounting for the temporal variability of mobile networks, such as variability due to cell loading.

51. Finally, we adopt a modified version of the proposed testing threshold to require that there must be at least five negative test components of the same type (upload or download) within the resolution 8 hexagon when 20 or fewer total challenge test components of that type have been submitted. Consistent with the approach originally proposed, when challengers have submitted more than 20 test components of the same type in a hexagon, we will require that a certain minimum percentage of the total number of test components of the same type in that hexagon be negative, ranging from at least 24% negative when challengers have submitted between 21 and 29 total tests, to at least 16% negative when challengers have submitted 100 or more tests. Once the percentage of negative test components of the same type submitted meets the

minimum negative percentage required (for example, for a sample of fewer than 21 tests, once there are at least five negative tests submitted), we will not require additional tests so long as both the geographic and temporal thresholds for a resolution 8 hexagon have been met. The failure rates we adopt were chosen to demonstrate that coverage does not reach a 90% probability threshold. We find that this 90% threshold is reasonable to use because most speed tests will be taken within the provider's cell (rather than solely at the edge of the cell) where the cell area probability should be greater than the modeled cell edge probability of 90%, and to simplify the process, we will use the 90% threshold for tests conducted anywhere in the cell. To avoid the risk that the testing threshold would be skewed by a disproportionate number of tests occurring in one location within a resolution 8 hexagon, however, we adopt a modified approach such that if the number of test components of the same type in a single point-hex represent more than 50% of the total test components in the resolution 8 hexagon (where there are four or more accessible point-hexes in the hexagon), the test components in that point-hex will count only toward meeting 50% of the testing threshold. In a resolution 8 hexagon where there are only three accessible point-hexes, if the number of test components in one point-hex represent more than 75% of the total test components in the hexagon where the geographic threshold is otherwise satisfied, the test components in that point-hex will count only toward 75% of the testing threshold. If fewer than three point-hexes are accessible, we will not apply a maximum percentage of total test components for a single point-hex as the risk that testing would be skewed by a disproportionate number of tests occurring in a single location is reduced. We believe that these changes mitigate the potential bias resulting from a disproportionate number of tests occurring in one point-hex, and that this revised testing threshold will result in greater variety of tests within each resolution 8 hexagon.

52. Verizon, CTIA, and T-Mobile generally support the adoption of a testing threshold. Verizon supports our evaluating challenges based on the percentage of tests in a cell that are below the relevant speed threshold, but expresses concern that the Commission's geographic threshold ''would allow cognizable challenges even if substantially all of the negative tests are in a single point-hex.'' The modified approach we adopt mitigates the potential problems Verizon raises because the Commission would adjust the testing threshold when a disproportionate number of tests occur in the same point-hex. T-Mobile contends that staff should adjudicate challenges based on a threshold number and percentage of ''negative'' tests, with a minimum of five tests for each resolution 10 hex cell and at least 50% of those negative. We decline to adopt T-Mobile's alternative proposal because, as discussed above, we believe resolution 10 hexagons are too small for the challenge process. We also find that T-Mobile's proposal to require that 50% of tests be negative, regardless of the number of tests run, would place a high burden on challengers, and could diminish legitimate indications that coverage is unavailable in particular areas. In contrast, the thresholds for the percentage of negative tests we adopt are based on the statistical significance necessary to demonstrate lack of coverage. We also decline to adopt Vermont DPS's proposal to allow a single test, or maximum of two tests to be used to show inadequate coverage at multiple locations within a resolution 8 hexagon. Vermont DPS's argument that the geographic and testing thresholds effectively prevent drive testing assumes that a challenger should be able to run all of the tests necessary to meet each threshold on a single drive through a resolution 8 hexagon, but if challengers find that they are having to drive at a slow pace to run an in-vehicle test in a resolution 9 hexagon, they may periodically stop to run tests in a stationary manner before moving on to the next resolution 8 hexagon. We anticipate that government and other third-party testers can use software that overlays the H3 indexing system and/or providers published maps on a drive test map and may therefore know whether they are keeping within a hex or moving into another one while doing a test. We note, however, that this may not be necessary since we will be combining challenges from consumers, governments, and other entities in a given area which would lessen the number of drive tests any one challenger will need to conduct. For this same reason, we disagree with the CPUC that the testing threshold will be extremely expensive and require complicated coordination of efforts. As discussed, we will aggregate challenges from multiple sources and no one entity will be required to conduct all tests needed to challenge a particular geographic area.

53. *User-Friendly Challenge Process.* AT&T concurs with our assessment that the challenge process we proposed is reasonable and user-friendly and supports the overall framework, including the use of the H3 geospatial indexing system. In addition, CTIA, T-Mobile, and AT&T agree that the proposal to combine test data from consumers, governments, and other entities is user-friendly and reduces burdens on challengers, who will not be required to collect and submit every drive test needed to sustain a challenge on their own. Although Public Knowledge/New America raise concerns about whether the challenge process is sufficiently user-friendly, they share our belief that the challenge process should be as streamlined and burden-free as possible for consumers and other entities; we note that our implementation of the consumer challenge process is consistent with the *Third Order*'s determination that challengers will collect and submit all speed test data needed to support a challenge, including the new speed test metrics and parameters we adopt, through the FCC Speed Test app or another app approved by OET to collect and submit challenge data to the Commission.

54. We disagree with commenters that argue that our challenge process is not ''user-friendly.'' RWA argues that the testing process is not ''user-friendly'' because consumers can test only the networks their handsets are authorized to use. It recommends requiring providers to allow tests by other networks' subscribers. The Commission has already determined that consumer challengers must submit certain identifying information, including that they are a subscriber or authorized user of the provider being challenged, to deter frivolous filings, and the Bureau and Offices were not delegated authority to change this requirement. Similarly, Vermont DPS recommends requiring providers to temporarily provide approved devices with post-paid service at no or reduced cost to governmental entities wishing to engage in a challenge. We decline to adopt Vermont DPS's request because we lack the authority to subsidize government challenges and believe it would be too burdensome to require providers to establish and bear the costs of such programs. Enablers argues (and Public Knowledge/New America agree) that '' 'testing parameters that amount to an exceedingly high burden of proof for consumers and other parties' run 'contrary to the Broadband DATA Act and [the Commission's] own policy goals.' '' Public Knowledge/New America accordingly encourage the Bureau and Offices to consider

''allow[ing] the option to use other trusted sources to challenge providers' claims.'' The Precision Ag Connectivity & Accuracy Stakeholder Alliance (PAgCASA) similarly claims that the proposed challenge process ''delineates a series of technical and non-technical steps [m]obile customers must initiate and successfully navigate when conducting their [c]hallenge process that . . . falls well short of being easy to use from a customer's perspective.'' These commenters also raise many issues that were already decided in the *Third Order* (*e.g.,* subscriber certifications and testing methodology and metrics) and are not delegated to the Bureau and Offices, or urge the Bureau and Offices to ignore the instructions given by the Commission, and would have been more appropriately filed as a petition for reconsideration of the *Third Order.* We reject the arguments of these commenters as untimely because they should have been filed as petitions for reconsideration to the extent that they raise issues already decided by the full Commission. Under Section 405(a) of the Communications Act of 1934, as amended, any party in a proceeding may file a petition for reconsideration within thirty days of public notice of the decision. These commenters raise issues that were decided by the Commission in the *Third Order,* which was published in the **Federal Register** on April 7, 2021. This publication date means that deadline for filing a petition for reconsideration of the *Third Order* was May 7, 2021. Because these commenters did not file their comments until September 2021, the Bureau and Offices find that the arguments are untimely and would have been more appropriately filed as petitions for reconsideration.

55. In conclusion, while the challenge processes and methodologies we adopt are by necessity detailed and technical, so as to assure that accurate and rigorous measurements are supplied to challenge providers' claimed broadband coverage, the Commission and Bureau and Offices have minimized the burdens placed on challengers by providing a user-friendly means for challengers to run speed tests using their mobile devices and submit all data via either the FCC Speed Test app or another OET-approved third-party app. As discussed, the Bureau and Offices were instructed to implement a number of complex and complicated tasks, among them, developing thresholds for determining when a cognizable challenge has been met, a procedure for resolving challenges, and adopting additional testing requirements if necessary. These obligations were delegated by the Commission within the context of the Broadband DATA Act, which requires the Commission to consider user-friendly challenge submission formats, reducing the time and expense burdens on consumers submitting challenges and providers responding to them, while at the same time considering lessons learned from the challenge process established under Mobility Fund Phase II, and the costs to consumers and providers resulting from a misallocation of funds because of a reliance on outdated and inaccurate maps. Indeed, financial assistance for underserved areas may, in the future, be based on updated Commission maps. Therefore, we find that the processes we adopt strike an appropriate balance, within the authority delegated to us by the Commission, to ensure the challenge process is easy to use and accessible for consumers and government and other entities and also results in high-quality challenges that will accurately correct any errors associated with providers' reported coverage maps.

2. Challenge Responses

56. *Notification of Challenges.* We adopt the *BDC Mobile Technical Requirements Proposed Rules'* proposed procedures for notifying service providers of cognizable challenges filed against them and for notifying challengers and providers of results of challenges. The *BDC Mobile Technical Requirements Proposed Rules* proposed that challenged mobile service providers would be notified via the online portal at the end of each calendar month of the hexagons that are subject to cognizable challenges. CTIA and T-Mobile express support for our proposal. We find this approach will help create a manageable process for providers by providing them with a standard set of deadlines rather than an erratic and potentially unpredictable set of innumerable deadlines for rebuttals that begin as soon as any given discrete area becomes challenged. We also adopt our proposal for mobile service providers and challengers to be notified monthly of the status of challenged areas, and parties will be able to see a map of the challenged area, and a notification about whether or not a challenge has been successfully rebutted, whether a challenge was successful, and if a challenged area was restored based on insufficient evidence to sustain a challenge. In the *Third Order,* the Commission directed that challenge and crowdsource data other than the location that is the subject of the challenge, the name of the provider, and details concerning the basis for the challenge must be kept private to protect challengers' privacy interests. Accordingly, before a service provider receives access to crowdsourced or challenge data, it will be required, within the BDC system, to acknowledge that it will use personally identifiable information that it receives for the sole purpose of responding to the challenge and that it will protect and keep private all such personally identifiable information. Such personally identifiable information may include challenger contact information, device information, and network information, as well as other personally identifiable information included in addition to evidence that a challenger submits.

57. *Timeframe for Responding to Challenges.* In the *Third Order,* the Commission determined that providers must either submit a rebuttal to a challenge or concede a challenge within 60 days of being notified of the challenge. Consistent with the *Third Order,* if the challenged provider concedes or fails to submit data sufficient to overturn the challenge within 60 days of notification, it must revise its coverage maps to reflect the lack of coverage in the successfully challenged areas.

58. In comments on the *BDC Mobile Technical Requirements Proposed Rules,* CCA argues that the Bureau and Offices should allow providers to seek a waiver of the 60-day deadline if the provider needs additional time to submit on-the-ground data due to unforeseen events or weather. Verizon contends that providers should be able to choose to seek either: (1) A waiver of rules that limit the permitted uses of infrastructure data or transmitter monitoring software in lieu of speed tests; or (2) a waiver of the 60-day deadline if the provider will rebut with speed test data. The Commission adopted the requirement that providers submit a rebuttal or concede a challenge in the *Third Order* based on its determination that permitting 60 days to respond to a challenge would make the challenge process more manageable for providers, while also providing for speedy resolution of challenges consistent with the requirements of the Broadband DATA Act. The Bureau and Offices do not have authority to change the required timeframe for provider responses. To the extent that a provider may wish to seek a waiver of the 60-day deadline for responding to a challenge in any individual case, it may do so under the Commission's generally applicable waiver rules.

59. *Future Challenges in Successfully Rebutted Areas.* We adopt our proposal

to make any areas where a provider has demonstrated sufficient coverage in a challenged area ineligible for subsequent challenge until the next biannual broadband availability data filing at least six months after the later of either the end of the 60-day response period or the resolution of the challenge. This ineligibility applies only with respect to the particular network technology and modeled environment for which the provider has demonstrated sufficient coverage. We deny Verizon and AT&T's request that the Bureau and Offices make successfully rebutted areas exempt from future challenges for a period of three years. We find that preventing future subsequent challenges for a period as long as three years could result in less accurate maps due to changes over time in technology and coverage. We find instead that limiting subsequent challenges for at least six months after the resolution of the challenge strikes an appropriate balance between avoiding a requirement that providers repeatedly confirm the same areas while ensuring that challengers have the opportunity to submit data regarding changed conditions. Although commenters assert that it is unlikely that coverage will be reduced in an area that was subject to challenge, an area that is subject to repeated cognizable challenges may highlight that significant technical issues continue to affect the availability of broadband service in that area. Permitting a subsequent challenge in these areas will help ensure that the Commission receives the most accurate and up-to-date coverage data reflecting consumers' on-the-ground experience. In any area in which a provider does not overturn the challenge but which is otherwise no longer considered challenged (*e.g.,* where, as a result of data submitted by the provider there is no longer sufficient evidence to sustain the challenge to that area but the provider's data fall short of confirming coverage in the area), the coverage area will be restored to its pre-challenge status and will be eligible for future challenges against it.

a. Rebutting Challenges With On-the-Ground Data

60. We adopt our proposal from the *BDC Mobile Technical Requirements Proposed Rules* that, when a challenged mobile service provider submits on-the-ground speed test data to rebut a challenge, the provider will be required to meet analogous thresholds to those required of challengers, adjusted to reflect the burden on providers to demonstrate that sufficient coverage exists at least 90% of the time in the challenged hexagon(s). Consistent with our proposal, the on-the-ground test data that providers submit must meet the same three thresholds required of challenger tests for both the upload and download components: (1) A geographic threshold; (2) a temporal threshold; and (3) a testing threshold, albeit with different values (*i.e.,* the number of tests and percentages) for test data for each threshold.

61. For the geographic threshold, the provider will need to meet the same geographic threshold required of challengers, but with positive test components rather than negative test components. At least four point-hexes of a resolution 8 hexagon must include two download test components taken within them, at least one of which must be positive, and at least four point-hexes of a resolution 8 hexagon must include two upload test components taken within them, at least one of which must be positive to demonstrate that adequate coverage occurs at multiple locations within the resolution 8 hexagon. We adopt a modified version of our proposed temporal threshold. To meet the temporal threshold under the approach we adopt, each resolution 8 hexagon will need to include a set of five positive download components with a time-of-day difference of at least four hours from another set of five positive download components, regardless of the date of the test and a set of five positive upload components with a time-of-day difference of at least four hours from another set of five positive upload components, regardless of the date of the test. We modify the threshold proposed in the *BDC Mobile Technical Requirements Proposed Rules* because we find that requiring more tests to be separated in time will help ensure that there is more consistent temporal diversity across several tests. For the testing threshold, we adopt our proposal that challenged providers must demonstrate statistically significant evidence that coverage is adequate to overturn a challenge using on-the-ground speed tests, based on the same statistical significance analysis used for determining challenges for both upload and download components. Specifically, in order for the testing threshold for a resolution 8 hexagon to be met, we require that at least 17 positive test components of the same type have been taken in the hexagon when the provider has submitted 20 or fewer test components of that type. When the provider has submitted more than 20 test components of the same type, we require that a certain minimum percentage of the total number of test components of that type in the hexagon must be positive, ranging from at least 82% positive, when providers have submitted between 21 and 34 total test components of the same type, to at least 88% positive, when providers have submitted 100 or more test components of the same type. The positive test rates we adopt were chosen to demonstrate that coverage does reach a 90% probability threshold, as opposed to the requirement that challengers demonstrate coverage does not reach a 90% probability threshold. Additionally, in line with the modification we adopt for challengers, if more than 50% of the test components of the same type are within a single point-hex where four or more point-hexes in the resolution 8 hexagon are accessible, the test components in that point-hex will be down-weighted to only account for 50% of the total test components when evaluating the testing threshold. If more than 75% of the tests are within one point-hex where there are three accessible hexes in the resolution 8 hexagon, the tests in that point-hex will be reduced to only account for 75% of the total tests when evaluating the testing threshold. By limiting the percentage of test components within any one point-hex that may contribute to a challenge response, this requirement will help ensure that there is sufficient diversity in the test data that a challenged provider submits. A provider may also demonstrate sufficient coverage in a resolution 8 hexagon that was not challenged in order to rebut a challenge to a lower-resolution hexagon containing the non-challenged resolution 8 hexagon (*i.e.,* the ''parent'' resolution 7 hexagon or ''grandparent'' resolution 6 hexagon). As discussed more fully in Section 3.2.4 of Appendix A—Technical Appendix (available at *https://www.fcc.gov/document/fcc-releases-bdc-mobile-technical-requirements-order*), for challenged hexagons at resolution 7 or 6, if the provider submits response data sufficient to demonstrate coverage in the hexagon's child hexagons such that fewer than four child hexagons would still be challenged, then the resolution 7 or 6 hexagon would no longer be challenged even if sufficient data were not submitted to rebut a challenge for the remaining child hexagons. In analyzing challenges, staff may consider other relevant data submitted by providers, request additional information from the challenged provider, and take other actions as may be necessary to ensure the reliability and accuracy of rebuttal data. These

actions may include rejecting speed tests or requiring additional testing.

62. In the *BDC Mobile Technical Requirements Proposed Rules,* we proposed to require providers to collect on-the-ground test data using mobile devices running either a Commission-developed app (*e.g.,* the FCC Speed Test app), another speed test app approved by OET to submit challenges, or other software if approved by staff. T-Mobile urges the Bureau and Offices to allow providers to use their own software tools to rebut challenges without seeking prior staff approval. If approval is needed, T-Mobile argues, then OET should commit to approve or reject such tools within 90 days of submission. Our proposal to require approval of testing software used by providers was based on the *Third Order's* direction to the Bureau and Offices to approve the equipment that providers may use to conduct on-the-ground testing to respond to verification inquiries, combined with the Commission's determination that providers rebutting challenges with on-the-ground test data would be subject to the same requirements and specifications that apply to providers submitting data in response to a Commission verification request. T-Mobile also asks the Commission to ''ensure the process for submitting and responding to challengers is user friendly'' by making the challenge portal ''compatible with widely used database software like Salesforce.'' We decline to adopt a requirement that the portal be compatible with specific types of software. However, we take other steps to provide flexibility for providers in responding to challenges, including, as described in more detail below, allowing them to use their own software tools to gather on-the-ground test data. We also anticipate that service providers and other entities will be able to build their own tools and integrate their own software and databases with the BDC system using a modern web-based Application Programming Interface (API).

63. While we continue to read these provisions as requiring the Bureau and Offices to approve any software tools providers may use to gather on-the-ground test data, we clarify that, to the extent that a provider chooses to use software other than the FCC Speed Test app or another speed test app approved by OET for use in the challenge process, we will consider such software approved for use in rebutting challenges provided that the software incorporates the test methodology and collects the metrics that approved apps must gather for consumer challenges and that government and third-party entity challenger speed test data must contain. We understand that certain technical network information and RF metrics that we would otherwise require are not currently available on Apple iOS devices. Therefore, until such time as such information and metrics are available on iOS devices, and the Bureau and Offices indicate that they will collect such information from iOS devices, providers must collect all of the required technical network information and RF metrics using a device that is able to interface with drive test software and/or runs the Android operating system. We also require providers conducting in-vehicle mobile tests (*i.e.,* drive tests) to conduct such tests with the antenna located inside the vehicle. We disagree with Verizon that providers should be able to choose whether or not to use an external antenna when conducting speed tests. Because most consumers will take in-vehicle tests using an antenna inside the vehicle, adopting this requirement for providers will help minimize discrepancies and ensure more consistent comparisons between on-the-ground test data supplied by challengers and data supplied by providers.

64. In order to inform our approval process and consistent with the requirement that applies to government and other entity challengers who choose to use their own software when submitting challenges, we require providers who choose to use their own software to submit a complete description of the methodologies used to collect their data and to substantiate their data through the certification of a qualified engineer or official. Permitting providers to use their own tools is consistent with the approach the Commission adopted for government and other entity challengers in collecting challenge data and it is preferable to requiring prior approval for providers wishing to use their own software tools because it will help streamline the challenge process by reducing the potential for any delays that might be caused by requiring prior review of specific software tools that providers may wish to use. It also will provide greater flexibility and reduce burdens on providers by allowing them to more easily use the software tools they may already be using in the ordinary course of their business.

65. We recognize that this approach is different than the approach we have adopted for third-party speed tests apps where we require OET approval before such apps may be used in the challenge process. We find, however, that the difference in treatment is justified and warranted. Mobile broadband service providers routinely test and monitor network performance as they develop their networks, and their software has been engineered specifically to obtain detailed speed test measurement data. Providers' software is unlikely to be constrained by limitations in the categories of data that can be collected; in contrast, and as discussed above, consumer-facing third-party apps (particularly apps run over iOS) cannot provide certain categories of information. We require approval for third-party speed test apps because we want to ensure that the apps measure coverage as accurately as possible and report information into the BDC system with the required certifications and in a useable format. In addition, requiring approval is necessary to hold the third-party app developers accountable for the accuracy and reliability of their tools and to allow us to inform consumers of the available third-party apps that meet our requirements and are approved for use in the challenge and crowdsource processes. In contrast, the Commission has greater jurisdiction over service providers, as providers are required under the Broadband DATA Act to ensure the accuracy of the coverage information they submit to the Commission. Permitting providers to use these existing performance measurement tools without individualized review and approval will help increase efficiency while continuing to ensure that the Commission receives high-quality data that will allow an apples-to-apples comparison between challenge data submitted by consumers and other entities and data supplied by providers using their own software. While we expect that this approach will benefit our administration of the challenge process, we retain the discretion to require prior approval of providers' software or to make changes to the required metrics via notice and comment at a later time. We also retain discretion to revoke the automatic grant of approval in instances where a provider's software is found to be unreliable or otherwise inconsistent with our objective of ensuring accurate mapping data.

66. We decline T-Mobile's request that we ''adopt a 90-day 'expiration' date for challenge data'' and instead adopt our proposal to make on-the-ground test data valid for one year from the test date. The process we adopt for submission of challenges ensures that providers have sufficient details to respond to challenges, including dates and times of speed tests. Moreover, to

the extent a provider improves its network coverage in an area, it can either remove the area from its current data and add it back in with its next biannual submission or rebut a challenge by submitting on-the-ground test data demonstrating network performance in the recently deployed area. We find that these alternatives strike a better balance in facilitating robust participation in the challenge process and ensuring high-quality data than requests to curtail the lifespan of valid challenge data.

b. Rebutting Challenges With Infrastructure Data

67. Under the rules adopted in the *Third Order,* providers may respond to challenges with infrastructure data rather than (or in addition to) on-the-ground speed test data. In cases where a challenged mobile service provider chooses to submit infrastructure data to respond to a challenge, we adopt our proposal to require the provider to submit the same data as required when a mobile provider submits infrastructure information in response to a Commission verification request, including information on the cell sites and antennas used to provide service in the challenged area. In the *Third Order,* the Commission directed OEA and WTB to provide guidance on the types of data that will likely be more probative in validating broadband availability data submitted by mobile service providers in different circumstances and in the *BDC Mobile Technical Requirements Proposed Rules,* we proposed to use infrastructure data, on their own, to adjudicate challenges in a limited set of circumstances. Specifically, we proposed that a challenged provider may use infrastructure data to identify tests within challenger speed test data that the provider claims are invalid or non-representative of network performance and proposed four circumstances under which a provider could claim a speed test was invalid, or non-representative. In response, CCA argues that providers should not be permitted to respond to a challenge with only infrastructure data because such data are predictive and are not as reliable as on-the-ground test data. CTIA and Verizon, by contrast, argue that the Bureau and Offices lack delegated authority to impose any limitation on providers' ability to submit infrastructure data to respond to challenges.

68. We find that our proposed approach strikes the best balance between providing flexibility for providers and ensuring that they respond to challenges with probative data. We continue to view data that reflect actual on-the-ground tests, as opposed to infrastructure data, generally to more accurately reflect user experience and therefore be of more probative value in most—but not all—circumstances. We disagree with CTIA and Verizon's argument that the Commission's decision to permit providers to respond with infrastructure data precludes us from adopting rules governing the circumstances under which such data can be used, on their own, to respond to challenges. While the Commission directed providers to ''submit to the Commission either on-the-ground test data or infrastructure data, so that Commission staff can examine the provider's coverage in the challenged area and resolve the challenge,'' it also ''directed OEA and WTB to develop the specific requirements and methodologies that providers must use in conducting on-the-ground testing and in providing infrastructure data'' and ''direct[ed] OEA and WTB to provide guidance about what types of data will likely be more probative in different circumstances.'' The Commission also found that ''if needed to ensure adequate review, OEA may also require that the provider submit other data in addition to the data initially submitted, including but not limited to, either infrastructure or on-the-ground testing data (to the extent not the option initially chosen by the provider).'' Defining the circumstances under which infrastructure data, on their own, may be used to rebut a challenge is consistent with these delegations of authority and offers guidance to providers about when the Commission will find infrastructure data to be as probative as on-the-ground test data, as well as when such data are likely to be sufficient to resolve a challenge.

69. We also disagree with Verizon that requiring a challenged provider to submit infrastructure data in cases where there may be other forms of evidence that can rebut a challenge is ''unnecessarily burdensome.'' In the *Third Order,* the Commission determined that providers may rebut a challenge by submitting to the Commission on-the-ground test data and/or infrastructure data, so that Commission staff can examine the provider's coverage in the challenged area and resolve the challenge, and may optionally include additional data or information in support of a response. The Bureau and Offices do not have the authority to change the Commission's decision or permit challenge responses that do not include either on-the-ground test data and/or infrastructure data.

70. While we adopt our proposal to use infrastructure data, on their own, to resolve challenges in a limited set of circumstances, we agree with commenters that providing additional flexibility will help providers submit responses efficiently. Therefore, we add to the list of circumstances where we will accept infrastructure data, on their own, to respond to a challenge. In the circumstances listed below, we find that infrastructure information will likely be as probative as on-the-ground test data and therefore a provider may submit infrastructure data, on their own, in response to challenge that would invalidate speed tests submitted by challengers. We disagree with CCA that the circumstances for submitting infrastructure data are not defined sufficiently and risk increasing burdens on challengers. We expect the circumstances outlined above to occur rarely and providers, not challengers, must demonstrate that one of these circumstances exists when responding to a challenge solely with infrastructure data.

71. First, we find that infrastructure information will likely be of comparable probative value when extenuating circumstances at the time and location of a given test (*e.g.,* maintenance or temporary outage at the cell site) caused service to be abnormal. In such cases, we adopt our proposal for providers to submit coverage or footprint data for the site or sectors that were affected and information about the outage, such as bands affected, duration, and whether the outage was reported to the FCC's Network Outage Reporting System (NORS), along with a certification about the submission's accuracy. We will then remove measurements in the reported footprint in the relevant band(s) made during the outage and, as appropriate, recalculate the statistics.

72. Second, we find that infrastructure data will likely be of comparable probative value when the mobile device(s) with which the challenger(s) conducted their speed tests are not capable of using or connecting to the radio technology or spectrum band(s) that the provider models as required for service in the challenged area. In such cases, we adopt our proposal for providers to submit band-specific coverage footprints and information about which specific challengers' device(s) lack the band or technology. We will then remove measurements from the listed devices in the relevant coverage footprint and recalculate the statistics.

73. Third, we find that infrastructure data will likely be of comparable probative value when speed tests were taken during an uncommon special event (*e.g.,* a professional sporting event or concert) that increased traffic on the network. As we previously stated, we recognize that in such cases mobile service providers would not have the same throughput they would in normal circumstances given the high volume of traffic on networks during these types of uncommon special events, so demonstrating the existence of coverage in the area by submitting infrastructure information would be persuasive for why speed tests were negative in such a scenario.

74. Fourth, we find that infrastructure data will likely be of comparable probative value when speed tests were taken during a period where cell loading was abnormally higher than the modeled cell loading factor. Speed tests taken during a period when cell loading is higher than usual can result in negative speed tests, and we thus anticipate that infrastructure information will be useful to remove the tests and recalculate the statistics for challenges in this situation. In such cases, we adopt our proposal to require providers to corroborate their claims by submitting cell loading data and we clarify that these data must both (a) establish that the cell loading for the primary cell(s) at the time of the tests was abnormally higher than modeled, and (b) include cell loading data for a one-week period before and/or after the provider was notified of the challenge showing as a baseline that the median cell loading for the primary cell(s) was not greater than the modeled value (*e.g.,* 50%). To meet this threshold, infrastructure data reporting cell loading at the time of test would need to show that actual loading was both higher than the modeled cell loading factor (*e.g.,* 50%) and higher than the 75th percentile of the 15-minute interval weekly cell loading data submitted as a cell loading baseline. Adopting the 75th percentile requirement would ensure that loading at the time is abnormally high because loading would be higher than the four busiest hours each day during the 6:00 a.m. to 10:00 p.m. daily window to submit challenges during the baseline. These clarifications should help address concerns about the utility of infrastructure data by ensuring that we receive robust evidence, based upon actual cell loading measurements, that higher-than-modeled cell loading at the time of the test is an abnormal occurrence. We also adopt our proposal that, if a high number of challenges show persistent over-loading, staff may initiate a verification inquiry to investigate whether mobile providers have submitted coverage maps based on an accurate assumption of cell loading in a particular area.

75. Fifth, in response to the record we find that infrastructure data will likely be of comparable probative value when a mobile device used in testing used a data plan that could result in slower service. In such cases, providers must submit information about which specific device(s) used in the testing were using a data plan that would have resulted in slower service and information showing that the provider's network did, in fact, slow the device at the time of the test.

76. Sixth, and also in response to the record, we find that infrastructure will likely be of comparable probative value when a mobile device used in the testing was either roaming or was used by the customer of an MVNO. As adopted above, we will not permit speed tests submitted by customers of an MVNO or whose devices are roaming on another provider's network to be counted as valid tests against the facilities-based provider's network on which the speed test was conducted. As stated above, because the agreements between a facilities-based provider and MVNOs or roaming partners often include limitations on the technology and speed available to or the network prioritization of devices used by consumers of the MVNO or roaming partner, we conclude that speed tests from such devices are not reliable evidence about the performance of the facilities-based provider's network. While we anticipate that the majority of such tests will fail our automated validations, there may be circumstances where the BDC system is unable to automatically identify these tests (*e.g.,* identifying whether an iOS device is roaming is not currently possible). In such circumstances, providers must identify which specific device(s) used in the testing were either roaming at the time or used by the customer of an MVNO, based upon their records.

77. After the provider identifies the speed tests it seeks to invalidate pursuant to one of the six circumstances we adopt above and submits all required infrastructure data in support of this contention, we will remove any invalidated speed tests and recalculate the challenged hexagons. Any challenged hexagons that no longer meet the thresholds required for a challenge would be restored to their status before the cognizable challenge was created. We note that where a provider rebuts a challenge using this process, the challenged hexagons that have been restored to their status before the cognizable challenge was created would continue to be eligible for subsequent challenges.

78. Where a challenged provider does not claim that a challenger's speed tests were invalid based upon one of the six circumstances listed above, Commission staff will consider any additional information submitted by the challenged provider or request additional information from the challenged provider. Such information must include on-the-ground speed test data and may also include other types of data, as specified in the *Third Order.* Staff will use this information to complete its adjudication of the challenge. Although we adopt the foregoing approach for considering infrastructure information in response to challenges, we note that we may make changes to this approach over time as we gain experience with administering the challenge process.

c. Other Data

79. In the *Third Order,* the Commission determined that providers may rebut a challenge by submitting to the Commission either on-the-ground test data and/or infrastructure data, and may optionally include additional data or information in support of a response, including drive testing data collected in the ordinary course of business, third-party testing data (such as speed test data from Ookla or other speed test app), and/or tower transmitter data collected from transmitter monitoring software. Consistent with the Commission's direction in the *Third Order,* OEA staff will review such data when voluntarily submitted by providers in response to challenges, and, if any of the data sources are found to be sufficiently reliable, staff will specify appropriate standards and specifications for each type of data and issue a public notice adding the data source to the alternatives available to providers to rebut a consumer challenge.

80. In the *BDC Mobile Technical Requirements Proposed Rules,* the Bureau and Offices sought comment regarding the conditions under which a provider's transmitter monitoring software can be relied upon by staff in resolving challenges. Commenters did not discuss specific conditions under which transmitter monitoring software should be relied upon, instead expressing general support for the use of such data and encouraging the Commission to develop standards for when such data would be sufficient for rebutting a challenge. Based on the

record, we find that there is insufficient evidence to determine, at this time, the conditions under which we may rely on transmitter monitoring software data to resolve challenges. Accordingly, we will review such data when voluntarily submitted by providers in response to challenges and, in doing so, we will consider, among other things, the extent to which the transmitter monitoring software data augment or reinforce the probative value of infrastructure or other data to rebut challenger speed test data, how such systems measure the geographic coordinates (longitude and latitude) of the end-user devices, how the data compare to the information collected from on-the-ground testing, and whether such software records instances of end-user devices not being able to connect to the network at all.

81. Several providers filed comments requesting additional flexibility in responding to challenges. They argue that, rather than only being permitted to voluntarily submit other types of data, such as data from field tests conducted in the ordinary course of business or third-party data, in addition to either on-the-ground test data or infrastructure data, providers should be able to submit such data on their own as a response to challenges. The Commission has already addressed requests for additional flexibility in responding to challenges, and the Bureau and Offices do not have authority to change the Commission's determinations. In the *Third Order,* the Commission considered arguments that providers should have additional flexibility to submit other types of data in responding to challenges, including, among others, drive testing data collected in the ordinary course of business. The Commission recognized the need for flexibility in provider responses, determining that providers may voluntarily submit other types of data beyond on-the-ground testing data or infrastructure data they are required to submit to rebut a challenge, but found that the record did not support a finding that such data were sufficient to serve as a complete substitute for either on-the-ground testing or infrastructure data. The Bureau and Offices do not have the discretion to change the Commission's decision. Although OEA has the delegated authority to adopt new alternatives as a substitute for on-the-ground data or infrastructure data, it can exercise such authority only after reviewing such data submissions, determining that they are sufficiently reliable, and specifying the appropriate standards and specifications for each type of data.

B. Collecting Verification Information From Mobile Providers

82. The Broadband DATA Act requires the Commission to ''verify the accuracy and reliability'' of the broadband internet access service data providers submit in their biannual BDC filings in accordance with measures established by the Commission. The Commission determined in the *Third Order* that OEA and WTB ''may request and collect verification data from a provider on a case-by-case basis where staff have a credible basis for verifying the provider's coverage data.'' In response to such an inquiry, the provider must submit either on-the-ground test data or infrastructure information for the specified area(s). The provider may also submit additional data, including but not limited to, on-the-ground test data or infrastructure data (to the extent such data are not the primary option chosen by the provider), or other types of data that the provider believes support its reported coverage. A mobile service provider has 60 days from the time of the request by OEA and WTB to submit, at the provider's option, on-the-ground or infrastructure data, as well as any additional data that the provider chooses to submit to support its coverage. OEA and WTB may require submission of additional data if such data are needed to complete the verification inquiry. The Commission directed OEA and WTB ''to implement this data collection and to adopt the methodologies, data specifications, and formatting requirements that providers shall follow when collecting and reporting [these] data.'' The *BDC Mobile Technical Requirements Proposed Rules* sought comment on processes and methodologies for determining areas subject to verification (*i.e.,* areas where Commission staff have a credible basis for verifying a mobile provider's coverage data in an area) and for the collection of on-the-ground test data and infrastructure information, as well as information from transmitter monitoring systems and other data. Below we discuss and expand on when a credible basis exists for initiating a verification inquiry. Additionally, we adopt approaches for submitting data in response to a verification request and discuss our efforts to balance the needs of this proceeding with the burdens placed on providers in verifying coverage.

1. Area Subject to Verification

83. To identify the portion(s) of a mobile provider's coverage map for which we will require verification data—referred to as the targeted area(s)—we will rely upon all available evidence, including submitted speed test data, infrastructure data, crowdsourced and other third-party data, as well as staff evaluation and knowledge of submitted coverage data (including maps, link budget parameters, and other credible information). We find this approach allows for needed flexibility while accounting for the relevant data at hand when selecting a targeted area. The adopted approach to the mobile verification process differs from the challenge process and the verification process proposed in the *BDC Mobile Technical Requirements Proposed Rules* by removing the testing and geographic threshold requirements of the challenge process. This reduces the burden on providers while still allowing for an accurate verification process and is discussed further below.

84. *A Credible Basis to Verify a Provider's Coverage Data.* We will conduct verification inquiries in areas where we find there is a ''credible basis'' for such an inquiry, and we will use an evidence-based analysis to determine whether a credible basis exists. The factors we will consider in this analysis include, but are not limited to, the geographic size of the area, the number of tests taken, the reliability of the tests, the parameters of the RF link budgets, infrastructure data accuracy, backhaul, and cell loading factor requirements. As discussed below, staff may also adjust the fade margins of the RF link budgets to calculate new ''core coverage'' areas using a standard propagation model, which would have a higher probability of coverage. For example, if testing data in an area exhibit an aberration compared to nearby areas and make that area appear as an outlier, this could constitute a credible basis to initiate a verification inquiry for that area. For example, assume an area is within a provider's 3G and 4G LTE coverage maps and there are many speed tests in the area on 3G but no tests recorded using 4G LTE from devices that are technologically capable of connecting to a 4G LTE network. This absence of tests on a superior technology would be considered an aberration in an area with many tests. Similarly, if speed tests submitted as challenges are sufficient to create many small, disparate challenges across a much larger area, these may be indicative of a pervasive problem, which could give staff a credible basis for conducting a verification inquiry. Another example where a credible basis could exist is an area where a significant

number of speed tests have been submitted as challenges but do not meet the thresholds to create cognizable challenges. A credible basis could also be established for an area without cognizable challenge data but where other available data, such as the results of staff's statistical analysis of crowdsourced data (including, *e.g.,* Kriging spatial-interpolation analysis), indicate that coverage data may be incorrect. Additionally, as discussed further below, once we determine that a ''critical mass'' of crowdsourced filings indicate a provider's coverage map may be inaccurate, Commission staff has a credible basis for verifying a provider's coverage data in that area. Notwithstanding any of the foregoing, we note that the Commission also retains the right to perform audits of provider submissions at random, even without the existence of a credible basis necessary to trigger a verification inquiry.

85. We believe that the aforementioned examples of the information we will consider, as well as the standards and types of analysis we intend to apply, when deciding where to initiate a verification inquiry provide sufficient guidance on this topic, and we therefore find it unnecessary to adopt additional restraints, as advocated by T-Mobile. Because the Broadband DATA Act gives the Commission the responsibility to ''verify the accuracy and reliability of [service providers' biannual coverage data],'' it is important that staff have enough discretion to consider whether coverage data are accurate based on a range of factors, including geographic size, on-the-ground tests taken, and the reliability of those tests, according to the particular data and circumstances of the data that are presented to us. On the other hand, the case-by-case nature of the data received from providers, the challenge process, and the crowdsourced data is sufficient to limit verification requests to areas where a reason exists to view the area as problematic. We believe the approach described here is the most reasonable and effective way to pursue the goals of this proceeding and the Broadband DATA Act. We do not seek to require superfluous information from providers, but if circumstances indicate that additional data or other information are necessary to verify coverage in an area where evidence suggests the coverage is problematic, we have an obligation to verify the data, and, in many cases, additional information will be necessary to verify the area's coverage and carry out the Commission's obligations under the Broadband DATA Act.

86. Multiple commenters express a strong general desire to reduce or minimize the burden placed on providers as a result of the verification process. For instance, Verizon claims that the methods proposed for determining an area subject to verification would create verification areas that are too large. It recommends initially testing the verification process on a smaller scale, such as in rural areas. It also recommends that the Bureau and Offices limit verification requests to one per map submission (and up to two per year) and limit the areas to be sampled in the verification process to three contiguous resolution 6 hexagons. T-Mobile supports focusing verification requests in rural areas. T-Mobile similarly requests that the Bureau and Offices limit verification requests, recommending that such requests cover an area of no more than 10,000 square miles in a given year.

87. We decline to adopt any specific limitations on the basis for initiating verification inquiries or the areas subject to verification, including instances where a provider is already required to conduct drive testing for other reasons. We likewise decline to adopt a limit on the number of verification inquiries that we initiate for a particular provider within a given timeframe. We also decline to limit the verification process to a smaller scale initially, or to focus verification requests in rural areas. The Broadband DATA Act envisions that the Commission will assess accuracy and reliability of broadband availability data, and we find it inappropriate to limit staff's ability to carry out its tasks to further the goals of both the Act and this proceeding. Although we decline to set a maximum size for the target area, we consider any target area with a size less than 50 resolution 8 hexagons to be de minimis and more appropriate for the mobile challenge process than the mobile verification process.

88. However, we are mindful of the burden that a large area subject to verification can pose for providers. For this reason, we will rely on a sampling method for verification inquiries. The sampling method we adopt, described more fully in the Technical Appendix, is a somewhat modified version of the proposed approach. It relaxes the burden on providers in nearly all cases and is generally more streamlined, but still falls well within the bounds of accepted statistical methodologies.

89. In its comments, Verizon requests that the Bureau and Offices allow providers at least 15 days to review and respond to a verification request before a request is officially made and starts the 60-day clock. We decline to adopt Verizon's request. We view this request as tantamount to requesting an amendment of the 60-day term stipulated in the *Third Order,* and such an amendment would be beyond the Bureau and Offices' delegated authority. Further, we find that allowing a pre-review period could cause delays in the verification process that would adversely affect the provision of accurate broadband coverage information to the public. Additionally, as verification requests are triggered when there is a credible basis, there is already reason to view the relevant area with concern, and we do not believe that this delay would outweigh the need to verify the data.

2. Sampling Methodology

90. *Gathering Statistically Valid Samples of Verification Data.* As proposed in the *BDC Mobile Technical Requirements Proposed Rules,* we require a mobile service provider subject to a verification inquiry to provide data for a statistically valid sample of areas within the targeted area. We will determine the statistically valid sample size by dividing the targeted area into hexagonal units based on the H3 indexing system at resolution 8; the aggregation of these hexagonal units comprises ''the frame.'' We will then categorize the hexagonal units that comprise the frame into non-overlapping, mutually exclusive groups (one ''stratum'' or multiple ''strata''). Each stratum will be based upon one or more variables that are correlated with a particular mobile broadband availability characteristic. These variables could include core/non-core coverage area (if available, and as explained further below), signal strength (from a provider's reported ''heat map'' or staff-performed propagation modeling), population, urban/rural status, road miles, clutter, and/or variation in terrain. For example, terrain variation is correlated with broadband availability due to the characteristics of radiofrequency propagation. Hexagons that are not accessible by roads will be excluded from all strata. We will then select a random sample of hexagons within each stratum for which service providers must conduct on-the-ground testing. As an alternative to on-the-ground testing, a provider can respond with infrastructure information covering the targeted area. To the extent mobile service providers receive personally identifiable information through the verification process by way of receiving crowdsource data, providers may only

use such information for the purpose of responding to a verification inquiry, and must protect and keep private all such personally identifiable information.

91. We find this sampling approach minimizes the cost and burden placed on service providers while ensuring that staff have sufficient data to verify coverage in a reliable way. Without such sampling, providers would need to submit substantially more data to verify their broadband availability, whereas requiring providers to submit speed test results for only a stratified random sample of units within a targeted area will minimize the time and resources associated with responding to the verification requests. This approach is also a more efficient and less burdensome approach than having providers perform annual drive tests, regularly submit infrastructure information, or submit data for their entire network coverage area. The stratification methodology will also ensure that variation in broadband availability will be as small as possible within hexagons in the same stratum. We anticipate this methodology will reduce the sample size and the cost of data collection.

92. *Failing to Verify Coverage in a Targeted Area.* If the provider fails to verify its coverage data, the provider will be required to submit revised coverage maps that reflect the lack of coverage in the targeted areas failing the verification within 30 days. When a provider submits such revised coverage data, we will re-evaluate the data submitted by the provider during the verification process by comparing it with the revised coverage data for the targeted area using the same methodology. If the targeted area still cannot be successfully verified, we will require that the provider submit additional verification data, such as additional on-the-ground tests, or that it further revise its coverage maps until the targeted area is successfully verified. We note, however, that at any point after the initial 30-day deadline has elapsed, we may treat any targeted areas that still fail verification as a failure to file required data in a timely manner and that the Commission may make modifications to the data presented on the broadband map (*i.e.,* by removing some or all of the targeted area from the provider's coverage maps). Cases where a provider fails to respond in a timely manner may also lead to enforcement action.

3. On-the-Ground Test Data

93. The approach we adopt for providers to respond to verification requests using on-the-ground test data is a modified version of what was proposed in the *BDC Mobile Technical Requirements Proposed Rules.* As requested by providers in the record, our modified approach is intended to lessen the burden on providers. These modified thresholds will still provide the Commission with sufficient data to evaluate a provider's coverage but aim to reduce the testing burden on the providers. First, rather than requiring tests to meet a geographic threshold, we adopt a revised requirement wherein staff will randomly select a single point-hex (*i.e.,* a child resolution 9 hexagon) within the resolution 8 hexagon selected for the sample where the provider must conduct its tests. Unlike in the challenge process, geographic variation in the on-the-ground test data submitted for the verification process is guaranteed by spatial random sampling approach; thus, the geographic threshold used in the challenge process is unnecessary here. Second, the specific testing threshold requirements that apply to challenges are not as relevant to verifications. Accordingly, the temporal threshold is the only relevant threshold from the challenge process necessary to ensure statistically valid results when submitting on-the-ground test data for the verification process. Third, we adopt a slight modification to the temporal threshold for verification responses. The temporal threshold proposed in the *BDC Mobile Technical Requirements Proposed Rules* requires the provider to record at least two tests within each of the randomly selected hexagons where the time of the tests are at least four hours apart, irrespective of date. We adopt the proposed temporal threshold for the verification process with a slight modification in certain circumstances. Specifically, we relax this threshold from what was proposed by requiring only a single test in a sampled hexagon if the provider establishes that any significant variance in performance was unlikely due to cell loading. The provider can establish this by submitting with its speed test data actual cell loading data for the cell(s) covering the hexagon sufficient to establish that median loading, measured in 15-minute intervals, did not exceed the modeled loading factor (*e.g.,* 50%) for the one-week period prior to the verification inquiry. We find that this modification will reduce the burden on providers without sacrificing statistical robustness because the temporal threshold exists to mitigate the likelihood that the speed measured in test data is unrepresentative of the speed when measured at different times of day, with different cell loading utilization that may exceed the provider's modeled loading assumptions.

94. We will evaluate the entire set of speed test results to determine the probability that the targeted area has been successfully verified. The upload and download components of a test will be evaluated jointly in the verification process (rather than separately, as in the challenge process). We will treat any resolution 8 hexagons in the sample where the provider fails to submit the required speed tests in the randomly selected point-hex as containing negative tests in place of the missing tests when performing this calculation. Providers must verify coverage of a sampled area using the H3 geospatial indexing system at resolution 8. The tests will be evaluated to confirm, using a one-sided 95% statistical confidence interval, that the cell coverage is 90% or higher. If the provider can show sufficient coverage in the selected resolution 8 hexagons, the provider will have successfully demonstrated coverage to satisfy the verification request in the targeted area. Sampling allows us to identify where to test and to draw statistically meaningful results about the performance in areas that are not sampled. We believe the specific thresholds and confidence interval that we adopt balance the costs to providers of verifying maps with the Commission's need to acquire a sample sufficient to accurately verify mobile broadband availability.

95. As proposed in the *BDC Mobile Technical Requirements Proposed Rules,* we require that mobile providers conduct on-the-ground tests consistent with the testing parameters and test metrics that we require for provider-submitted test data in the challenge process. As required in the challenge process for in-vehicle mobile tests, providers must conduct in-vehicle mobile tests in the verification process with the antenna located inside the vehicle. As noted above, because most consumers will take in-vehicle tests using an antenna inside the vehicle, adopting that requirement for providers will help minimize discrepancies and ensure more equivalent comparisons between on-the-ground test data supplied by consumers and data supplied by providers.

96. We decline to ask for on-the-ground test data from mobile providers on a continuous or quarterly basis as part of the verification process as proposed by Enablers. As noted above, we are mindful of the burden placed on provider resources and find a continuous or quarterly rolling

submission requirement unnecessarily burdensome.

97. Commission staff may also leverage spatial interpolation techniques, such as Kriging, to evaluate and verify the accuracy of coverage maps based on on-the-ground data. Spatial interpolation techniques can be an alternative or complementary approach to specifying an exact testing threshold, since spatial interpolation techniques require fewer data to compare with predictions using propagation models.

4. Infrastructure Information

98. In the *BDC Mobile Technical Requirements Proposed Rules,* we noted the Commission found that infrastructure information can provide an important means to fulfill its obligation to independently verify the accuracy of provider coverage maps. We also reiterated the Commission's conclusion that collecting infrastructure data from mobile service providers will enable the Commission to verify the accuracy and reliability of submitted coverage data as required under the Broadband DATA Act.

99. In determining how best to utilize infrastructure data to verify a provider's coverage, the Bureau and Offices proposed that Commission staff evaluate whether a provider has demonstrated sufficient coverage for each selected hexagon using standardized propagation modeling. Under that proposed approach, staff engineers would generate their own predicted coverage maps using the infrastructure data submitted by the provider (including link budget parameters, cell-site infrastructure data, and the information provided by service providers about the details of the propagation models they used). Using those staff-generated maps, the proposed approach anticipated that Commission staff would evaluate whether each selected hexagon has predicted coverage with speeds at or above the minimum values reported in the provider's submitted coverage data. The Bureau and Offices sought comment on this proposed approach to verifying coverage using standardized propagation modeling, as well as on other ways more generally that infrastructure data could be used to evaluate the sufficiency of coverage in the proposed verification process. In the *BDC Mobile Technical Requirements Proposed Rules,* we noted staff may also consider other relevant data submitted by providers during the verification process, may request additional information from the provider (including on-the-ground speed test data, if necessary), and may take steps to ensure the accuracy of the verification process. Alternatively, we sought comment on other ways to use the submitted infrastructure and link budget data to perform initial verification of the claimed coverage within the selected hexagons using standard propagation models as well as appropriate terrain and clutter data. We stated we could evaluate the provider's link budgets and infrastructure data for accuracy against other available data, such as Antenna Structure Registration and spectrum licensing data. This alternative approach would include using a staff projection of speeds, available crowdsourced data at the challenged locations, and any other information submitted by or requested from a provider in order to verify coverage. The Bureau and Offices further discussed leveraging spatial interpolation techniques to evaluate and verify the accuracy of coverage maps based on available crowdsourcing and on-the-ground data. We sought comment on both the original and alternative approaches and invited comment on any other ways that infrastructure data and staff propagation modeling could be used to verify a provider's coverage in a targeted area.

100. We adopt the *BDC Mobile Technical Requirements Proposed Rules'* proposal that, if a provider chooses to submit infrastructure information in response to a verification request, it must provide such data for all cell sites and antennas that serve or affect coverage in the targeted area. As set forth in that notice, staff may use these infrastructure data—in conjunction with link-budget data from the provider, standard sets of clutter and terrain data, other factors, and standardized propagation modeling—to inform our decision about whether the provider has verified its claimed coverage. However, we agree with several commenters that it would be difficult for staff to account for the intricacies of a provider's dynamic network configuration and replicate provider models with staff's own propagation models and that the proposed approach is not necessary to accomplish the Commission's goals with respect to the verification process. Rather than attempt to replicate the results of providers' modeling, we expect staff will rely on a more flexible approach to its analysis. For example, in appropriate cases staff may choose to estimate a ''core coverage area,'' in which coverage at the modeled throughput is highly likely to exist, and would focus its verification efforts instead on areas outside of that ''core coverage area''—but within the service provider's claimed coverage area (*i.e.,* close to the cell edge)—and may consider other data that could be relevant (*e.g.,* cell loading or signal strength measurements) to determine whether to seek additional information in furtherance of a verification inquiry for areas within the core coverage area.

101. While each analysis will turn on the relevant facts and circumstances, we offer one possible example of the approach in an effort to provide guidance about how the staff's analysis might work. In this scenario, Commission engineers would first confirm that the backhaul, technology, and other network resources reported for the base station(s) that serve(s) the targeted area are sufficient to meet or exceed the required speed thresholds. Second, staff could use propagation modeling to estimate the provider's core coverage area within the targeted area using more conservative parameters (including a higher cell edge probability) than required of the propagation modeling the provider used to generate its coverage data. Third, staff could analyze downlink and uplink cell loading data submitted by the provider as part of its infrastructure data to confirm that the median cell loading values are less than or equal to the cell loading factor modeled by the provider (*e.g.,* 50%). Fourth, staff could then evaluate the signal strength information from all available speed test measurements—including those submitted as challenges, crowdsourced data, or on-the-ground data in response to a verification inquiry. For a verification inquiry, the system would evaluate whether the portion of the target area falls outside of the staff-determined core coverage area. If the targeted area falls within the core coverage area, then we would consider other relevant evidence (if any) to determine whether further inquiry is necessary or appropriate.

102. In cases where staff's analysis indicates that infrastructure data alone would be insufficient to resolve the verification inquiry, staff may determine to sample a new set of areas and in appropriate cases may also take into account additional infrastructure data and information on the core coverage areas, where staff expect adequate coverage is highly likely. Staff could then request additional information, such as on-the-ground data, to complete the verification process. Staff may also consider infrastructure data independently and review for anomalies.

103. Several commenters argue that Commission staff should not generate

propagation models with the submitted infrastructure information or do so only in limited cases. For example, Verizon urges Commission staff to limit predictive studies to localized examinations of the reasonableness of a service provider's map and clarify that successful speed test data would preclude staff propagation modeling or outweigh countervailing staff propagation modeling results. We clarify that where a provider submits valid speed test data in sample-selected areas, staff propagation studies based on infrastructure data should not be necessary. We also clarify that while staff has the option to create predictive maps based on providers' infrastructure data, we are not required to do so. However, the option to create staff propagation studies is a tool necessary to retain in the analyzation of collected infrastructure data and fulfillment of our obligations under the Broadband DATA Act.

104. *Initial Verification of Claimed Coverage.* We adopt our proposal to perform initial verification of claimed coverage as an alternative way to use infrastructure data to assess providers' coverage data. We will compare the provider's link budget and infrastructure data with other available data for accuracy, such as Antenna Structure Registration and spectrum licensing data. If staff believe, after making these comparisons, that there is a technical flaw in a provider's maps (*e.g.,* a model was run with the wrong parameters), we will then determine if this flaw would result in a significant difference in coverage. If staff estimation of speed (*e.g.,* resulting from staff-performed propagation modeling or other related calculations), along with the available crowdsourced data at the challenged locations, does not predict speeds at or above the minimum values reported in the provider's submitted coverage data, Commission staff will consider any additional information submitted by the provider or request other data from the provider; other data may include on-the-ground data. No commenters addressed this alternative to perform initial verification of claimed coverage.

105. *Additional required infrastructure information.* We adopt the proposal to expand the categories of infrastructure information that providers must submit. As anticipated, we find that such information is necessary to analyze verification inquiries adequately. In addition to the types of infrastructure information listed as examples in the *Third Order,* providers must submit the following parameters: (1) Geographic coordinates of each transmitter measured with typical GPS Standard Positioning Service accuracy or better; (2) per site classification (*e.g.,* urban, suburban, or rural); (3) elevation above ground level for each base station antenna and other transmit antenna specifications (*i.e.,* the make and model, beamwidth (in degrees), radiation pattern, and orientation (azimuth and any electrical and/or mechanical down-tilt in degrees) at each cell site); (4) operate transmit power of the radio equipment at each cell site; (5) throughput and associated required signal strength and signal-to-noise ratio; (6) cell loading distribution (we will require providers to submit information on the actual loading for each cell site that serves the targeted area, including, for example, the average number of active radio resource control channel users and average bandwidth carrying user traffic for both the downlink and uplink carriers measured in 15-minute intervals for the one-week period before the provider received the verification inquiry); (7) areas enabled with carrier aggregation and a list of band combinations; and (8) any additional parameters and fields that are listed in the most-recent specifications for wireless infrastructure data adopted by OEA and WTB in accordance with 5 U.S.C. 553.

106. Some commenters argue that the Commission should not require infrastructure data fields beyond what was required in the *Third Order.* Verizon advocates for deleting proposed fields it called unnecessary, unclear, or unable to be readily provided. CTIA says the ''Bureaus should not second-guess a provider's cell-loading factor if the data indicates higher than average cell loading in a given area at a given time.'' CTIA also urges the Commission not to collect additional infrastructure information due to its sensitive and confidential nature and the burdens this collection would impose; CTIA contends this collection would be inconsistent with the Broadband DATA Act, and staff should rather tailor its requests to specific issues after discussion with the provider.

107. The data fields we adopt here are necessary to help predict more precisely the users' speeds, and the potential burdens of providing these data are outweighed by the necessity of the information. To elaborate, required signal strengths and signal-to-noise (SNR) ratio data are critical factors that enable or impede the speed at which users may connect and are thus required to estimate the users' speeds. Cell loading distribution is the measured cell loadings observed for each cell over time (*e.g.,* every 15 minutes or less for each cell on the day of interest). Cell loading distribution is also necessary to calculate the final users' speeds and analyze challenges, as evidenced by the inclusion of a minimum 50% cell loading specification in the Broadband DATA Act. A provider's measured cell loading factor is the best way to verify actual cell loading; the cell loading factor is not being second-guessed. In areas with carrier aggregation, a list of spectrum band combinations used for carrier aggregation is necessary to analyze the capacity of the cell, and will be used in conjunction with cell loading data to evaluate more precisely the disputed areas of the coverage map. More detailed infrastructure data specifications are listed in § 1.7006(c)(2) of the final rules.

108. While we do not prioritize one information source over another, we noted above that where providers' responses to verification inquiries include valid speed test data for each sampled area, staff propagation studies based on infrastructure data should not be necessary. As previously noted, we are sensitive to confidentiality and security concerns in the collection of mobile infrastructure information, and infrastructure information submitted by providers at the request of staff will be treated as presumptively confidential. We are also sensitive to not imposing undue burden on providers and have therefore not mandated the submission of infrastructure data in response to every verification inquiry. We may engage in discussions with a provider when necessary, after which we can request specific areas in which to collect the data. When staff find that infrastructure data are necessary to verify coverage consistent with the Broadband DATA Act, the infrastructure data fields enumerated herein are necessary for staff to carry out that obligation.

5. Transmitter Monitoring Information

109. The Commission directed OEA and WTB to review transmitter monitoring information submitted voluntarily by providers in addition to on-the-ground and infrastructure information. T-Mobile asserts that providers should be allowed to submit data from alternative sources, including transmitter monitoring information, to satisfy verification requests. Verizon states that transmitter monitoring information ''provides a comprehensive picture of network performance.'' We agree that these data could be helpful, to the extent that they support potential reasons for service disruptions during the time interval in which measurements were performed.

Therefore, we will consider transmitter monitoring information voluntarily submitted by a provider in addition to on-the-ground testing or infrastructure data in response to a verification inquiry. We do not believe, however, that the record supports a finding that such data constitute a sufficient substitute for the on-the-ground testing or infrastructure data required by the *Third Order* to respond to a verification inquiry.

C. Collecting Verified Broadband Data From Government Entities and Third Parties

110. We adopt our proposal for governmental entities and third parties to submit verified on-the-ground test data using the same metrics and testing parameters that mobile providers must use when submitting on-the-ground test data in response to a verification request. We also note, as set forth in the *Third Order,* government and other third-party entities that submit verified broadband availability data must file their broadband availability data in the same portal and under the same parameters as providers. This includes a certification by a certified professional engineer that he or she is employed by the government or other third-party entity submitting verified broadband availability data and has direct knowledge of, or responsibility for, the generation of the government or other entity's Broadband Data Collection coverage maps. We find that assigning consistent, standardized procedures for governmental entities and third parties to submit on-the-ground data is necessary to ensure that the Commission receives consistent, reliable data and that the broadband availability maps are as accurate and precise as possible. The record exhibits support for this approach. Next Century Cities advocates the Commission develop outreach and explanatory materials to encourage participation from state and local leaders, and we will be making such materials available to state, local, and Tribal government entities to file verified data. We are mindful of PAgCASA's concerns that imposing these standards will not result in the submission of verified data from governmental entities and third parties. We believe, however, that this approach is the most efficient and effective way for providers and staff to review verified data from governmental entities and third parties. This approach minimizes variables between different datasets and thus helps ensure that staff and other parties may more efficiently and effectively evaluate competing data (*e.g.,* verified on-the-ground tests submitted by a governmental entity versus on-the-ground tests conducted by the provider) with an apples-to-apples comparison to determine the source of any data discrepancies. Assigning consistent, standardized procedures for governmental entities and third parties to submit verified on-the-ground data is appropriate and necessary to ensure the broadband availability maps are as accurate and precise as possible.

111. We also adopt our proposal that, to the extent the Commission is in receipt of verified on-the-ground data submitted by governmental entities and third parties, such data may be used when the Commission conducts analyses as part of the verification processes and will be treated as crowdsourced data. Governmental entities and third parties may also choose to use these data to submit a challenge, provided they meet the requirements for submission of a challenge under the Commission's rules.

112. Enablers advocates that the Commission create a ''strong active testing-based verification layer with sampling of nationwide coverage'' and revisit the decision to require propagation maps instead of continuous drive testing. To that end, Enablers notes that its solution allows for cost-effective, continuous active testing by third parties to better produce statistically valid samples and advocates that its approach be adopted. To the extent that government entities and third parties choose to submit verified data, we note that the Commission requires them to submit their data under the same parameters as providers. The Bureau and Offices lack the authority to override decisions by the full Commission. We note, however, that if Enablers or other parties submit crowdsourced data consistent with the specifications outlined below, we will treat those data as such.

D. Crowdsourced Data

113. The Broadband DATA Act requires the Commission to ''develop a process through which entities or individuals . . . may submit specific information about the deployment and availability of broadband internet access service . . . on an ongoing basis . . . to verify and supplement information provided by providers.'' In the *Second Order,* the Commission adopted a crowdsourcing process to allow individuals and entities to submit such information. The Commission required that crowdsourced data filings contain: The contact information of the filer, the location that is the subject of the filing (including the street address and/or GPS coordinates of the location), the name of the provider, and any relevant details about the deployment and availability of broadband internet access service at the location. The Commission also required that crowdsourced data filers certify that, ''to the best of the filer's actual knowledge, information, and belief, all statements in the filing are true and correct.'' As the Commission has clarified, the Bureau and Offices, together with the Wireline Competition Bureau (WCB), will use crowdsourced data to ''identify[ ] trends,'' and ''individual instances or patterns of potentially inaccurate or incomplete deployment or availability data that warrant further investigation or review.'' Crowdsourced information is intended to ''verify and supplement information submitted by providers for potential inclusion in the coverage maps.'' Notably, the Commission also expressly reserved the right to investigate provider filings in instances that warrant further investigation based on the specific circumstances presented by crowdsourced data.

114. We provide further guidance and adopt rules regarding the crowdsourced data process as described below. We provide additional information about updates we are making to the FCC Speed Test app's technical standards and requirements to configure the app for submission of mobile challenge and crowdsourced data. We also outline the procedures OET will follow for approving third-party speed test apps for these purposes. We establish requirements for consumers and other entities to submit any crowdsourced data to the online portal using the same parameters and metrics providers would use when submitting on-the-ground data in response to a Commission verification request, with some simplifications, as described above. Finally, we provide guidance on our methodology for evaluating mobile crowdsourced data through an automated process—a process that will assist us in establishing when crowdsourced data filings reach a ''critical mass'' sufficient to merit further inquiry. Once the automated process identifies areas where verification may be warranted, Commission staff will conduct an evaluation based upon available evidence such as speed test data, infrastructure data, crowdsourced and other third-party data, as well as staff's review of submitted coverage data (including maps, link budget parameters, and other credible information) to determine whether a credible basis for conducting a verification inquiry has been established

using the standards outlined in greater detail below.

1. Tools To Submit Crowdsourced Data

115. In the *BDC Mobile Technical Requirements Proposed Rules,* the Bureau and Offices proposed a process for consideration of crowdsourced data submitted through data collection apps used by consumers and other entities, including methods to prioritize the consideration of crowdsourced data submitted through apps that are determined to be ''highly reliable'' and that ''have proven methodologies for determining network coverage and network performance.'' We noted that the Commission directed the Bureau and Offices (along with WCB) to consider ''(1) whether the application uses metrics and methods that comply with current Bureau and Office requirements for submitting network coverage and speed test data in the ordinary course; (2) whether the speed test app used has enough users that it produces a dataset to provide statistically significant results for a particular provider in a given area; and (3) whether the application is designed so as not to introduce bias into test results.'' The Bureau and Offices noted that ''data submitted by consumers and other entities that do not follow any specific metrics and methodologies may be less likely to yield effective analysis and review . . . of providers' mobile broadband availability.'' Commenters did not provide any suggestions or recommendations on how to prioritize consideration of crowdsourced data.

116. We find that the FCC Speed Test app is a reliable and efficient tool for users to submit crowdsourced mobile coverage data to the Commission. The FCC Speed Test app allows users to submit specific information about the availability of mobile broadband service and its performance and meets the requirements outlined in the Commission's *Second Order.* We also make clear that we will include both stationary and mobile in-vehicle speed test results in crowdsourced data. Specifically, we find the FCC Speed Test app sufficiently meets the considerations that the Commission set forth. First, we find the FCC Speed Test app uses metrics and methods that comply with current requirements for submitting network coverage and speed test data in the ordinary course. These include upload speed, download speed, latency and other network performance metrics. These metrics are consistent with the network performance metrics required to be collected by the Commission under the 2020 Broadband DATA Act and the 2008 Broadband Data Improvement Act. Next, we find that the FCC Speed Test app is designed to minimize bias in test results. The FCC Speed Test app's test system architecture implements dedicated off-net servers hosted by a Content Delivery Network (CDN) to provide robust and reproducible test results for effective representation of network performance. The test servers are deployed at Tier 1 major peering/transit locations to minimize bias which is a practical approach to measure network performance. With regard to whether the FCC Speed Test app produces a dataset sufficient to provide statistically significant results for a particular provider in a given area as it pertains to crowdsourced data, we note that we will not be analyzing speed test results from the FCC Speed Test app in isolation. Rather, we will aggregate and/or cluster all speed tests conducted with the FCC Speed Test app—along with those conducted with an authorized third-party speed test app and those conducted by government or other entities using their own hardware or software—for a particular provider in a particular area during our analysis, as described further below. We anticipate that this aggregation and/or clustering process will lead to statistically valid results by provider and geographic area. We therefore find that the FCC Speed Test app meets the required criteria and is a reliable, efficient method for those interested to use when submitting crowdsourced mobile coverage data to the Commission.

117. As discussed, OET maintains a technical description that describes the metrics and methodologies used in the existing FCC Speed Test app. We note that RWA requests that the FCC Speed Test app display whether users are roaming and, if so, identify the roaming network. The FCC Speed Test app currently has the ability to provide network roaming information via the app's local data export feature for download and upload speed tests and latency tests; however, this capability is not available for Apple iOS devices as certain technical network information and RF metrics are currently not available on those devices. In order to ensure ample public participation in the crowdsourcing process, we clarify that consumers wishing to submit crowdsourced data may use a device running either the iOS or Android operating system to collect speed test data and submit it as crowdsourced information; for the same reasons discussed above, however, we require government, other third-party, and provider entities to collect all of the required technical network information and RF metrics using a device that can interface with drive test software and/or runs the Android operating system. We also clarify, as discussed earlier, that speed tests conducted by a customer of an MVNO will be considered and evaluated as crowdsourced data.

118. Regarding third-party speed test apps used to collect challenge and crowdsourced data on mobile wireless broadband availability, the BDC system will accept challenge and crowdsourced data from third-party applications approved by OET that collect the required data set forth in the relevant data specification for mobile challenge and crowdsourced data (*e.g.,* contact information, geographic coordinates, and required certifications) and in a format that comports with the application programming interface (API) for the backend of the BDC system. To the extent that consumers and other entities choose to submit on-the-ground crowdsourced mobile speed test data, such data will be collected using a similar measurement methodology as the FCC Speed Test app and submitted in a similar format to that which challengers and providers will use when submitting speed tests. We will thus only find third-party apps to be ''highly reliable'' and to ''have proven methodologies for determining network coverage and network performance'' if OET has approved them based upon the processes and procedures we will adopt for review of third-party apps for use in the mobile challenge process, and we will only allow for submission of crowdsourced data from such approved apps. As noted above, OET will release a public notice announcing the process for approving third-party apps for use in the mobile challenge process, inviting third-party app proposals, and seeking comment on third-party apps being evaluated. As previously mentioned, OET will announce and publish a web page to maintain a list of approved third-party apps and any available data specifications for third-party apps. We also will consider as crowdsourced data speed tests taken with an authorized app that do not meet the criteria needed to create a cognizable challenge or are otherwise not intended to be used to challenge the accuracy of a mobile service provider's map.

119. Finally, we recognize that changes in technology and other considerations may require us to periodically revaluate these initial determinations in order to satisfy the Act's provisions for submitting crowdsourced data. The Bureau and Offices will modify the process for collecting mobile crowdsourced data

over time, as experience dictates may be necessary and appropriate to improve our procedures and assure that the maps we make are as reliable and accurate as possible.

2. Crowdsourced Data Submitted in the Online Portal

120. We will use crowdsourced data to ''identify individual instances, or patterns of potentially inaccurate or incomplete deployment or availability data that warrant further investigation or review.'' In light of this given purpose, we believe it is reasonable to provide those collecting crowdsourced data with increased flexibility to facilitate making the process more user-friendly. Specifically, on-the-ground crowdsourced data must include the same parameters and metrics as required for on-the-ground speed test data submitted through the mobile service challenge process, except that we will allow on-the-ground crowdsourced data to include any combination of download speed and upload speed (rather than both). Crowdsourced data should include valid on-the-ground speed tests and will be categorized and evaluated based on the upload and download speed tests as ''positive'' or ''negative'' tests, similar to speed tests in the challenge process. In the *BDC Mobile Technical Requirements Proposed Rules,* the Bureau and Offices noted that the Commission directed them, together with WCB, to establish and use an online portal for crowdsourced data filings and to use the same portal for challenge filings. The Bureau and Offices will release additional guidance on how consumers and other entities can use the online portal to submit crowdsourced data once the portal is available.

121. Staff will validate submitted crowdsourced speed test data and exclude those that are, for example, anomalous, do not conform to the data specifications, or do not otherwise present reliable evidence and then evaluate the crowdsourced data as described further below to determine whether a critical mass of crowdsourced filings suggest that a provider has submitted inaccurate or incomplete information. This approach helps ensure that the crowdsourced data staff analyzes are valid and reliable while also affording consumers some added flexibility by allowing on-the-ground crowdsourced data to include any combination of download speed and/or upload speed rather than both. Similarly, mobile providers will be notified of a crowdsource filing but will not be required to respond to crowdsource filings unless and until Commission staff request that they do so, based on the procedures outlined below. We believe this process is an efficient and effective way for staff to analyze and review a provider's mobile broadband availability using crowdsourced data.

122. T-Mobile supports making certain speed test metrics optional for crowdsourced data and not to require providers to automatically respond to crowdsourced data filings, stating they are appropriately tailored and will serve to limit burdens on providers without compromising the need for the Commission to ensure that it receives verified and reliable data. We agree that making certain test metrics optional for the crowdsourced data filings and also not requiring providers to respond to crowdsourced data filings (absent a Commission inquiry) serves to limit the burdens on filers and providers without compromising the reliability of the crowdsourced data, with the goal of providing as broad and robust crowdsourced data as possible.

3. When Crowdsourced Filings Reach a ''Critical Mass''

123. In the *Second Order,* the Commission directed staff to initiate inquiries when a ''critical mass'' of crowdsourced filings suggest that a provider has submitted inaccurate or incomplete information and directed us to provide guidance on when crowdsourced filings reach such a critical mass. We sought comment in the *BDC Mobile Technical Requirements Proposed Rules* on when inquiries based on a critical mass of crowdsourced filings could be initiated. Specifically, we proposed to evaluate crowdsourced data in the first instance with an automated process to identify areas that would trigger further review.

124. *Establishing Critical Mass.* We adopt our proposal and will evaluate mobile crowdsourced data through a combination of automated processing and further review by Commission staff. As described in more detail below, the automated process will identify areas for further review by first excluding or ''culling'' any anomalous or otherwise unusable speed test information and then using data clustering to identify groupings of potential targeted areas where a provider's coverage map is inaccurate that would trigger further review. Staff will then review the identified potential targeted areas and any other relevant data to confirm whether this cluster presents a credible basis to warrant verification. Under this approach, areas identified from crowdsourced data using this methodology would be subject to a verification inquiry consistent with the mobile verification process adopted herein.

125. We note that commenters generally support our proposals regarding when crowdsourced data should trigger an inquiry about the accuracy of a provider's broadband mapping information. Verizon, for example, finds reasonable our proposals regarding which crowdsourced information to consider. Specifically, Verizon states that the Commission's proposal is reasonable to accept as crowdsourced information speed tests taken with an authorized app that do not meet the criteria needed to create a cognizable challenge or are otherwise not intended to be used to challenge the accuracy of a mobile service provider's map. Additionally, Verizon states the Commission should adopt the proposal to permit consumers and other entities to submit crowdsourced data collected using either the FCC Speed Test app or other speed test apps approved by OET. Furthermore, T-Mobile supports our proposal to initiate an inquiry when crowdsourced data suggest that a provider has submitted inaccurate or incomplete coverage data. Ookla agrees, pointing out that ''crowdsourcing allows for the rapid, cost-effective collection of actionable, accurate broadband data.''

126. We expect that the minimum data standards and structured vetting process we adopt for evaluating crowdsourced data described below address concerns about any bias in, and the reliability of, the crowdsourced data collected. For example, because the automated process we describe below will filter out anomalies or other unusable speed test information, we believe this filtering process sufficiently addresses Verizon's concerns about including inaccurate speed test information in any crowdsourced dataset due to possible varying test conditions. Further, because the process will also employ a clustering methodology to identify trends or patterns suggesting persistent coverage issues over time, we believe the crowdsourced data will be an efficient and effective means with which to inform, but not decide, a provider's claimed deployment and availability of broadband internet access service and thereby be an important part of the Commission's available data verification options.

127. Other commenters offer different views regarding our proposal to evaluate crowdsourced data. RWA requests more clarity, suggesting that we define what the ''critical mass'' is to trigger an inquiry in rural and urban areas. Public Knowledge/New America, seeking to

bolster the usefulness and value of crowdsourced information, opposes our proposal to initiate a verification inquiry only when there is a ''critical mass of'' crowdsourced data. Instead, they argue that staff should make it easier for crowdsourced data to inform our verification inquiries. We find that the requirement we adopt to initiate an inquiry in response to crowdsourced data when a critical mass of these data suggest that a provider has submitted incomplete or inaccurate information strikes the best balance. This approach allows for the crowdsourcing process to highlight problems with the accuracy of a provider's mobile broadband coverage maps and is an important tool in the Commission's verification process. As Ookla observes ''crowdsourcing uses large numbers of samples to identify useful conclusions.'' The crowdsourcing process we adopt provides a user-friendly way for interested filers to provide crowdsourced data to the Commission in a cost-effective way without requiring providers to respond automatically to such filings. Because the process is user-friendly, we also believe it will incentivize greater participation in the crowdsourced data gathering process. We believe this strikes the right balance and helps us ensure more reliable mobile broadband coverage data.

128. *Automated Process.* We will evaluate mobile crowdsourced data first through an automated process to identify potential areas that warrant further review and evaluation by Commission staff. Specifically, we adopt a modified version of our proposal in the *BDC Mobile Technical Requirements Proposed Rules* regarding the automated process and will evaluate crowdsourced filings using a two-step process by first excluding any anomalous or otherwise unusable tests submitted as crowdsourced data and then by using data clustering (an industry standard tool for clustering GIS data) to identify potential targeted areas where crowdsourced tests indicate a provider's coverage map is inaccurate. Areas identified by the automated process then would be subject to further review and evaluation by Commission staff of available evidence, such as speed test data, infrastructure data, crowdsourced and other third-party data, and the staff's review of submitted coverage data, including maps, link budget parameters, and other credible information to make a determination as to whether a credible basis for conducting a verification inquiry has been established and whether a verification request is appropriate.

129. More particularly, the automated process will involve an analysis at the end of each month that will include aggregating the crowdsourced data into H3 hexagons at resolution 8, and categorizing each hexagon for purposes of further analysis. Next, we will apply a clustering algorithm to spatially cluster these hexagons. We will track the growth of the clusters of hexagons over time and if the level of negative speed tests is observed for three consecutive months, will make a determination of whether crowdsourced data have reached a ''critical mass'' warranting verification. The details of this process are described in more detail in the Technical Appendix. We note that the Density Based Spatial Clustering of Applications with Noise (DBSCAN) algorithm we will employ is one of the 10 default tools for clustering GIS data in the industry standard Esri ArcGIS software and is commonly used to perform this type of data clustering analysis. In fact, the DBSCAN algorithm we will employ is one of the most commonly used methods for data clustering analysis.

130. Verizon opposes the use of an automated process to analyze crowdsourced data as well as the use of data clustering to identify potential targeted areas where crowdsourced tests indicate that a provider's coverage map is inaccurate, and asks that, should we adopt these proposals, we provide more detail about their mechanics and seek further comment on the proposed algorithm, data sources, and criteria the processes will use for identifying potential targeted areas for further review and evaluation. We proposed to use an automated process to identify potential areas that would trigger further review using a methodology similar to the mobile verification process, with certain simplifications. More specifically, we proposed to use data clustering to identify potential targeted areas where crowdsourced tests suggest that a provider's coverage map is inaccurate and also sought comment on any alternative methods for determining when a critical mass of crowdsourced filings suggest a provider may have submitted inaccurate or incomplete information. We did not receive any comments suggesting any alternative methods for the critical mass determination. We adopt a modified version of our proposal as described above. Employing the modified automated process we adopt is a reasonable approach to analyze crowdsourced data because of the anticipated volumes of data. Using data clustering to identify potential targeted areas for further Commission staff review and evaluation is also a reasonable way to group crowdsourced data together for a particular area within a coverage map. In this regard, we note that a data clustering approach for the identification of clusters of concern will reduce the amount of staff work and assure that an unbiased analysis has provided evidence that specific areas warrant further review by Commission staff. We believe the modified version of the automated process we adopt, including the use of data clustering, is sufficiently detailed and, taken together with the added safeguard of subsequent staff evaluation, addresses Verizon's request for more information about the automated process itself and the data clustering and other criteria the process will use as described below to identify potential areas for further review and evaluation.

131. *Staff Evaluation.* As noted above, the data identified in this process will inform, but not decide, a provider's claimed deployment and availability of broadband internet access service and thereby be an important part of the Commission's available verification options. If the automated process suggests that an area has persistent coverage issues, Commission staff will evaluate the data and make a final determination as to whether clusters of hexagons identified in this manner for three consecutive months have, indeed, reached ''critical mass.'' Staff may consider other relevant data submitted by providers, consumers and/or third parties; may request additional information; and may take other actions as may be necessary to ensure the reliability and accuracy of the provider's coverage data and any applicable crowdsourced data. Should automated processing establishing a ''critical mass'' of crowdsourced filings combined with staff evaluation suggest a provider's coverage map is inaccurate, Commission staff will have a ''credible basis'' for verifying a provider's coverage data. Under this approach, areas identified from crowdsourced data using this methodology would be subject to a verification inquiry consistent with the mobile verification process adopted herein. Finally, we reiterate that we may initiate an inquiry, in the absence of a critical mass of crowdsourced filings, to collect and request verification data from a provider where there is a credible basis for doing so based upon a holistic review of all data available to staff (including crowdsourced data, data associated with challenges, verified data from government or third-party entities, or broadband availability data included

in the provider's initial filing). On a case-by-case basis, staff may thus have a credible basis for initiating a verification inquiry if warranted by the specific circumstances of a crowdsourced data filing in the context of all other data available to staff.

4. Public Availability of Crowdsourced Data

132. The Commission determined in the *Second Order* that all information submitted as part of the crowdsourcing process will be made public, except for personally identifiable information (PII) and data required to be confidential under § 0.457 of its rules. The Commission also directed OEA to make crowdsourced data publicly available as soon as practicable after submission and to establish an appropriate method for doing so. No commenters addressed, or provided any alternatives to, our proposal in the *BDC Mobile Technical Requirements Proposed Rules* to make crowdsourced data filings available to the public or offered any suggestions about any specific ways to protect PII or other sensitive information.

133. We therefore adopt our proposal to make crowdsourced data available via the Commission's public-facing website. This will include data collected via designated third-party apps. This publicly available information will depict coverage data and other associated information but will not include any PII or other data required to be confidential under § 0.457. Since designated third-party apps will be collecting data on behalf of the Commission, we expect similar handling of PII or other confidential information by third-party designees. We also adopt a modified version of our proposal and will update the public crowdsourced data at least biannually in order to make available the most up-to-date data. This is consistent with the Commission's requirement to update the Fabric every six months to ensure the most up-to-date information is available for all of the locations identified in the common dataset and will ensure the crowdsourced data provided is also current, reliable and robust.

E. Other Matters

134. *Additional Mapping Information.* We reject calls to require providers at this time to submit additional information with their maps. Next Century Cities and Public Knowledge/New America recommend that providers be required to include other performance and affordability information, such as the throughput speeds experienced by broadband consumers, signal strength, and pricing information. The Commission declined to adopt pricing and throughput data filing requirements for fixed services in the *Third Order,* and did not delegate authority to the Bureau and Offices to add such requirements for mobile services. The Broadband DATA Act defines standardized propagation modeling at defined throughput speeds for 4G–LTE coverage. The Commission followed Congress's approach and required mobile broadband providers to model broadband coverage, including 3G and 5G–NR services, based on standardized propagation modeling. We thus decline to require providers to model actual mobile throughput. Even if we had the delegated authority adopt a rule to require the modeling of mobile throughput, we note that doing such modeling would be a computationally difficult, if not impossible, task for mobile broadband providers. Instead, we will use on-the-ground data collected through the challenge and crowdsource processes to improve the accuracy of the coverage maps. The Commission did specifically consider whether to standardize signal strength for mobile propagation maps, and instead adopted a requirement for providers to submit ''heat maps.'' Mobile providers are therefore already required to submit maps showing Reference Signal Received Power (RSRP) or Received Signal Strength Indicator (RSSI) signal levels for each technology. Additionally, in adopting rules to implement the Broadband DATA Act, the Commission focused on ensuring that the public has access to more precise coverage maps, but did not delegate to the Bureau and Offices the authority to adopt new mapping requirements such as requiring providers to include affordability or pricing data for their broadband services. We also find it would be inconsistent with the Commission's reasoning to adopt these types of pricing requirements for mobile maps, but not fixed maps.

135. *Expanding the Types of Data That Can Be Used to Challenge Maps.* CPUC, Public Knowledge/New America, and Vermont DPS recommend allowing interpolation techniques to be used for challenging provider-submitted maps. The Commission explicitly adopted a requirement that consumers and government and other entities submit speed test data to support their mobile coverage challenges, and did not grant the Bureau and Offices authority to accept data other than on-the-ground speed tests to challenge coverage. We therefore lack delegated authority to accept interpolations or statistical sampling as challenge data in lieu of actual, valid speed tests.

136. *Expanding the Types of Data That Can Be Used for Verified Data.* CPUC and Vermont DPS likewise recommend allowing interpolations of speed test results by government entities to identify areas requiring validation. Such spatial interpolation techniques could include the Kriging technique discussed in the *BDC Mobile Technical Requirements Proposed Rules.* In contrast, T-Mobile states that the Commission must reject any proposal premised on interpolation. To the extent governments or other entities submit on-the-ground speed test data through our crowdsource process, we agree with CPUC and Vermont DPS that the results of spatial interpolation analyses would be useful additional information on which to determine if there is a credible basis for verifying a provider's coverage data. However, the Commission directed that verified mobile on-the-ground data be submitted ''through a process similar to the one established for providers making their semiannual [BDC] filings,'' and the Bureau and Offices do not have discretion to change that approach. Since interpolation is a projection, it therefore does not meet the requirements established for ''verified'' broadband availability data under the Broadband DATA Act. Therefore, while we may use interpolation in our analysis of on-the-ground data submitted either as part of the challenge process or as crowdsourced data when conducting a holistic review to ensure the accuracy of coverage data (*e.g.,* when evaluating whether there is a credible basis for conducting a verification inquiry), we are unconvinced that accepting interpolated data on their own would give us the necessary understanding of on-the-ground performance consistent with our obligations under the Broadband DATA Act and Commission Orders.

137. *Decline to Require Providers to Offer Challenge Incentives.* We will not, as urged by some commenters, require that providers offer subscribers incentives to conduct speed tests or submit voluntary challenges. Once we implement the challenge process, we believe that consumers and third parties will be motivated to provide us with data where they believe providers' coverage maps are inaccurate or incomplete. Relatedly, the Commission noted in the *Third Order* that speed test results submitted by consumer challengers that do not reach the threshold of a cognizable challenge will nevertheless be incorporated in the analysis of crowdsourced data, and similarly that on-the-ground test data

submitted by governmental and third-party entities that do not reach the threshold of a cognizable challenge also will be considered in the analysis of crowdsourced data. We believe that combining these speed test results along with other available data, including other available crowdsourced data, will provide us with a robust and accurate dataset, thereby obviating the need for provider-offered incentives to spur consumers and third parties into submitting challenges or collecting crowdsourced data to submit to us. The user-friendly challenge process we implement should facilitate consumers and other entities alike in submitting challenges and crowdsourced mobile coverage data. As one commenter observes, ''[d]ue to known shortcomings in mobile coverage maps[,] . . . the Commission needs a good challenge process'' and should ''allow the use of crowd-sourced data to challenge providers' claims.'' We agree, and believe that we have put efficient and effective challenge and crowdsource processes and procedures in place.

138. *Pre-Publication Commission Review of Maps.* We decline to establish an additional period of review for the Commission to perform a ''quick look'' at the data that service providers submit before publishing maps rendering the data. CCA suggests an ''initial review and sampling process,'' which ''could be automated, although there is likely no complete substitute for some degree of manual review and sampling,'' to identify ''significant and overt errors''; CCA cites the Commission's initial review of spectrum license transfer applications prior to placing them on public notice as a potential framework for a similar initial review process. It also recommends staff conduct random sampling or statistical analysis and comparison of the data provided by each provider to detect clear errors, and then quickly review maps for errors such as failure to account for terrain and clutter, excessive signal propagation at co-located sites, failure to use the required resolution, understated/overstated service in populated areas, depicted service ceasing at artificial boundaries, and failure to match the coverage maps on providers websites. CTIA and Public Knowledge/New America agree that such a process could be helpful, reasoning that a Commission-led initial review would eliminate a costly and open-ended burden on challengers who, they argue, will expend time and energy identifying overt errors that carriers never should have submitted.

139. While we recognize the theoretical benefits of a ''quick look'' of provider-submitted maps before they are made available to the public to challenge, we find that these are outweighed by the significant delay that this would introduce into the challenge process. Requiring the Commission to independently analyze provider submissions or conduct field surveys would significantly delay when this information is made available for the public to challenge. It also would be difficult to operationalize meaningful and practical standards to be applied in a ''quick look.'' The Commission will be collecting data and rendering multiple maps for scores of mobile and fixed providers, and it would clearly be wholly impracticable for staff to review every map of every provider before making them available to the public and to other federal, state, and local government agencies, Tribal entities, and other third parties. In order to build a process to undertake this type of review, we would need to decide, for example, which maps to review; how much time to spend reviewing them; and what kinds of ''significant and overt'' errors to look for. Commenters who support this pre-screening of provider data offer virtually no input on these fundamental implementation challenges, and we note that adopting CCA's suggested ''quick look'' approach in the absence of a more complete record on issues like these would likely require additional notice and comment. Additionally, the Broadband DATA Act created a framework whereby mobile service providers submit propagation maps based on a standardized set of propagation model details; in turn, the Commission is required to publish the data mobile service providers submit, and outside stakeholders are permitted to challenge mobile service providers' broadband coverage assumptions or submit crowdsource information to help us further refine and validate mobile service providers' propagation maps. Creating a ''quick look'' process could interfere with Congress's intent that we leverage public input to improve the maps over time.

140. That is not to say that we have not already planned to undertake certain data validations a part of the BDC submission process to preempt or remediate any overt errors. The BDC system will perform dozens of data validations and automatic processing steps on uploaded data and will alert the provider when any of the data fail one of these steps. These validations and processing steps will—for the first time—allow for the Commission's systems to automatically detect many of the GIS data and mapping issues that have historically been found in data submitted by providers after a time-consuming and largely manual review by staff for each Form 477 filing round. The new validations and automatic processing will flag a number of factors that would undermine the accuracy of a provider's data, including geometric errors in maps and overt errors in providers' assumptions. Moreover—and also for the first time—the BDC system will require providers to review and correct maps rendered from their data and to confirm that they uploaded the correct data and that any changes made as a result of data validations (*e.g.,* automatic repairs of invalid geometries and incorrect map projections) are correct, all prior to certifying their submissions. We anticipate that these additional validations and processing steps will significantly improve the process to submit data and, by preventing a provider from completing its submission until it has successfully undergone these data validations, will prevent the lengthy back-and-forth between filers and FCC staff that has typically occurred after the submission of Form 477 data. We believe that the new validations and automatic processing will help correct many, if not all, of the problems CCA discusses. The Bureau and Offices will maintain discretion to develop additional tools in the future to provide automatic feedback to carriers as we receive more data.

141. *Use of BDC Data.* RWA requests that Bureau and Offices clarify when the data collection, Fabric, and coverage maps will be ''complete'' for the purposes of awarding broadband deployment funds. We note that decisions regarding specific programs and how to use BDC data to determine areas of eligibility are outside the scope of this proceeding.

142. *Non-substantive Changes.* Finally, we make two non-substantive changes. First, we correct the numbering of 47 CFR 1.7006(e)(1). In particular, we redesignate the first paragraph (e)(1)(iv) as paragraph (e)(1)(iii). Second, in the second sentence of 47 CFR 1.7006(f) introductory text, we change the first instance of the word ''or'' to ''of''.

II. Supplemental Final Regulatory Flexibility Analysis

143. As required by the Regulatory Flexibility Act of 1980, as amended (RFA) a Supplemental Initial Regulatory Flexibility Analysis (Supplemental IRFA) was incorporated in the *BDC Mobile Technical Requirements Proposed Rules* released in July 2021 in this proceeding. The Commission prepared Initial and Final Regulatory Flexibility Analyses in connection with

the *Digital Opportunity Data Collection Report and Order* (73 FR 37869, July 2, 2008) and *Further Notice of Proposed Rulemaking* (82 FR 40119, Aug. 24, 2017), *Second Order* and *Third Further NPRM,* and *Third Order (collectively, Broadband Data Act Proceedings).* Written public comments were requested on the IRFAs prepared for the *Further Notice of Proposed Rulemakings* that are part of the *Broadband Data Act Proceedings.* Additionally, the Commission sought written public comment on the proposals, including comments on the Supplemental IRFA, in the *BDC Mobile Technical Requirements Proposed Rules.* No comments were filed addressing the Supplemental IRFA or the IRFAs incorporated in the *Broadband Data Act Proceedings.* This Supplemental Final Regulatory Flexibility Analysis (Supplemental FRFA) supplements the Final Regulatory Flexibility Analyses (FRFAs) in the *Broadband Data Act Proceedings* to reflect actions taken in this document and conforms to the RFA.

A. Need for, and Objectives of, the Order

144. The Broadband DATA Act requires the Commission to collect granular data from providers on the availability and quality of broadband internet access service and to verify the accuracy and reliability of the broadband coverage data submitted by providers. In its *Second Order* and *Third Further NPRM,* and *Third Order,* the Commission adopted some of the Broadband DATA Act's requirements, developed the framework for the BDC, established processes for verifying providers' broadband data submissions, and established a data challenge process. The Commission delegated authority to the Bureau and Offices to design and construct the new mapping system, which includes setting forth the specifications and requirements for the challenge, verification, and crowdsourcing processes. Following the December 27, 2020, Congressional appropriation of funding for the implementation of the Broadband DATA Act, the Commission began to implement challenge, verification, and crowdsourcing processes involving broadband data coverage submissions.

145. In this document, pursuant to their delegated authority, the Bureau and Offices take the next steps toward obtaining better coverage data and implementing the requirements of the Broadband DATA Act. More specifically, the Bureau and Offices take action to carry out their responsibility to develop technical requirements for verifying service providers' coverage data, a challenge process that will enable consumers and other third parties to dispute service providers' coverage data, and a process for consumers and other entities to submit crowdsourced data on mobile broadband availability. These measures will help the Commission, Congress, other federal and state policy makers, Tribal entities, consumers, and other third parties better evaluate the status of broadband deployment throughout the United States.

146. This document discusses the technical requirements to implement the mobile challenge, verification, and crowdsourcing processes required by the Broadband DATA Act, such as parameters and metrics for on-the-ground test data and a methodology for determining the threshold for what constitutes a cognizable challenge requiring a provider response. It also provides guidance on what types of data will likely be more probative in different circumstances. Additionally, this document discusses detailed processes and metrics for providers to follow when responding to a Commission verification request, for government entities and other third parties to follow when submitting verified broadband coverage data, and for challengers to follow when contesting providers' broadband coverage availability. We believe this level of detail is necessary to formulate the processes and procedures to enable better evaluation of the status of broadband deployment throughout the United States and to meet the Commission's obligations under the Broadband DATA Act.

B. Summary of Significant Issues Raised by Public Comments in Response to the IRFA

147. There were no comments filed that specifically addressed the proposed rules and policies presented in the Supplemental IRFA.

C. Response to Comments by the Chief Counsel for Advocacy of the Small Business Administration

148. Pursuant to the Small Business Jobs Act of 2010, which amended the RFA, the Commission is required to respond to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA) and to provide a detailed statement of any change made to the proposed rules as a result of those comments. The Chief Counsel did not file comments in response to the proposed rules in this proceeding.

D. Description and Estimate of the Number of Small Entities to Which the Rules Will Apply

149. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the rules adopted herein. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small-business concern'' under the Small Business Act. A ''small-business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

150. As noted above, Regulatory Flexibility Analyses were incorporated into the *Broadband Data Act Proceedings* and the *BDC Mobile Technical Requirements Proposed Rules.* More specifically, the FRFAs incorporated in the *Broadband Data Act Proceedings* described in detail the small entities that might be significantly affected in the proceedings. Accordingly, in this Supplemental FRFA, we hereby incorporate by reference from the FRFAs in the *Broadband Data Act Proceedings* the descriptions and estimates of the number of small entities that might be significantly affected, as well as the associated analyses, set forth therein.

E. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

151. We expect that the granular data collection for the challenge and verification processes in this document will impose some new reporting, recordkeeping, or other compliance requirements on some small entities. Specifically, as part of the challenge process, challenged mobile service providers are notified monthly via the online portal of the challenged hexagons at the end of each calendar month. Mobile providers of broadband internet access service must submit a rebuttal (consisting of either on-the-ground test data or infrastructure data) to the challenge or concede the challenge within 60 days of being notified of the challenge. A challenge respondent may submit supplemental data in support of its rebuttal, either voluntarily or, in some cases, in response to a request from OEA. When rebutting a challenge with on-the-ground data, the provider must meet analogous thresholds (geographic, temporal, and testing) to

those required of challengers, adjusted to reflect the burden on providers to demonstrate that sufficient coverage exists at least 90% of the time in the challenged hexagons. When a provider submits only infrastructure data to rebut a challenge, the provider must submit the same data as required when a mobile provider submits infrastructure information in response to a Commission verification request.

152. As part of the verification process, mobile providers of broadband internet access service must submit coverage data in the form of on-the-ground test data or infrastructure information on a case-by-case basis in response to a Commission request to verify mobile broadband providers' biannual BDC data submissions in a targeted area. For on-the-ground test data, we adopted an approach for providers to reply to verification requests using on-the-ground test data to verify networks which require mobile providers to submit data using the H3 geospatial indexing system at resolution 8. The tests will be evaluated to confirm, using a one-sided 95% statistical confidence interval, that the cell coverage is 90% or higher. Providers must also meet a temporal threshold in verification inquiry submissions that may be relaxed from that required in the challenge process. Additionally, consistent with our proposal in the *BDC Mobile Technical Requirements Proposed Rules,* state, local, and Tribal government entities as well as other third parties who voluntarily submit on-the-ground test data as verified data must use the same metrics and testing parameters that mobile providers must use when submitting on-the-ground test data, to ensure the consistency and accuracy of the broadband availability maps.

153. This document allows providers to submit infrastructure information in response to a verification request as proposed in the *BDC Mobile Technical Requirements Proposed Rules.* If a provider chooses to submit infrastructure information in response to a verification request, it must provide such data for all cell sites and antennas that serve or affect coverage in the targeted area. To the extent that the infrastructure information submitted by a provider in response to a verification request standing alone is not sufficient to demonstrate adequate coverage, the Commission may request additional information be submitted by the provider to complete the verification process. This document expands the categories of infrastructure information that providers must submit when collecting and reporting mobile infrastructure data by adopting the eight additional data categories proposed in the *BDC Mobile Technical Requirements Proposed Rules* which will enable a more precise evaluation of the challenged area of a provider's coverage map. Further, recognizing the need to allow flexibility for responding providers, this document also allows providers to submit other types of data to supplement on-the-ground or infrastructure information, such as transmitter monitoring information, data from their own field tests conducted in the ordinary course of business, and data collected using their own software tools.

154. With regard to the reporting or submission of crowdsourced data, the Bureau and Offices were directed by Commission to establish and use an online portal for crowdsourced data filings and to use the same portal for challenge filings. As proposed in the *BDC Mobile Technical Requirements Proposed Rules* to the extent state, local, and Tribal government entities, other entities, or consumers choose to submit on-the-ground crowdsourced mobile speed test data in the online portal, the data submission must use measurements similar to the methodology used by the FCC's speed test app and be submitted in a similar format to that which challengers and providers are required to use when submitting speed tests. Likewise, if state, local, and Tribal government entities, other entities, or consumers choose to submit preliminary on-the-ground crowdsourced mobile speed test information prior to availability of the online portal, the data collection requirements require use of a similar measurement methodology as the FCC's speed test app and submission in a format similar to the one used for speed tests.

155. The requirements we adopt in this document continue the Commission's actions to implement the Broadband DATA Act and develop more accurate, more useful, and more granular broadband availability data to advance our statutory obligations and continue our efforts to close the digital divide. We conclude that it is necessary to adopt these rules to produce broadband deployment maps that will allow the Commission to precisely target scarce universal service dollars to where broadband service is lacking. We are cognizant of the need to ensure that the benefits resulting from use of the data outweigh the reporting burdens imposed on small entities. The Commission believes, however, that any additional burdens imposed by our revised reporting approach for providers and state, local, and Tribal government entities are outweighed by the significant benefit to be gained from producing more accurate broadband deployment data and map. We are likewise cognizant that small entities will incur costs and may have to hire attorneys, engineers, consultants or other professionals to comply with this document. Moreover, although the Commission cannot quantify the cost of compliance with the requirements in this document, we believe that the reporting and other requirements we have adopted are necessary to comply with the Broadband DATA Act and ensure the Commission obtains complete and accurate broadband coverage maps.

F. Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

156. The RFA requires an agency to describe any significant, specifically small business, alternatives that it has considered in reaching its approach, which may include the following four alternatives (among others): ''(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.''

157. The requirements adopted in this document balance the need for the Commission to generate more precise and granular mobile broadband availability maps with any associated costs and burdens on mobile broadband providers and other entities participating in the BDC process. The Commission has considered the comments in the record and is mindful that some small entities will have to expend resources and will incur costs to comply with requirements in this document. In reaching the requirements we adopted in this document, there were various approaches and alternatives that the Commission considered but did not adopt, which we discuss below, that will prevent small entities from incurring additional burdens and will minimize the economic impact of compliance.

158. The mobile challenge process requirements adopted by the Commission will facilitate the collection of sufficient measurement information to ensure the mobile challenge process

is statistically valid while, at the same time, meeting the Commission's statutory obligation to keep the challenge process ''user-friendly.'' The adopted requirements strike a balance between ensuring that small entities, including but not limited to state, local, and Tribal governments, as well as consumers and other third-party challengers, can use the challenge process, and ensuring that providers, including small providers, are not unreasonably burdened by responding to every speed test that shows a lack of coverage. The mobile challenge process we have adopted includes a process to determine whether there is a cognizable challenge to which a provider is required to respond rather than requiring a provider to respond to any and all submitted challenges. This will minimize the economic impact for small providers to the extent they are subject to challenges. For challengers, the mobile challenge process allows drive test data meeting specific testing parameters to be submitted via a mobile app—the data must be collected using mobile devices running either a Commission-developed app (*i.e.,* the FCC Speed Test app) or another speed test app approved by OET—and allows governmental entities and other third-party challengers to use their own software and hardware, which contributes to the ''user-friendly'' nature of the challenge process. Additionally, the speed test data from state, local, and Tribal governments, consumers and other third-party challengers will be aggregated as part of the mobile challenge process to ensure that one challenger is not required to submit all of the speed test data needed to create a challenge, thereby lessening the load as well as the costs and resources required for small entities and others who participate in the mobile challenge process to create a cognizable challenge.

159. The notification process adopted in this document to inform service providers of cognizable challenges filed against them and inform challengers and service providers of the status and results of challenges will be done on a monthly basis via the online portal. This approach should be more manageable, more administratively efficient, and thereby less costly for small entities and other providers by providing them with a standard set of deadlines rather than having a rolling set of multiple deadlines, while also ensuring that challengers have the opportunity to submit additional evidence in support of their challenge submissions if desired. Providers and challengers will have access to all relevant information through the online portal, including a map of the challenged area(s), notification of whether or not a challenge has been successfully rebutted, whether a challenge was successful, and if a challenged area was restored based on insufficient evidence to sustain a challenge.

160. The mobile service challenge process metrics for mobile providers to follow when responding to a Commission verification request seek to balance the need for the Commission to establish valuable methods for verifying coverage data with the need to reduce the costs and burdens associated with requiring mobile providers to submit on-the-ground test data and infrastructure information. For example, in order to ensure the challenge process is user-friendly for challengers and workable for mobile providers to respond to and rebut challenges, the challenged mobile service providers who choose to submit on-the-ground speed test data are required to meet analogous thresholds as the challengers to demonstrate that the challenged areas have sufficient coverage. Providers are required to submit on-the-ground data to demonstrate that sufficient coverage exists at least 90% of the time and meet the same three threshold tests as challengers. We considered but declined a proposal to define a challenge area based on the test data submitted by the challengers on our belief that our proposal is both user-friendly and supported by sufficient data while also targeting a more precise geographic area where broadband coverage is disputed and limits the burden on providers in responding to challenges.

161. We also declined to adopt several recommendations from commenters which would have expanded the scope of requirements for the challenge process and increased costs for small and other providers. More specifically, we declined to include voice maps in the challenge process, noting that Broadband DATA Act makes no mention of allowing challenges to voice maps, and the Commission decided that the mobile challenge process applies only to broadband (*i.e.,* not voice) coverage maps. Further, we declined to require providers to provide additional information such as performance and affordability information like throughput speeds experienced by consumers, signal strength, and pricing information with their maps. In the *Third Order,* the Commission specifically declined to adopt pricing and throughput data on fixed services, and we do not believe the Bureau and Offices have discretion to add such requirements in this document.

162. For small entities and other providers who use on-the-ground test data to rebut challenges, we provide greater flexibility in the collection of on-the-ground test data and reduce burdens on providers by allowing them to use the software tools they may already be using. To the extent that a provider chooses to use software other than the FCC Speed Test app or another speed test app approved by OET for use in the challenge process, we will consider such software approved for use in rebutting challenges provided that the software collects the metrics that approved apps must collect for consumer challenges and that governmental and third-party challengers' speed test data must contain. This approach will help minimize costs for small and other providers and increase efficiency, while continuing to ensure that the Commission receives high quality data that will allow an equivalent comparison between challenge data submitted by consumers and other entities, and data created by providers using their own software. We note however, that we retain the discretion to require prior approval of providers' software tools or make changes to the required metrics via notice and comment at a later time. Similarly, we provide small and other providers flexibility to rebut challenges by allowing the use of infrastructure data, on their own, to adjudicate challenges in a limited set of circumstances.

163. In our adoption of parameters for the collection of verification information, we recognize that it may be more costly for small providers to obtain on-the-ground test data. We take steps to address this issue by adopting a targeted and more inclusive approach. Specifically, we identify the portion of a provider's coverage map (targeted area) that may require verification data and will conduct our determination based upon all available evidence. The scope of all available evidence includes speed test data, infrastructure data, crowdsourced and other third-party data, as well as staff evaluation and knowledge of submitted coverage data (including maps, link budget parameters, and other credible information). Thus, rather than a one-size-fits-all requirement, this approach will allow Commission staff to evaluate whether a verification request is warranted and for providers to submit the type of data in response to a verification request that most cost-effectively supports their coverage calculations. To further minimize the costs and burden placed on small and

other service providers, while ensuring Commission staff have access to sufficient data to demonstrate coverage, we will use sampling of the target area and require service providers to provide verification data which covers a statistically valid sampling of areas for which sufficient coverage must be demonstrated to satisfy the verification request. By using a sampling plan to demonstrate broadband availability, we decrease the data submission requirements allowing small and other providers to avoid the costs that would have been associated with submitting considerably more data. Additionally, we declined a request to require providers to submit actual on-the-ground test data on a continuous or quarterly basis as such a requirement would be unnecessarily burdensome.

164. To ensure consistency, reliability, comparability, and verifiability of the data the Commission receives, in this document we require state, local, and Tribal government entities and other third parties, including small entities that fall within these categories, to comply with the challenge process applicable to providers. Consistent with our approach for providers which does not carve out different or lower standards for smaller providers, requiring state, local, and Tribal government entities and third parties to submit on-the-ground test data using analogous thresholds we adopted for mobile providers will ensure that the Commission implements a standardized process resulting in broadband availability maps that are as accurate and precise as possible. We are cognizant however, that on-the-ground test data can be more costly to obtain and can impose burdens for small entities. Therefore, our consideration of appropriate verification data sources took into consideration both the usefulness and costs of on-the-ground test data, and the fact that this type of data may not be necessary in every situation, particularly where infrastructure information is available which based on our analysis will likely be of comparable probative value to on-the-ground test data in certain situations.

165. Finally, in the *Second Order,* the Commission adopted a crowdsourcing process to allow individuals and entities to submit information about the deployment and availability of broadband internet access service. Consistent with the data collection and submission requirements adopted in this document for the mobile challenge and verification process, governmental entities and other third parties, including small entities that fall within these categories, can submit on-the-ground crowdsourced mobile speed test data using the online portal that will be used by providers for the challenge and verification processes. As mentioned above in Section E, crowdsourced data will be collected using a similar measurement methodology and submitted in a format similar to the format challengers and providers use to submit speed test data. In adopting this approach for crowdsourced data, the continued consistency will minimize the cost and administrative burdens for small entities and further ensure the uniformity, dependability, comparability, and verifiability of the data received by the Commission in the mobile challenge, verification, and crowdsourcing processes.

G. Report to Congress

166. The Commission will send a copy of the *Order,* including the Supplemental FRFA, in a report to be sent to Congress pursuant to the Congressional Review Act. In addition, the Commission will send a copy of the *Order,* including the Supplemental FRFA, to the Chief Counsel for Advocacy of the SBA. A copy of the *Order* and Supplemental FRFA (or summaries thereof) will also be published in the **Federal Register**.

III. Ordering Clauses

167. Accordingly, *it is ordered* that, pursuant to sections 1–4, 7, 201, 254, 301, 303, 319, 332, and 641–646 of the Communications Act of 1934, as amended, 47 U.S.C. 151–154, 157, 201, 254, 301, 303, 319, 332, 641–646, the *Order is adopted*.

168. *It is further ordered* that part 1 of the Commission's rules *is amended* as set forth in Appendix B of the *Order.*

169. *It is further ordered* that the *Order shall be* effective 30 days after publication in the **Federal Register**.

170. *It is further ordered* that the Office of the Managing Director, Performance Evaluation and Records Management, *shall send* a copy of the *Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 1

Administrative practice and procedure, Broadband, Broadband mapping, Communications, Internet, Reporting and recordkeeping requirements, Telecommunications.

Federal Communications Commission.

Amy Brett,

Chief of Staff, Wireless Telecommunications Bureau.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 1 as follows:

PART 1—PRACTICE AND PROCEDURE

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

Authority: 47 U.S.C. chs. 2, 5, 9, 13; 28 U.S.C. 2461 note, unless otherwise noted.

■ 2. Amend § 1.7001 by adding paragraph (a)(20) to read as follows:

§ 1.7001 Scope and content of filed reports.

(a) * * *

(20) *H3 standardized geospatial indexing system.* A system developed by Uber Technologies, Inc., that overlays the Earth with hexagonal cells of different sizes at various resolutions. The smallest hexagonal cells are at resolution 15, in which the average hexagonal cell has an area of approximately 0.9 square meters, and the largest are at resolution 0, in which the average hexagonal cell has an area of approximately 4.25 million square kilometers. Hexagonal cells across different resolutions are referred to as a ''hex-n'' cell, where n is the resolution (*e.g.,* ''hex-15'' for the smallest size hexagonal cell). The H3 standardized geospatial indexing system employs a nested cell structure wherein a lower resolution hexagonal cell (the ''parent'') contains approximately seven hexagonal cells at the next highest resolution (its ''children''). That is, a hex-1 cell is the ''parent'' of seven hex-2 cells, each hex-2 cell is the parent of seven hex-3 cells, and so on.

* * * * *

■ 3. Amend § 1.7006 by:
■ a. Redesignating paragraphs (b)(2) through (4) as paragraphs (b)(3) through (5);
■ b. Adding new paragraph (b)(2);
■ c. Revising newly redesignated paragraphs (b)(4) and (5) and paragraphs (c) and (e)(1)(i);
■ d. Removing paragraph (e)(1)(ii);
■ e. Redesignating paragraph (e)(1)(iii) and the first paragraph (e)(1)(iv) as paragraphs (e)(1)(ii) and (iii);
■ f. Revising newly redesignated paragraph (e)(1)(ii) and paragraphs (e)(2), (4), and (6);
■ g. Adding paragraph (e)(7);
■ h. Revising paragraphs (f) introductory text and (f)(1)(i);

■ i. Removing ''and'' from the end of paragraph (f)(1)(ii);
■ j. Removing the period at the end of paragraph (f)(1)(iii) and adding ''; and'' in its place;
■ k. Adding paragraph (f)(1)(iv); and
■ l. Revising paragraphs (f)(2), (3), and (5).

The additions and revisions read as follows:

§ 1.7006 Data verification.

* * * * *

(b) * * *

(2) On-the-ground crowdsourced data must include the metrics and meet the testing parameters described in paragraphs (c)(1)(i) and (ii) of this section, except that the data may include any combination of download speed and upload speed rather than both.

* * * * *

(4) If, as a result of crowdsourced data and/or other available data, the Commission determines that a provider's coverage information is likely not accurate, then the provider shall be subject to a verification inquiry consistent with the mobile verification process described in paragraph (c) of this section.

(5) All information submitted as part of the crowdsourcing process shall be made public via the Commission's website, with the exception of personally identifiable information and any data required to be confidential under § 0.457 of this chapter.

(c) *Mobile service verification process for mobile providers.* Mobile service providers must submit either infrastructure information or on-the-ground test data in response to a request by Commission staff as part of its inquiry to independently verify the accuracy of the mobile provider's coverage propagation models and maps. In addition to submitting either on-the-ground data or infrastructure data, a provider may also submit data collected from transmitter monitoring software. The Office of Economics and Analytics and the Wireless Telecommunications Bureau may require the submission of additional data when necessary to complete a verification inquiry. A provider must submit its data, in the case of both infrastructure information and on-the-ground data, within 60 days of receiving a Commission staff request. Regarding on-the-ground data, a provider must submit evidence of network performance based on a sample of on-the-ground tests that is statistically appropriate for the area tested. A provider must verify coverage of a sampled area using the H3 geospatial indexing system at resolution 8. The on-the-ground tests will be evaluated to confirm, using a one-sided 95% statistical confidence interval, that the cell coverage is 90% or higher. In submitting data in response to a verification request, a provider must record at least two tests within each of the randomly selected hexagons where the time of the tests are at least four hours apart, irrespective of date, unless, for any sampled hexagon, the provider has and submits alongside its speed tests actual cell loading data for the cell(s) covering the hexagon sufficient to establish that median loading, measured in 15-minute intervals, did not exceed the modeled loading factor for the one-week period prior to the verification inquiry, in which case the provider is required to submit only a single test for the sampled hexagon. We will treat any tests within the sampled accessible point-hex that are outside the coverage area as valid in the case where tests were not recorded within the coverage area. If the required sampled point-hex continue to have missing tests, we will also consider tests that fall slightly outside the required point-hex but within the typical Global Positioning System (GPS) average user range error as valid when no tests are recorded within the point-hex. If the sampled point-hex still has missing tests, we would set those missing required speed tests as negative tests when performing the final adjudication. For in-vehicle mobile tests, providers must conduct tests with the antenna located inside the vehicle.

(1) When a mobile service provider chooses to demonstrate mobile broadband coverage availability by submitting on-the-ground data, the mobile service provider must provide valid on-the-ground tests within a Commission-identified statistically valid and unbiased sample of its network.

(i) On-the-ground test data must meet the following testing parameters:

(A) A minimum test length of 5 seconds and a maximum test length of 30 seconds. These test length parameters apply individually to download speed, upload speed, and round-trip latency measurements, and do not include ramp up time. The minimum test duration requirement will be relaxed once a download or upload test measurement has transferred at least 1,000 megabytes of data;

(B) Reporting test measurement results that have been averaged over the duration of the test (*i.e.,* total bits received divided by total test time); and

(C) Conducted outdoors between the hours of 6:00 a.m. and 10:00 p.m. local time; and

(ii) On-the-ground test data must include the following metrics for each test:

(A) Testing app name and version;

(B) Timestamp and duration of each test metric;

(C) Geographic coordinates (*i.e.,* latitude/longitude) measured at the start and end of each test metric measured with typical GPS Standard Positioning Service accuracy or better, along with location accuracy;

(D) Consumer-grade device type(s), brand/model, and operating system used for the test;

(E) Name and identity of the service provider being tested;

(F) Location of test server (*e.g.,* hostname or IP address);

(G) Signal strength, signal quality, unique identifier, and radiofrequency metrics of each serving cell, where available;

(H) Download speed;

(I) Upload speed;

(J) Round-trip latency;

(K) Whether the test was taken in an in-vehicle mobile or outdoor, pedestrian stationary environment;

(L) For an in-vehicle test, the speed the vehicle was traveling when the test was taken, where available;

(M) An indication of whether the test failed to establish a connection with a mobile network at the time and place it was initiated;

(N) The network technology (*e.g.,* 4G LTE (Long Term Evolution), 5G–NR (New Radio)) and spectrum bands used for the test; and

(O) All other metrics required per the most recent specification for mobile test data adopted by Office of Economics and Analytics and the Wireless Telecommunications Bureau in accordance with 5 U.S.C. 553.

(2) When a mobile service provider chooses to demonstrate mobile broadband coverage availability by submitting infrastructure data, the mobile service provider must submit such data for all cell sites and antennas that serve or interfere with the targeted area.

(i) Infrastructure data must include the following information for each cell site that the provider uses to provide service for the area subject to the verification inquiry:

(A) The latitude and longitude of the cell site measured with typical GPS Standard Positioning Service accuracy or better;

(B) The cell and site ID number for each cell site;

(C) The ground elevation above mean sea level (AMSL) of the site (in meters);

(D) Frequency band(s) used to provide service for each site being mapped

including channel bandwidth (in megahertz);

(E) Radio technologies used on each band for each site;

(F) Capacity (megabits per second (Mbps)) and type of backhaul used at each cell site;

(G) Number of sectors at each cell site;

(H) Effective Isotropic Radiated Power (EIRP, in decibel-milliwatts (dBm)) of the sector at the time the mobile provider creates its map of the coverage data;

(I) Geographic coordinates of each transmitter site measured with typical GPS Standard Positioning Service accuracy or better;

(J) Per site classification (*e.g.,* urban, suburban, or rural);

(K) Elevation above ground level for each base station antenna and other transmit antenna specifications (*i.e.,* the make and model, beamwidth (in degrees), radiation pattern, and orientation (azimuth and any electrical and/or mechanical down-tilt in degrees) at each cell site);

(L) Operate transmit power of the radio equipment at each cell site;

(M) Throughput and associated required signal strength and signal-to-noise ratio;

(N) Cell loading distribution;

(O) Areas enabled with carrier aggregation and a list of band combinations; and

(P) Any additional parameters and fields that are listed in the most-recent specifications for wireless infrastructure data released by the Office of Economics and Analytics and the Wireless Telecommunications Bureau in accordance with 5 U.S.C. 553.

(ii) [Reserved]

* * * * *

(e) * * *

(1) * * *

(i) Name, email address, and mobile phone number of the device on which the speed test was conducted;

(ii) Speed test data. Consumers must use a speed test app that has been designated by the Office of Engineering and Technology, in consultation with the Office of Economics and Analytics and the Wireless Telecommunications Bureau, for use in the challenge process. Consumer challenges must include on-the-ground test data that meets the requirements in paragraphs (c)(1)(i) and (ii) of this section, and must also report the timestamp that test measurement data were transmitted to the app developer's servers, as well as the source IP address and port of the device, as measured by the server;

* * * * *

(2) Consumer speed tests will be used to create a cognizable challenge based on the following criteria:

(i) The smallest challengeable hexagonal cell is a hexagon at resolution 8 from the H3 standardized geospatial indexing system.

(ii) The download and upload components of a speed test will be evaluated separately.

(iii) A ''positive'' component is one that records speeds meeting or exceeding the minimum speeds that the mobile service provider reports as available where the test occurred (*e.g.,* a positive download component would show speeds of at least 5 Mbps for 4G LTE, and a positive upload component would show speeds of at least 1 Mbps for 4G LTE). A ''negative'' component is one that records speeds that fail to meet the minimum speeds that the mobile service provider reports as available where the test occurred.

(iv) A point-hex shall be defined as one of the seven hex-9s from the H3 standardized geospatial indexing system nested within a hex-8.

(v) A point-hex shall be defined as accessible where at least 50% of the area of the point-hex overlaps with the provider's reported coverage data and the point-hex overlaps with any primary, secondary, or local road in the U.S. Census Bureau's TIGER/Line Shapefiles.

(vi) A hex-8 from the H3 standardized geospatial indexing system shall be classified as challenged if the following three thresholds are met in the hex-8 for either the download or upload components.

(A) *Geographic threshold.* When there are at least four accessible point-hexes within the hex-8, each must contain two of the same test components (download or upload), one of which is a negative test. The threshold must be met for one component entirely, meaning that a challenge may contain either two upload components per point-hex, one of which is negative, or two download components per point-hex, one of which is negative. The minimum number of point-hexes in which tests must be recorded must be equal to the number of accessible point-hexes or four, whichever number is lower. If there are no accessible point-hexes within a hex-8, the geographic threshold shall not need to be met;

(B) *Temporal threshold.* A hex-8 cell must include a set of two negative test components of the same type with a time-of-day difference of at least four hours from another set of two negative test components of the same type, regardless of the date of the tests; and

(C) *Testing threshold.* At least five speed test components of the same type within a hex-8 cell are negative when a challenger has submitted 20 or fewer test components of that type.

(*1*) When challengers have submitted more than 20 test components of the same type, the following minimum percentage of the total number of test components of that type in the cell must be negative:

(*i*) When challengers have submitted 21–29 test components, at least 24% must be negative;

(*ii*) When challengers have submitted 30–45 test components, at least 22% must be negative;

(*iii*) When challengers have submitted 46–60 test components, at least 20% must be negative;

(*iv*) When challengers have submitted 61–70 test components, at least 18% must be negative;

(*v*) When challengers have submitted 71–99 test components, at least 17% must be negative; and

(*vi*) When challengers have submitted 100 or more test components, at least 16% must be negative.

(*2*) In a hex-8 with four or more accessible point-hexes, if the number of test components of the same type in one point-hex represent more than 50% of the total test components of that type in the hex-8 but still satisfies the geographic threshold, the components in that point-hex will count only towards 50% of the threshold. In a hex-8 where there are only three accessible point-hexes, if the number of test components of the same type in one point-hex represent more than 75% of the total test components of that type in the hex-8 but still satisfies the geographic threshold, the components in that point-hex will count only towards 75% of the threshold.

(*3*) Once the percentage of negative components of the same type recorded meets the minimum negative percentage required (or for a sample of fewer than 21 components, once there are at least five negative component submitted), no additional tests are required so long as both the geographic and temporal thresholds for a hex-8 have been met.

(vii) A larger, ''parent'' hexagon (at resolutions 7 or 6) shall be considered challenged if at least four of the child hexagons within such a ''parent'' hexagon are considered challenged.

(viii) Mobile service providers shall be notified of all cognizable challenges to their mobile broadband coverage maps at the end of each month. Challengers shall be notified when a mobile provider responds to the challenge. Mobile service providers and challengers both shall be notified

monthly of the status of challenged areas and parties will be able to see a map of the challenged area and a notification about whether or not a challenge has been successfully rebutted, whether a challenge was successful, and if a challenged area was restored based on insufficient evidence to sustain a challenge.

* * * * *

(4) To dispute a challenge, a mobile service provider must submit on-the-ground test data that meets the requirements in paragraphs (c)(1)(i) and (ii) of this section, (for in-vehicle mobile tests, providers must conduct tests with the antenna located inside the vehicle), or infrastructure data that meets the requirements in paragraph (c)(2)(i) of this section to verify its coverage map(s) in the challenged area. To the extent that a mobile service provider believes it would be helpful to the Commission in resolving a challenge, it may choose to submit other data in addition to the data initially required, including but not limited to either infrastructure or on-the-ground testing (to the extent such data are not the primary option chosen by the provider) or other types of data such as data collected from network transmitter monitoring systems or software, or spectrum band-specific coverage maps. Such other data must be submitted at the same time as the primary on-the-ground testing or infrastructure rebuttal data submitted by the provider. If needed to ensure an adequate review, the Office of Economics and Analytics may also require that the provider submit other data in addition to the data initially submitted, including but not limited to either infrastructure or on-the-ground testing data (to the extent not the option initially chosen by the provider) or data collected from network transmitter monitoring systems or software (to the extent available in the provider's network). If a mobile provider is not able to demonstrate sufficient coverage in a challenged hexagon, the mobile provider must revise its coverage maps to reflect the lack of coverage in such areas.

(i) A ''positive'' component is one that records speeds meeting or exceeding the minimum speeds that the mobile service provider reports as available where the test occurred (*e.g.,* a positive download component would show speeds of at least 5 Mbps for 4G LTE, and a positive upload component would show speeds of at least 1 Mbps for 4G LTE). A ''negative'' component is one that records speeds that fail to meet the minimum speeds that the mobile service provider reports as available where the test occurred.

(ii) A point-hex shall be defined as one of the seven nested hexagons at resolution 9 from the H3 standardized geospatial indexing system of a resolution 8 hexagon.

(iii) A point-hex shall be defined as accessible where at least 50% of the area of the point-hex overlaps with the provider's reported coverage data and the point-hex overlaps with any primary, secondary, or local road in the U.S. Census Bureau's TIGER/Line Shapefiles.

(iv) A mobile service provider that chooses to rebut a challenge to their mobile broadband coverage maps with on-the-ground speed test data must confirm that a challenged area has sufficient coverage using speed tests that were conducted during the 12 months prior to submitting a rebuttal. A provider may confirm coverage in any hex-8 cell within the challenged area. This includes any hex-8 cell that is challenged, and also any non-challenged hex-8 cell that is a child of a challenged hex-7 or hex-6 cell. Confirming non-challenged hex-8 cells can be used to confirm the challenged hex-7 or hex-6 cell. To confirm a hex-8 cell, a provider must submit on-the ground speed test data that meets the following criteria for both upload and download components:

(A) *Geographic threshold.* Two download components, at least one of which is a positive test, and two upload components, at least one of which is a positive test, are recorded within a minimum number of point-hexes within the challenged area, where the minimum number of point-hexes in which tests must be recorded must be equal to the number of accessible point-hexes or four, whichever number is lower. If there are no accessible point-hexes within a hex-8, the geographic threshold shall not need to be met.

(B) *Temporal threshold.* A hex-8 cell will need to include a set of five positive test components of the same type with a time-of-day difference of at least four hours from another set of five positive test components of the same type, regardless of the date of the test.

(C) *Testing threshold.* At least 17 positive test components of the same type within a hex-8 cell in the challenged area when the provider has submitted 20 or fewer test components of that type. When the provider has submitted more than 20 test components of the same type, a certain minimum percentage of the total number of test components of that type in the cell must be positive:

(*1*) When a provider has submitted 21–34 test components, at least 82% must be positive;

(*2*) When a provider has submitted 35–49 test components, at least 84% must be positive;

(*3*) When a provider has submitted 50–70 test components, at least 86% must be positive;

(*4*) When a provider has submitted 71–99 test components, at least 87% must be positive;

(*5*) When a provider has submitted 100 or more test components, at least 88% must be positive; and

(*6*) In a hex-8 with four or more accessible point-hexes, if the number of test components of the same type in one point-hex represent more than 50% of the total test components of that type in the hex-8 but still satisfies the geographic threshold, the components in that point-hex will count only toward 50% of the threshold. In a hex-8 where there are only three accessible point-hexes, if the number of test components of the same type in one point-hex represent more than 75% of the total test components of that type in the hex-8 but still satisfies the geographic threshold, the components in that point-hex will count only toward 75% of the threshold.

(D) *Use of FCC Speed Test App or other software.* Using a mobile device running either a Commission-developed app (*e.g.,* the FCC Speed Test app), another speed test app approved by OET to submit challenges, or other software provided that the software adopts the test methodology and collects the metrics that approved apps must perform for consumer challenges and that government and third-party entity challenger speed test data must contain (for in-vehicle mobile tests, providers must conduct tests with the antenna located inside the vehicle):

(*1*) Providers must submit a complete description of the methodologies used to collect their data; and

(*2*) Providers must substantiate their data through the certification of a qualified engineer or official.

(E) *Use of an appropriate device.* Using a device that is able to interface with drive test software and/or runs on the Android operating system.

(v) A mobile service provider that chooses to rebut a challenge to their mobile broadband coverage maps with infrastructure data on their own may only do so in order to identify invalid, or non-representative, speed tests within the challenger speed test data. The mobile service provider must submit the same data as required when a mobile provider submits infrastructure information in response to a

Commission verification request, including information on the cell sites and antennas used to provide service in the challenged area. A provider may submit only infrastructure data to rebut a challenge if:

(A) Extenuating circumstances at the time and location of a given test (*e.g.,* maintenance or temporary outage at the cell site) caused service to be abnormal. In such cases, a provider must submit coverage or footprint data for the site or sectors that were affected and information about the outage, such as bands affected, duration, and whether the outage was reported to the FCC's Network Outage Reporting System (NORS), along with a certification about the submission's accuracy;

(B) The mobile device(s) with which the challenger(s) conducted their speed tests are not capable of using or connecting to the radio technology or spectrum band(s) that the provider models for service in the challenged area. In such cases, a provider must submit band-specific coverage footprints and information about which specific device(s) lack the technology or band;

(C) The challenge speed tests were taken during an uncommon special event (*e.g.,* professional sporting event) that increased traffic on the network;

(D)(*1*) The challenge speed tests were taken during a period where cell loading was abnormally higher than the modeled cell loading factor. In such cases, providers must submit cell loading data that both:

(*i*) Establish that the cell loading for the primary cell(s) at the time of the test was abnormally higher than modeled; and

(*ii*) Include cell loading data for a one-week period before and/or after the provider was notified of the challenge showing as a baseline that the median loading for the primary cell(s) was not greater than the modeled value.

(*2*) If a high number of challenges show persistent over-loading, staff may initiate a verification inquiry to investigate whether mobile providers have submitted coverage maps based on an accurate assumption of cell loading in a particular area;

(E) The mobile device(s) with which the challenger(s) conducted their speed tests used a data plan that could result in slower service. In such cases, a provider must submit information about which specific device(s) used in the testing were using such a data plan and information showing that the provider's network did, in fact, slow the device at the time of the test; or

(F) The mobile device(s) with which the challenger(s) conducted their speed tests was either roaming or was used by the customer of a mobile virtual network operator. In such circumstances, providers must identify which specific device(s) used in the testing were either roaming at the time or used by the customer of a mobile virtual network operator based upon their records.

(vi) If the Commission determines, based on the infrastructure data submitted by providers, that challenge speed tests are invalid, such challenge speed tests shall be ruled void, and the Commission shall recalculate the challenged hexagons after removing any invalidated challenger speed tests and consider any challenged hexagons that no longer meet the challenge creation threshold to be restored to their status before the challenge was submitted.

* * * * *

(6) After a challenged provider submits all responses and Commission staff determines the result of a challenge and any subsequent rebuttal has been determined:

(i) In such cases where a mobile service provider successfully rebuts a challenge, the area confirmed to have coverage shall be ineligible for challenge until the next biannual broadband availability data filing six months after the later of either the end of the 60-day response period or the resolution of the challenge.

(ii) A challenged area may be restored to an unchallenged state, if, as a result of data submitted by the provider, there is no longer sufficient evidence to sustain the challenge to that area, but the provider's data fall short of confirming the area. A restored hexagon would be subject to challenge at any time in the future as challengers submit new speed test data.

(iii) In cases where a mobile service provider concedes or loses a challenge, the provider must file, within 30 days, geospatial data depicting the challenged area that has been shown to lack sufficient service. Such data will constitute a correction layer to the provider's original propagation model-based coverage map, and Commission staff will use this layer to update the broadband coverage map. In addition, to the extent that a provider does not later improve coverage for the relevant technology in an area where it conceded or lost a challenge, it must include this correction layer in its subsequent filings to indicate the areas shown to lack service.

(7) Commission staff are permitted to consider other relevant data to support a mobile service provider's rebuttal of challenges, including on-the-ground data or infrastructure data (to the extent such data are not the primary rebuttal option submitted by the mobile service provider). The Office of Economics and Analytics will review such data when voluntarily submitted by providers in response to challenges, and if it concludes that any of the data sources are sufficiently reliable, it will specify appropriate standards and specifications for each type of data and will issue a public notice adding the data source to the alternatives available to providers to rebut a consumer challenge.

(f) *Mobile service challenge process for State, local, and Tribal governmental entities; and other entities or individuals.* State, local, and Tribal governmental entities and other entities or individuals may submit data to challenge accuracy of mobile broadband coverage maps. They may challenge mobile coverage data based on lack of service or poor service quality such as slow delivered user speed.

(1) * * *

(i) Government and other entity challengers may use their own software and hardware to collect data for the challenge process. When they submit their data the data must meet the requirements in paragraphs (c)(1)(i) and (ii) of this section, except that government and other entity challengers may submit the International Mobile Equipment Identity (IMEI) of the device used to conduct a speed test for use in the challenge process instead of the timestamp that test measurement data were transmitted to the app developer's servers, as well as the source IP address and port of the device, as measured by the server;

* * * * *

(iv) If the test was taken in an in-vehicle mobile environment, whether the test was conducted with the antenna outside of the vehicle.

(2) Challengers must conduct speed tests using a device advertised by the challenged service provider as compatible with its network and must take all speed tests outdoors. Challengers must also use a device that is able to interface with drive test software and/or runs on the Android operating system.

(3) For a challenge to be considered a cognizable challenge, thus requiring a mobile service provider response, the challenge must meet the same thresholds specified in paragraph (e)(2) of this section.

* * * * *

(5) To dispute a challenge, a mobile service provider must submit on-the-ground test data or infrastructure data to verify its coverage map(s) in the challenged area based on the

methodology set forth in paragraph (e)(4) of this section. To the extent that a service provider believes it would be helpful to the Commission in resolving a challenge, it may choose to submit other data in addition to the data initially required, including but not limited to either infrastructure or on-the-ground testing (to the extent such data are not the primary option chosen by the provider) or other types of data such as data collected from network transmitter monitoring systems or software or spectrum band-specific coverage maps. Such other data must be submitted at the same time as the primary on-the-ground testing or infrastructure rebuttal data submitted by the provider. If needed to ensure an adequate review, the Office of Economics and Analytics may also require that the provider submit other data in addition to the data initially submitted, including but not limited to either infrastructure or on-the-ground testing data (to the extent not the option initially chosen by the provider) or data collected from network transmitter monitoring systems or software (to the extent available in the provider's network).

* * * * *

■ 4. Amend § 1.7008 by revising paragraph (d)(2) to read as follows:

§ 1.7008 Creation of broadband internet access service coverage maps.

* * * * *

(d) * * *

(2) To the extent government entities or third parties choose to file verified data, they must follow the same filing process as providers submitting their broadband internet access service data in the data portal. Government entities and third parties that file on-the-ground test data must submit such data using the same metrics and testing parameters the Commission requires of mobile service providers when responding to a Commission request to verify mobile providers' broadband network coverage with on-the-ground data (*see* § 1.7006(c)(1)).

* * * * *

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Part V

Department of Justice

Drug Enforcement Administration

OakmontScript Limited Partnership; Decision and Order; Notice

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 21–03]

OakmontScript Limited Partnership; Decision and Order

On October 20, 2020, a former Assistant Administrator, Diversion Control Division, of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to OakmontScript Limited Partnership (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJ Ex.) 1, (OSC) at 1. The OSC proposed the revocation of Respondent's DEA Certificates of Registration Nos. RO0504680 and RO0527082 (hereinafter, CORs or registrations) and the denial of any pending application to modify or renew the registrations and any applications for any other DEA registrations pursuant to 21 U.S.C. 823, 824, 958, and other federal laws, because Respondent's ''registration[s are] inconsistent with the public interest,'' as that term is defined in 21 U.S.C. 823(b), (d), and (e); 824(a); and 958(c). *Id.*

In response to the OSC, Respondent timely requested a hearing before an Administrative Law Judge. ALJ Ex. 2. The hearing in this matter was conducted from March 8–12, 2021, at the DEA Hearing Facility in Arlington, Virginia, with the parties and their witnesses participating through video-teleconference.*[A] On June 11, 2021, Administrative Law Judge Paul E. Soeffing (hereinafter, ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, Recommended Decision or RD). Neither party filed exceptions to the RD.

Having reviewed the entire record, I agree with the ALJ's Recommended Decision and I adopt it with minor modifications, as noted herein.*[B]

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge *[C] [1]

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

The Allegations

The Government alleges that the Respondent's CORs should be revoked because OakmontScript exported controlled substances prior to obtaining its exporter COR, exported controlled substances it was not approved to export, demonstrated a lack of candor about controlled substances it was exporting, falsified a copy of its distributor DEA registration, distributed controlled substances to an individual not registered with the DEA, exported controlled substances to fulfill prescriptions for underage patients, and failed to keep complete and accurate records.

The Evidence

Stipulations of Fact

The Government and the Respondent have agreed to the below stipulations, which I recommend be accepted as fact in these proceedings: [2]

(1) OakmontScript Limited Partnership (''OakmontScript'') [was] registered with the DEA as a distributor licensed to handle controlled substances within Schedules II–V under DEA COR No. RO0504680 (''Distributor COR'') at 1500 District Ave., Burlington, MA 01803–5069. DEA COR No. RO0504680 was first issued on October 7, 2016. [Respondent surrendered both registrations on December 22, 2021, therefore terminating these registrations.*[D] Omitted.]

(2) OakmontScript is registered with the DEA as an exporter licensed to handle controlled substances within Schedules II–V under DEA COR No. RO0527082 (''Exporter COR'') at 1500 District Ave., Burlington, MA 01803–

*[A] [This footnote has been relocated from RD n.1.] OakmontScript filed its Request for Hearing *pro se,* represented by Jufang (''Shirley'') Shi, its President and Chief Pharmacist. In the Order for Prehearing Statements issued by the tribunal on November 19, 2020, the tribunal advised the Respondent of its right under 21 CFR 1316.50 to seek representation by a qualified attorney at the Respondent's own expense. ALJ Ex. 3 at 1. At the Prehearing Conference held on January 5, 2021, this tribunal reiterated to the Respondent's representative the Respondent's right to obtain counsel. The Prehearing Ruling also discussed the Respondent's right to obtain counsel. ALJ Ex. 7 at 1 n.1.

*[B] I have made minor, nonsubstantive, grammatical changes to the RD and nonsubstantive conforming edits. Where I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the ALJ's opinion, I have noted the edits in brackets, and I have included specific descriptions of the modifications in brackets or in footnotes marked with an asterisk and a letter. Within those brackets and footnotes, the use of the personal pronoun ''I'' refers to myself—the Administrator.

*[C] I have omitted the RD's discussion of the procedural history to avoid repetition with my introduction.

[1] [Footnote relocated, *see supra* n.*A.]

[2] The parties agreed to the following stipulations at the Prehearing Conference held on January 5, 2021. ALJ Ex. 7 at 2–3. The parties did not file any further Joint Stipulations.

*[D] On January 3, 2022, I was notified by the Office of Administrative Law Judges that Respondent had surrendered its distributor and exporter registrations by submitting two DEA–104 surrender forms signed by Respondent's representative, Jufang Shi. Pursuant to DEA regulations, Respondent's registrations terminated on the day of the surrender, and Respondent is no longer authorized to distribute or export controlled substances under federal law. 21 CFR 1301.52 (''[T]he registration of any person . . . shall terminate, without any further action by the Administration, if and when such person . . . surrenders a registration.'') On January 20, 2021, the Government filed a letter informing me of Respondent's surrender. However, notably the Government did not request that I dismiss this matter.

Although Respondent's registrations have terminated, the Agency has discretion to adjudicate this Order to Show Cause to Finality. *See Jeffrey D. Olsen, M.D.,* 84 FR 68,474, 68,479 (2019) (declining to dismiss an immediate suspension order as moot when the registrant allowed the subject registration to expire before final adjudication); *Steven M. Kotsonis, M.D.,* 85 FR 85,667, 85,668–69 (2020) (concluding that termination of a DEA registration under 21 CFR 1301.52 does not preclude DEA from issuing a final decision on an order to show cause against that registration and stating that the Agency would assess such matters on a case-by-case basis to determine if a final adjudication is warranted or if the matter should be dismissed); *The Pharmacy Place,* 86 FR 21,008, 21,008–09 (2021) (adjudicating to finality a registration terminated under 21 CFR 1301.52 in order to create a final record of allegations and evidence related to the matter); *Creekbend Community Pharmacy,* 86 FR 40,627, 40,628 n.4 (2021) (same).

As in *The Pharmacy Place* and *Creekbend,* I have evaluated the particular circumstances of this matter and determined that the matter should be adjudicated to finality. 86 FR at 21,008–09; 86 FR 40,627, 40,628 n.4. As my predecessor identified in *Olsen,* ''[b]ecause nothing in the CSA prohibits an individual or an entity from applying for a registration even when there is . . . a history of having a registration suspended or revoked. . . . having a final, official record of allegations, evidence, and the Administrator's decisions regarding those allegations and evidence, assists and supports future interactions between the Agency and the registrant or applicant.'' 84 FR at 68,479. Here, absent a final adjudication, there would be no final record of the allegations and evidence from this matter. (*Contrast with Kotsonis* in which the plea agreement and judgment from the respondent's concurrent criminal case provided a final record on which the Agency could rely in any future interactions with the respondent. 85 FR at 85,667). Adjudicating this matter to finality will create an official record the Agency can use in any future interactions with Respondent's owners, employees, or other persons who were associated with Respondent. Moreover, as in *The Pharmacy Place* and *Creekbend,* ''adjudicating this matter to finality will create a public record to educate current and prospective registrants about the Agency's expectations regarding the responsibilities of registrant pharmacies under the CSA and allow stakeholders to provide feedback regarding the Agency's enforcement priorities and practices.'' 86 FR 21,008–09 (applying *Olsen,* 84 FR 68,479); 86 FR 40,627, 40,628 n.4 (same).

It is noted that I recognize the importance of the parties' ability to request dismissal of a case, even after it has been forwarded to me for final adjudication. However, because surrenders are unilaterally submitted by the Respondent, without explicit instructions from both parties, I cannot assume the intent of a surrender is to dismiss the case. In this case, I assume that the Government has determined that a final decision on the merits will further DEA's adjudicatory efforts and law enforcement goals, because its letter to me regarding the surrender significantly omits any indication otherwise.

5069. DEA COR No. RO0527082 was first issued on December 5, 2017. It will expire by its terms on December 31, 2021.[3]

(3) OakmontScript has a Controlled Substance Registration, #MA0092875, as a Drug Distributor for Schedules II–V with the Commonwealth of Massachusetts, Department of Public Health, Drug Control Program.

(4) Dr. Jufang ''Shirley'' Shi is OakmontScript's general partner, owner, and Resident Agent. She also serves as its Managing Director, President, and Chief Pharmacy Officer.

(5) Dr. Shi is New England Executive Care Limited Partnership's (''NEEC'') Resident Agent.

(6) Dr. L.W. is NEEC's General Partner. Dr. L.W. also has served as a consultant with OakmontScript. He has acted as OakmontScript's supervisory physician. He was employed by OakmontScript on an as-needed basis.

(7) On or about September 16, 2016, DEA conducted a pre-registration investigation of OakmontScript's then application for a distributor registration.

(8) On or about June 22, 2017, DEA conducted a pre-registration investigation of OakmontScript's then application for an exporter registration.

(9) On or about July 26, 2018, DEA conducted an on-site inspection for OakmontScript's Distributor COR at OakmontScript's registered location pursuant to a Notice of Inspection.

(10) In or around January, 2017, OakmontScript falsified a print out of its DEA Distributor COR in order to set up a customer account with another company, Pharmacy Buying Association (''PBA''). Specifically, OakmontScript's DEA registration was altered so that the word ''Distributor'' was replaced with the word ''Pharmacy'' under the Business Activity section of the registration.

(11) OakmontScript employed an intern from January 1, 2017, to February 2018.

(12) Diazepam (brand name ''Valium'') is a Schedule IV controlled substance benzodiazepine class drug, commonly used to treat anxiety, muscle spasms, and seizures.

(13) Briviact is the brand name for brivaracetam, a Schedule V controlled substance commonly used to treat seizures.

(14) Belviq is the brand name for lorcaserin, a Schedule IV controlled substance commonly used to control appetite.

(15) Lyrica is the brand name for pregabalin, a Schedule V controlled substance commonly used to treat nerve and muscle pain and seizures.

(16) Clobazam (brand names include ''Sympazan'' and ''Onfi'') is a Schedule IV controlled substance benzodiazepine class drug that is commonly used to control seizures.

(17) Lunesta is the brand name of eszopiclone, a Schedule IV controlled substance that is commonly used as a sedative.

The Government's Case

The Government's case consisted of testimony from three witnesses: (1) Diversion Investigator (''DI'') 1, (2) DI 2, and (3) DI 3. Below is a summary of the testimony of these witnesses.[4]

DI 1

DI 1 has been employed with the DEA for eighteen years. Tr. 35. For ten years, until 2010, she worked as a Registration Program Specialist in the New York Field Division where she reviewed applications and conducted background checks regarding registrants who applied for DEA registrations. Tr. 36–37. She currently serves as a DI in Boston where she does on-site inspections and educates applicants on the guidelines required by the Controlled Substances Act (''CSA''). Tr. 35, 37. She received a three-month training in Quantico and has worked on over eighty cases as a DI. Tr. 35, 37–38. She is familiar with DEA regulations and the CSA. Tr. 38.

In August 2016, DI 1 was assigned as the lead investigator to the Respondent's first DEA application as a distributor, which was ultimately assigned COR No. RO504680. Tr. 38–39, 43. On September 16, 2016, DI 1 coordinated with the Massachusetts Department of Health, through a Senior Investigator, to conduct an on-site inspection of OakmontScript. Tr. 44–45. During the inspection, DI 1 met with OakmontScript's Dr. Shi and L.W. Tr. 44–45. Dr. Shi informed DI 1 of her intention to potentially distribute controlled substances to international customers. Tr. 45–46. DI 1 explained to Dr. Shi that she would need to apply for a second DEA registration as an exporter, and to fill out a Form DEA–161, Application for Permit to Export Controlled Substances (''DEA Form 161''), and a Form DEA–236, Declaration of Exportation (''DEA Form 236''), which both apply to Schedule II–V controlled substances. Tr. 46–47. *But see* Tr. 94–95 (When questioned by the Respondent what schedule of controlled substances apply to a DEA Form 161, DI 1 stated ''I don't recall'' and when questioned regarding what controlled substances apply to a DEA Form 236 stated ''Schedule III through V.'').[5]

DI 1 had conversations with Dr. Shi explaining the term ''end-use statement,'' which is a statement that is provided by a pharmaceutical company or researcher stating the use of the drug. Tr. 47–49. DI 1 explained that an ''ultimate user'' is an individual that would use controlled substances for his or her own personal medical use and that some people use the term ''end user'' and ''ultimate user'' interchangeably. Tr. 49–50. DI 1 further explained that ''ultimate user'' and ''end user'' are different from the ''end-use statement,'' which is something that is ''more for a business . . . a company for research purposes'' and is documented in writing. Tr. 50.

DI 1 also discussed record-keeping requirements with Dr. Shi, including the requirement to create an initial inventory of controlled substances she has on site after her application is approved. Tr. 50. She explained that Dr. Shi needed to create a biennial inventory every two years, not to commingle records from her distributor registration and any future exporter registration, and to maintain records for two years. Tr. 50–51. As of April 28, 2017, DI 1's understanding was that OakmontScript had not exported any controlled substances, which was based on an email from OakmontScript stating ''we do not have any executed controlled items to report during last two quarters.'' Tr. 61; Gov't Ex. 4.

OakmontScript first applied for an exporter registration with the DEA in April of 2017. Tr. 60. At some point, OakmontScript submitted a second exporter application.[6] Tr. 62. Because the first exporter application was still pending action by DEA, DI 1 contacted Dr. Shi to inquire why she had filed a second exporter application, to which Dr. Shi responded that she wanted to import, not export. Tr. 62. Therefore, DI

[3] The parties agreed during the Prehearing Conference that since the filing of the Government's Prehearing Statement, DEA COR No. RO0527082 was renewed and [was] due to expire [again] on December 31, 2021.

[4] I do not make any findings of fact in these summaries. Any facts necessary for a disposition of this case are set forth in the Analysis section of this Recommended Decision.

[5] The tribunal admitted a blank DEA Form 236 with instructions as Government Exhibit 47. For ''Type of Declaration'' the form includes a check box for export of ''Non-narcotic substances in Schedules III or IV and all substances in Schedule V,'' but does not have a check box for Schedules I or II. Gov't Ex. 47 at 1. The instruction page for the form states that its purpose is ''[t]o obtain information regarding the importation of nonnarcotic substances in Schedules III, IV, and V and the exportation of nonnarcotic substances in Schedules III and IV and all substances in Schedule V.'' Gov't Ex. 47 at 2.

[6] OakmontScript first applied for an exporter registration for Schedules III, IV, and V in April 2017 and then later requested Schedule II. Tr. 114, 115, 117.

1 contacted DEA Headquarters and had the second exporter application converted into an importer application. Tr. 62–63. The second exporter application, which was converted to an importer application, was ultimately withdrawn. Tr. 63.

On June 22, 2017, Mr. L.U. sent DI 1 an email requesting that Schedule II be added to the existing exporter application and DI 1 added this request for Schedule II to the exporter application on OakmontScript's behalf. Tr. 74–76; Gov't Ex. 50. DI 1 and the Senior Investigator from the Department of Health conducted a pre-registration inspection of OakmontScript for its exporter application on June 22, 2017. Tr. 69–71. They discussed with Dr. Shi security and record-keeping requirements including creating an initial inventory and maintaining records for at least two years. Tr. 71–72. DI 1 also discussed the importance of maintaining the DEA Form 161s and DEA Form 236s as well as the enduse statements. Tr. 72–73. DI 1 also instructed Dr. Shi that records must be kept separate for separate registrations. Tr. 73. It was DI 1's understanding that OakmontScript had not exported or distributed any controlled substances. Tr. 70–71. At this inspection, DI 1 also noted that OakmontScript's safe was not connected to an alarm system, which was a security concern because OakmontScript was storing Schedule II drugs, which have a higher security standard. Tr. 77, 78.

On September 1, 2017, DI 1 went back to OakmontScript for a return visit to test the safe's alarm after being notified by OakmontScript that the alarm would be professionally installed on August 30th. Tr. 80–81, 83. On this visit, DI 1 found no issues with the alarm. Tr. 83. However, at this time, DI 1 noted that OakmontScript should obtain a larger-sized safe pending the approval of its exporter application, which she communicated to OakmontScript on September 6, 2017. Tr. 84–85. DI 1 had a third visit on September 22, 2017, when she observed that OakmontScript purchased a larger safe and DI 1 tested the security system. Tr. 85–86.

Sometime in October 2017, DI 1's supervisor informed her that OakmontScript added over 170 drug codes to its exporter application, which DI 1 thought to be an excessive amount of drug codes because OakmontScript had previously stated that it was only intending to export small amounts of Oxycodone. Tr. 86–87, 96–97, 100. DI 1 testified that a drug code ''is a code that's assigned . . . to a controlled substance for identification purposes for individuals or pharmaceutical companies who are engaging in manufacturing, exporting, importing or distributing controlled substances.'' Tr. 86. DI 1 brought this issue to Dr. Shi's attention on November 17, 2017, and Dr. Shi stated that she had to select the drug code for each controlled substance on the web page in order to move to the next screen in the application process. Tr. 87–88. DI 1 worked with Dr. Shi, walked her through modifying the application, and eventually Dr. Shi applied for five drug codes. Tr. 88–89.

On December 5, 2017, DEA COR No. RO0527082, an exporter registration, was assigned to OakmontScript. Tr. 90–91; Gov't Ex. 1B. DI 1 had no indication that OakmontScript had exported any controlled substances prior to this approval date. Tr. 91–92.

DI 1's testimony included a discussion of the investigation of OakmontScript's first DEA application as a distributor, COR No. RO0504680, OakmontScript's two applications for exporter registrations, OakmontScript's request to add Schedule II to its exporter application, and OakmontScript's withdrawn importer application.

Throughout her testimony, DI 1 was generally consistent, genuine, and credible.[7] As a public servant, DI 1 has no personal stake in the revocation of the Respondent's registrations. There was no indication during her testimony that she had any animus against OakmontScript or any of its employees. I therefore find her testimony to be entirely credible and it will be afforded considerable weight.

DI 2

DI 2 received a bachelor's degree in political science from the College of Charleston and worked as a paralegal for several years prior to joining the DEA. Tr. 124. She received a twelve-week training in Quantico when she became an investigator. Tr. 125.

She has been employed as a DI for the DEA for approximately three years and works in the Boston Field Office. Tr. 124. As a DI, she ensures that DEA registrants are abiding by the DEA rules and regulations and the CSA to ensure there is no diversion of controlled substances from the point of manufacture to the end user. Tr. 125, 126. She has worked as a lead investigator on approximately twenty to thirty investigations. Tr. 125–26.

DI 2 first became familiar with OakmontScript on July 26, 2018, when she met Dr. Shi to conduct an inspection regarding OakmontScript's distributor registration.[8] Tr. 126–27, 128. DI 2 conducted an alarm test, performed a closing inventory, and reviewed OakmontScript's records. Tr. 130. DI 2 noted two issues with OakmontScript's record-keeping: (1) Commingling records by keeping some of its distributor records with its exporter records[9] and (2) a lack of any transfer documents showing the transfer of controlled substances between the distributor and exporter registrations. Tr. 131–33, 136. After she identified these issues, she discussed them with Dr. Shi and Dr. Shi stated that she understood and would not commingle records in the future. Tr. 133.[10] As to the transfer documents, Dr. Shi created a template form that she stated she would use in the future. Tr. 133. DI 2 was not aware that OakmontScript had any inconsistencies with its records relating to exports and did not receive any documents indicating that OakmontScript had exported controlled substances before receiving its exporter registration. Tr. 134.

DI 2's testimony was limited to a one-time inspection of OakmontScript's distributor registration. As a public servant, DI 2 has no personal stake in the revocation of the Respondent's registrations. There was no indication during her testimony that she had any animus against OakmontScript or any of its employees. I therefore find her testimony to be entirely credible and it will be afforded considerable weight.

DI 3

Background

DI 3 received her bachelor's degree in business administration in 2015. Tr. 143. Prior to working with the DEA, she was working with the Department of the Army in California, where she mainly conducted background investigations. Tr. 143. She was then promoted to a headquarters position in Detroit, Michigan, where she worked until 2017,

[7] DI 1 explained to Dr. Shi that she would need to apply for a second DEA Registration as an exporter, and to fill out a DEA Form 161 and a DEA Form 236, which both apply to drug schedules II–V. Tr. 46–47; *but see* Tr. 94–95 (When questioned by the Respondent what schedule of controlled substances apply to a DEA Form 161, DI 1 stated, ''I don't recall,'' and when questioned regarding what controlled substances apply to a DEA Form 236, she stated, ''Schedule III through V.'') [I find these statements to be confusing and inconsistent, but not to detract from the overall credibility of DI 1].

[8] Dr. Shi consented to this inspection. Tr. 128–29; *See* Gov't Ex. 6.

[9] DI 2 noted that OakmontScript was required to do an inventory for its distributor registration and its exporter registration and keep separate records for each registration. Tr. 138–39.

[10] DI 2 did not ''believe [Dr. Shi] knew about the commingling but once corrected, she understood.'' DI 2 further believed that Dr. Shi thought that transfer documents were only required for Schedule II drugs. Tr. 133–34.

when she was hired by the DEA. Tr. 143. She received a twelve-week training in Quantico at the DEA Academy and had six months of on-the-job training with a field investigator. Tr. 144–45. She received her master's degree in public policy in February 2021. Tr. 143.

DI 3 currently works as a DI for the DEA in the New England Field Division, in Boston, Massachusetts. Tr. 141–42. She has been a DI for three years. Tr. 142. As a DI, she investigates the diversion of controlled substances from licit channels to illicit channels by conducting investigations including completing accountability audits, reviewing records, testing security, and conducting on-site inspections. Tr. 143–44. She has led approximately seventy investigations and assisted on thirty. Tr. 145. She is familiar with the CSA and her job is to ensure public safety. Tr. 145, 766.

OakmontScript Assignment

DI 3 became familiar with OakmontScript in fiscal year 2019 when she was assigned to conduct an in-depth cyclical investigation of OakmontScript's exporter registration. Tr. 145–46. DI 3 reviewed OakmontScript's articles of limited partnership, with a date of organization of May 27, 2016, which indicate that Dr. Shi is the general partner and resident agent of OakmontScript. Tr. 146–49. Dr. Shi had explained to DI 3 that OakmontScript's business model was to procure controlled substances to export to foreign pharmaceutical companies for reverse engineering, so the companies can break down the controlled substance to recreate it. Tr. 150, 151, 760.

New England Executive Care (''NEEC'') is an entity with a date of organization of May 10, 2018, with Dr. Shi listed as its resident agent and Dr. L.W. and Dr. Donghui Yu listed as the general partners and it has some type of relationship with OakmontScript. Tr. 152–54. DI 3 is still unclear what NEEC's business model is and its full connection to OakmontScript. Tr. 155. Dr. L.W. is a consulting physician for OakmontScript and reviews patients' medical records and possibly prescriptions to determine if the drug being exported is appropriate for the patients' treatment. Tr. 155, 620–21.

February 19, 2019 Inspection

DI 3, DI 1, and DI 4, conducted an inspection of OakmontScript on February 19, 2019, and began their investigation by showing Dr. Shi their credentials and presenting a Notice of Inspection, which Dr. Shi signed. Tr. 156–58; Gov't Ex. 7. They discussed recordkeeping and the DIs explained that they would be conducting a controlled substance accountability audit.[11] Tr. 159.

The initial inventory date was February 19, 2018, and based on OakmontScript's self-reporting that it did not have any substances on hand, the initial count was a zero balance. Tr. 167, 763. According to the closing inventory dated February 19, 2019, which was signed by DI 3, DI 4, and a representative from OakmontScript, OakmontScript did not have any of the eight controlled substances the DIs chose to audit on that date. Tr. 159–60; Gov't Exs. 8, 9.

DI 3 also discussed drug codes[12] with Dr. Shi and it is standard practice for her to discuss what drug codes a registrant is authorized to handle and whether the registrant is handling any other drug codes. Tr. 175–76, 597.[13] DI 3 had accessed the DEA registration system and made a list of drug codes that OakmontScript was authorized to handle, and asked OakmontScript what drugs codes it was handling.[14] Tr. 183; Gov't Ex. 11. Dr. Shi reported there were no other drug codes that OakmontScript was exporting or handling other than what DI 3 listed and that there were two drug codes OakmontScript was no longer handling. Tr. 189, 598, 889.

[11] The accountability audit is a fixed moment in time when the registrant has conducted a physical hand count of any controlled substances it has on hand and the DIs include anything the registrant has purchased or transferred. Tr. 165–66. The DIs then take a closing inventory based on what has been distributed, dispensed, etc. Tr. 166.

[12] A drug code, or Administrative Controlled Substance Code Number, is a four-digit code that is assigned to each controlled substance and certain DEA registrants are allowed to handle only specific drug codes for which they have been approved. Tr. 169, 868. For example, a DEA registrant who is an exporter is only able to purchase and export controlled substances for which it has an authorized drug code and cannot engage in exporting drugs for which it does not have the necessary drug code. Tr. 176–77. When exporting drugs, the registrant needs to report the drug codes in an export declaration, such as a DEA Form 236, to include the drug code, strength, quantity, shipping destination, shipping origin location, the anticipated date it is being released, the anticipated date it should arrive, and the drug's intended use. Tr. 178.

[13] Dr. Shi asked DI 3 questions during her direct examination that led to a discussion about drug codes OakmontScript had requested in December 2020. Tr. 880–88. These discussions are not part of the Order to Show Cause that is the subject of the proceedings before this tribunal.

[14] If a registrant wants to make a change to its registration, including adding or removing drug codes, it may request a modification of registration online or contact the local DEA office by email or phone, and adding drug codes can be approved at the field level, but may require further inspection. Tr. 273–74, 800, 874–75, 876. There is no uniform guidance on how the DEA handles a request for adding or removing a drug code. Tr. 879.

Although the closing inventory was good because ''it tied out to zero,'' there were issues with OakmontScript's recordkeeping, including a failure to take an initial inventory, and there were also issues with the alarm system. Tr. 190, 192. DI 3 discussed these issues with her group supervisor and her group supervisor asked her to return to OakmontScript to conduct an alarm test and conduct an expanded controlled substance accountability audit going back to December 5, 2017, which is when OakmontScript first received its DEA exporter registration. Tr. 192–93.

March 29, 2019 Inspection

On March 29, 2019, DI 3 completed another inspection with DI 5 and the audit did not show any discrepancies. Tr. 195–97. Dr. Shi provided a pack of additional documents to DI 3 and stated that she was having problems filing the DEA Form 236 for OakmontScript's exports. Tr. 198–201; Gov't Ex. 12. After reviewing these documents, DI 3 determined that OakmontScript was having issues with the DEA Form 236 because OakmontScript did not have the authority to export the controlled substances as it did not have the appropriate drug codes in its registration for most of the drugs. Tr. 201. Therefore, OakmontScript was unable to select the drug codes from the online drop-down box in the DEA Form 236. Tr. 201–02, 613. Despite being unable to fill out the DEA Form 236, Dr. Shi ''exported them anyways'' and she did not think ''it was a big deal.'' Tr. 204. Ultimately, DI 3 found that OakmontScript had violated the CSA by not filling out the DEA Form 236s, by exporting drugs prior to holding its exporter registration,[15] and exporting drugs it did not have authorization to handle. Tr. 205.

Follow-Up to March 29, 2019 Inspection

On April 23, 2019, DI 3 had a phone call with Dr. Shi and requested a detailed list of exports OakmontScript had conducted because it was apparent that OakmontScript had exported a lot more than what Dr. Shi had previously stated. Tr. 206. DI 3 also discussed a fraudulent DEA registration. Tr. 206. During this discussion, Dr. Shi stated that OakmontScript had conducted its first export in May or June of 2017. Tr. 206.

After the April 23, 2019 phone call, DI 3 and Dr. Shi had an email exchange in which Dr. Shi continued to provide conflicting information, so DI 3 asked

[15] DEA registrants are required to provide the proximate date of export and to provide return information within thirty days. Tr. 759–60; *See* Gov't Ex. 47; 21 CFR 1304.22(d).

for further clarifying information. Tr. 208–21. *See* Gov't Exs. 16, 17, 18, 19, 20. After reviewing the several documents Dr. Shi emailed, DI 3 noted several issues, including that OakmontScript was not keeping complete and accurate records related to its controlled substance transactions, was unable to complete the DEA Form 236s, and was creating shipping labels well in advance of dropping off the controlled substances with the common carrier for shipment. Tr. 222–24; Gov't Exs. 16, 17, 18, 19, 20 at 9 (Dr. Shi responded to an email from DI 3 and indicated that the shipping label for an export of Belviq was ''created on date of 10/13/2017, but drop-off on later date while waiting for receiving party get ready for custom clearance.'').

May 8, 2019 Inspection

DI 3 served two administrative subpoenas on OakmontScript with DI 5 on May 8, 2019, that were issued based on the serious violations that DI 3 discovered since conducting her initial inspection on February 19, 2019.[16] Tr. 235–40; Gov't Ex. 24.[17]

OakmontScript kept track of each controlled substance it exported or distributed by assigning a purchase order number, usually starting with ''OKS-'' and followed by a series of numbers. Tr. 242. At the inspection, Dr. Shi provided DI 3 a large packet that was divided into smaller bundles by invoice, that DI 3 later may have reordered chronologically, but she did not remove or add any pages to the stack. Tr. 243–48, 709, 794–95; *See* Gov't Ex. 26. DI 3 discussed with Dr. Shi OakmontScript's exports for direct patient use, including a shipment of clobazam that was potentially sent to an underage patient, a fraudulent DEA registration, and OakmontScript's relationship with NEEC. Tr. 256.

May 13, 2019 Inspection

On May 13, 2019, DI 3 and DI 5 performed another inspection. Tr. 268. DI 3 discussed various topics with Dr. Shi, including a detailed discussion of all the violations DI 3 uncovered. Tr. 268–69. Prior to this visit, DI 3 had also reached out to DEA Headquarters to verify whether OakmontScript had properly completed DEA Form 236s for its exports. Tr. 269–70; Gov't Ex. 48.

Alteration of Distributor Certificate of Registration

A registrant receives a hard-copy certificate of registration, which is an official government document, based on DEA approval to hold a registration, which includes the company's or individual's name, the registered location address, the registrant's DEA registration number, the business activity for which the entity is approved, and—for exporters, importers, and bulk manufacturers—the drug codes that they are approved to handle. Tr. 272–73.

DI 3 had been reviewing OakmontScript's case files and discovered that there was a report filed by the Kansas City District Office of the DEA, naming OakmontScript as fraudulently creating a DEA registration. Tr. 275. OakmontScript had altered its distributor registration to indicate that it was a pharmacy and submitted it to Pharmacy Buying Association (''PBA'').[18] Tr. 275. PBA has a DEA registration and DI 3 spoke to one of PBA's Regulatory Compliance Team Leaders, B.W., and received email correspondence from B.W. that noted PBA ''only sell[s] to pharmacies'' and it does not ''sell to other distributors.'' Tr. 275–78; Gov't Ex. 55. PBA also requires customers to send a copy of their state pharmacy license and a copy of their DEA registration when they send in their account application. Tr. 278; Gov't Ex. 55. B.W. further noted that OakmontScript sent PBA a DEA registration indicating it was a pharmacy and after PBA performed its due diligence, PBA discovered that the document was altered. Tr. 278; Gov't Ex. 55. PBA reported OakmontScript and denied OakmontScript's account. Tr. 278; Gov't Ex. 55.

The DEA registration OakmontScript provided to PBA listed its business activity as ''pharmacy,'' even though the COR of RO0504680 corresponded to OakmontScript's distributor registration. Tr. 286; Gov't Exs. 14, 55. Dr. Shi took responsibility for the falsified registration. Tr. 290–93.

On April 23, 2019, DI 3 discussed the falsified registration with Dr. Shi on the phone. Tr. 293. Dr. Shi stated that she had hired an intern and Dr. Shi instructed the intern to establish relationships with OakmontScript's competitors to determine how they conduct business. Tr. 293–94. After PBA refused to establish a relationship with OakmontScript, the intern altered the DEA registration to list OakmontScript as a pharmacy. Tr. 294; Gov't Ex. 14. During this phone call, Dr. Shi indicated to DI 3 that she had fired the intern as a result of this incident. Tr. 294. However, in an email dated April 24, 2019, Dr. Shi indicated that the intern moved back to China and her employment dates were January 1, 2017, to February 2018. Tr. 297; Gov't Ex. 20 at 13. The phone conversation and email were therefore in ''direct conflict'' and it appeared that the intern had not been fired for falsifying the registration. Tr. 297–98. Dr. Shi also texted information regarding this incident in May 2019 where she said if the incident regarding the falsified registration ''constitutes any offensive sort, 'I' should take responsibility. If any actions taken toward, please address to me directly.'' Tr. 300–01; Gov't Ex. 29.

DI 3 had a follow-up inspection on May 13, 2019, and asked Dr. Shi why the intern's employment dates seemed to span an additional year after the date of the fraudulent DEA registration. Tr. 301–02. Dr. Shi stated that she had ties with the intern's family, who she felt had pressured her to keep the intern employed. Tr. 302. Dr. Shi also explained that the intern had come to her and explained that PBA would not ''do business with them because they viewed OakmontScript as a competitor'' and Dr. Shi had told the intern to ''do whatever is needed'' and to ''[g]ive them basically whatever they want in order to establish this . . . client relationship with them.'' Tr. 303. DI 3 was never able to contact the intern to discuss this violation with her. Tr. 304. OakmontScript was not able to obtain controlled substances from PBA. Tr. 304.

In this instance, DI 3 found that Dr. Shi had exhibited a lack of candor [19] because Dr. Shi initially stated that the intern had been fired and later stated the intern had not been fired, but maintained a position at OakmontScript and actually left the country and her

[16] At the May 8, 2019, meeting, DI 3 also discussed the Letter of No Objection (''LONO'') and that she had learned from someone at DEA Headquarters that a LONO must come from a foreign national government and not from a provincial or state-level government. Tr. 889–91, 893, 895–96, 910–11, 1432–33. A LONO is provided by the importing country stating that it has no objection to a controlled substance being imported into that country. Tr. 910, 1431–32.

[17] The tribunal questioned DI 3 regarding markings on the administrative subpoenas. Tr. 790–91; Gov't Ex. 24. DI 3 stated that the various check and dash marks made on the front pages of the subpoenas were made by OakmontScript. Tr. 790. DI 3 further explained that when she had served the subpoenas, she had not made scanned copies that were hand-signed by the diversion program manager and these were copies that were provided by OakmontScript. Tr. 790–91.

[18] PBA is a distributor of controlled substances and non-controlled substances that only sells to pharmacies. Tr. 275, 1444; *See* Gov't Ex. 55.

[19] Upon direct questioning by the tribunal, DI 3 testified that Dr. Shi exhibited a lack of candor when she ''led me to believe that [the intern] had been fired for her actions related to that forged DEA registration'' and that in their conversation Dr. Shi did use the exact word ''fired.'' Tr. 792–93. DI 3 did not believe this was a simple mistake by Dr. Shi. Tr. 793.

position with OakmontScript because her visa had expired. Tr. 307, 788.

February 2020 Subpoena

DI 3 served another administrative subpoena on OakmontScript on February 28, 2020, and issued an administrative subpoena to NEEC after learning that Dr. L.W. was writing prescriptions for direct patient care at Dr. Shi's request.[20] Tr. 389–95; Gov't Exs. 37, 38.

In response to the subpoenas, David Schumacher sent a letter dated March 26, 2020, indicating he was an attorney representing OakmontScript and NEEC and that neither OakmontScript nor NEEC had any records that were responsive to the subpoena, but he did re-produce certain documentation to DI 3 and addressed certain questions DI 3 posed in a March 10, 2020 email. Tr. 397–98; Gov't Ex. 42. DI 3 followed up with questions to Mr. Schumacher in an April 14, 2020 email, and he subsequently sent an email to DI 3 on April 17, 2020, which responded to some of these questions. Tr. 402–03; Gov't Ex. 44. DI 3 sent her April 14, 2020, email to seek clarification regarding two identical prescriptions she identified for clobazam and what role they played in the export of this controlled substance. Tr. 405; Gov't Ex. 44.

Invoice OKS–00243 (Diazepam)

OakmontScript received diazepam, 10 milligram gel on May 16, 2017, from McKesson that appears to have been shipped by OakmontScript on June 10, 2017. Tr. 352–53, 366, 432; Gov't Exs. 12 at 14, 26 at 20.[21] However on other documentation, the shipping date is listed as May 18, 2017, and the client's name is listed as Par Pharmaceutical, an Endo International Company. Tr. 356, 1448; Gov't Ex. 17 at 3. In other documentation, the shipping date is listed as May 18, 2017, and the client is listed as Cangzhou People's Hospital. Tr. 357, 1449; Gov't Ex. 18 at 3. Furthermore, Dr. Shi sent an email to DI 3 on April 23, 2019, indicating that she was unsure of the exact date of export because the ''shipping label was not retrievable due to USPS system update'' and Ms. Liu has ''made edit in the date multiple times and she thought the proper date is on the date of payment. . . .'' Tr. 358–59, 386, 1449; Gov't Exs. 20 at 8, 28 at 22.[22] The ''ship to name'' is listed as H.H.[23] at Cangzhou People's Hospital in China and Dr. Shi's guess of the ''best possible date'' of shipment was the date of payment on May 18, 2017. Tr. 361–63, 1449–50; Gov't Ex. 21 at 9. The use was listed as ''for research'' and the ''bill to'' party was H.X.Z. at Par Pharmaceutical and the ship to party was Dr. H.H. at Cangzhou People's Hospital in China. Tr. 365, 435; Gov't Ex. 26 at 19.

One of the license transfer documents for this export indicates that the diazepam was transferred from OakmontScript's distributor registration to its exporter registration on May 7, 2018. Tr. 371–72, 435; Gov't Exs. 26 at 21, 28 at 77. A different license transfer document indicates that the date of transfer was May 20, 2017. Tr. 371, 436; Gov't Ex. 26 at 22.[24] Other documentation provided by OakmontScript states that the diazepam prescription was made based on a request from a family in China for Patient S.Z. and was shipped sometime in May 2019. Tr. 407–09; Gov't Ex. 44 at 1–2. OakmontScript was unable to complete a DEA Form 236 for this export.[25] Tr. 352–53; Gov't Exs. 12 at 14, 16 at 2.

DI 3 confronted Dr. Shi regarding this conflicting information at the on-site inspection on May 8, 2019. Tr. 363. Dr. Shi recalled that this diazepam had been shipped for direct patient use in China. Tr. 363–64. Dr. Shi stated that OakmontScript had to label the reason for export as ''research'' in order to get the shipment past Chinese Custom Officials and that the actual intended use of the diazepam was for direct patient use. Tr. 366, 1446.

DI 3 was also confused by documents provided by Dr. Shi because although they appeared to be the exact same documents—a prescription written in Chinese, a hospital's government licenses, and a doctor's medical license—these documents were provided in stacks for two different invoices. Tr. 380–83; Gov't Ex. 26 at 12–14, 30–32. Based on a translation that DI 3 ultimately obtained for these documents, DI 3 learned that both prescriptions were for diazepam. Tr. 383.

OakmontScript also failed to include a DEA Form 236 for this invoice, which it was required to do. Tr. 416–19. Furthermore, OakmontScript's distributor registration and exporter registration do not allow for OakmontScript to fill prescriptions, as such prescriptions may only be filled by a pharmacist. Tr. 420–23, 429; 21 U.S.C. 1306.06. OakmontScript also did not provide the information required under Section 3a or Section 3b of the DEA Form 236.[26] Tr. 418–19; Gov't Ex. 48. Based on the records, OakmontScript appears to have exported 10 milligrams of diazepam under invoice number OKS–00243 prior to obtaining its DEA exporter registration on December 5, 2017. Tr. 423–25, 1433, 1452.

Furthermore, invoice OKS–00243 did not provide the DEA registration of the doctor prescribing the controlled substance and the patient's home address. Tr. 430–31. *See* 21 CFR 1306.05(a).[27] DI 3 stated that this failure to provide the required information is a danger to the public because the information is needed to ensure registered practitioners are prescribing appropriately. Tr. 431.

Invoice OKS–00301 (Briviact)[28]

OakmontScript received 10 milligrams and 100 milligrams of

[20] As discussed *supra,* Dr. L.W. was listed as a general partner of NEEC. Tr. 154. Furthermore, based on Dr. Shi's statements, it was unclear to DI 3 as to what role NEEC was playing in OakmontScript's exports. Tr. 393–94.

[21] This McKesson invoice listed OakmontScript's address as 15 New England Executive Park. Gov't Ex. 26 at 20. Dr. Shi explained that this address and the 1500 District Avenue address (OakmontScript's current address) are the same address. Tr. 367. Dr. Shi stated that the whole area where OakmontScript is located got ''reorganized'' and OakmontScript's address changed, but OakmontScript never changed its physical location. Tr. 368.

[22] This was concerning for DI 3 because a registrant is required to know when it has conducted a transaction with a controlled substance and OakmontScript was unable to provide this information. Tr. 360.

[23] In the translated prescription, H.H. appears to be a doctor in China. Tr. 413; Gov't Ex. 45 at 4. DI 3 conducted a search within the DEA database and determined that Dr. H.H. did not have a DEA registration. Tr. 413–14.

[24] DI 3 indicated that ''it seems more likely . . . that this license transfer document from May 20, 2017, is the more likely of the two to be accurate,'' based on comparing the McKesson invoice that was dated in 2017. Tr. 436.

[25] This is noted as ''no XFER'' in the Excel spreadsheets in the documents provided by OakmontScript, which indicates that OakmontScript was not able to fill out a DEA Form 236 for a particular drug. Tr. 202.

[26] Section 3a of DEA Form 236 requires that, for exports, the exporter ''list the U.S. port of export (port name, city, state) from where the shipment departs the United States and the anticipated date it will depart.'' Gov't Ex. 47 at 1, 2. Section 3b of DEA Form 236 requires that, for exports, the exporter ''list the foreign port of import (port name, city, country) and the anticipated date it will arrive.'' Gov't Ex. 47 at 1, 2.

[27] The personal use exemption allows someone who is traveling across international boundaries to take a controlled substance with them and a third-party shipping a controlled substance overseas would not fall within a personal use exemption. Tr. 437–38.

[28] Throughout her testimony, DI 3 mentioned that there were several handwritten notes or post-it notes with writing on the certain documents, and that these notes were in the documents when they were presented to her by OakmontScript. Tr. 373. There was one instance, however, where DI 3 acknowledged that she had made a handwritten note. Tr. 375–76; Gov't 26 at 25. Specifically, she had written the word ''Par'' next to the ''Bill To'' line of this invoice. She also made handwritten notes in Government Exhibit 26 noting that the

Continued

Briviact on July 12, 2017, that were shipped in August 2017—four months prior to OakmontScript receiving its exporter registration. Tr. 440–57, 1433; Gov't Exs. 12 at 7, 20 at 8, 26 at 35–36, 27 at 2, 28 at 27.[29] However, in other documentation provided by OakmontScript, this OKS–00301 invoice is not included in what is supposed to be a list of all controlled substances OakmontScript has exported. *See* Gov't Ex. 18 at 3–4. In other documentation, the commercial invoice for invoice OKS–00301 indicates that this shipment occurred May 8, 2019, and the indicated use was listed as ''research.'' [30] Gov't Ex. 26 at 33, 34.

OakmontScript did not file a DEA Form 236 for this invoice because it was unable to do so. Tr. 443, 456–57; Gov't Exs. 20 at 8, 48. Dr. Shi claimed that OakmontScript did not need to make a declaration to Customs and Border Control as the value of the shipment was less than $2500. Tr. 443; Gov't Ex. 20 at 8.[31]

Invoice OKS–00315–1 (Belviq)

OakmontScript received 10 milligrams of Belviq on September 18, 2017, which was shipped on November 1, 2017, and OakmontScript was not able to file a DEA Form 236 for this prescription. Tr. 457–70; Gov't Exs. 12 at 3, 20 at 8,[32] 26 at 38–39, 27 at 2, 28 at 6. However, Belviq is omitted from two Excel spreadsheets that were provided to DI 3 by Dr. Shi, which were supposed to include all of OakmontScript's exports. Gov't Ex. 17 at 2–3, 18 at 3–4. Also, a different invoice provided by OakmontScript is dated September 18, 2017. Gov't Ex. 26 at 37. Another commercial invoice is dated May 8, 2019. Gov't Ex. 26 at 40. Based on the November 1, 2017, shipping date, OakmontScript exported this Belviq product approximately one month before it obtained its exporter registration. Tr. 470, 1433.

Invoice OKS–00315–2 (Lyrica)

This invoice included several strengths of Lyrica: 25 milligram, 50 milligram, 75 milligram, 100 milligram, 150 milligram, 200 milligram, 225 milligram, and 300 milligram tablets. Tr. 470.

OakmontScript purchased Lyrica on September 12, 2017, from American Pharma Wholesale and it was shipped sometime between November 17 through 21 of 2017 to Changzhou Pharmaceuticals in China and OakmontScript did not file a DEA Form 236 because it was unable to do so.[33] Tr. 470–83, 895; Gov't Exs. 12 at 9–10, 26 at 41–43, 27 at 2, 28 at 8, 78, 48. However, in other documentation provided by OakmontScript, Lyrica is not listed as an export. Gov't Exs. 17 at 2–3, 18 at 3–4. Furthermore, in other documentation, the invoice is dated August 2017. Gov't Exs. 26 at 44, 28 at 31. This shipment of Lyrica was shipped approximately one month prior to OakmontScript receiving its exporter registration. Tr. 483, 1433.

Invoice OKS–00108 (Belviq XR)

OakmontScript received Belviq on July 20, 2017, and shipped the same quantity of Belviq XR 20 milligrams on December 1, 2017. Tr. 483–95; Gov't Exs. 12 at 3; 26 at 45, 47, 27 at 2, 28 at 5, 19 (the shipping date is listed as December 1, 2017), 76 (the date OakmontScript transferred the Belviq from its distributor to exporter registration is listed as November 29, 2017). However, in other documentation provided by OakmontScript, Belviq is not listed as an export. Gov't Exs. 17 at 2–3, 18 at 3–4. In other documentation provided by OakmontScript, the shipping label for this invoice was created on October 13, 2017, and the customer was listed as Jiangsu Alicorn Pharmaceutical Co. Ltd in China. Gov't Ex. 20 at 9. There are also various dates included in the ''Import Drugs Approval Notice'' including February 16, 2017 and February 15, 2018. Gov't Ex. 26 at 46; Tr. 489. The packing list that OakmontScript provided is dated May 8, 2019. Gov't Ex. 28 at 19. OakmontScript did not file a DEA Form 236 for this export. Tr. 494. Regardless of whether the shipment was exported on December 1, 2017 or October 13, 2017, this shipment would have been exported prior to OakmontScript obtaining its exporter registration. Tr. 495, 1433.

Invoice OKS–00650 (Lunesta)

OakmontScript received Lunesta in May 2018 and shipped the Lunesta to Disha Pharmaceutical Group on May 21, 2018. Tr. 499–535; Gov't Exs. 12 at 17, 17 at 3, 18 at 3, 28 at 94. The Lunesta was shipped to Mr. Z.Y. at an address in the United States in Kearny, New Jersey. Tr. 1455; Gov't Ex. 22 at 10–11. Another document for this export that is dated May 3, 2017, states that this shipment was shipped to P.Z. in New Jersey. Tr. 515, 522–23; Gov't Ex. 26 at 87.

Upon further investigation, DI 3 realized that this was a domestic distribution or distributing to a registrant in the United States, as opposed to an export. Tr. 508, 510, 529, 533, 904–05; Gov't Exs. 22 at 10–11, 26 at 88, 89, 92, 27 at 3, 28 at 66, 67, 68. OakmontScript did not fill out a DEA Form 236 for this export. Tr. 500–01.

A distributor is not permitted to distribute controlled substances to an ultimate user and there is no coincidental activity that permits a distributor to provide controlled substances to non-DEA individuals or persons or companies. Tr. 511–12, 723. Distribution occurs between registrants while dispensing would take place through a prescription being filled by a pharmacy after a practitioner prescribes a controlled substance. Tr. 513.

DI 3 discussed this invoice with Dr. Shi. Tr. 513–14. Dr. Shi stated that she was provided a business card showing that Mr. Z.Y. was an employee of Disha Pharmaceutical Group, a pharmaceutical company in China, and that he was getting ready to move to China and asked that the Lunesta be shipped to his home address in New Jersey, and paid via personal payment. Tr. 514, 516, 531, 534–35. This invoice indicates that the ''bill to'' party was Disha Pharmaceutical Group. Tr. 530–31; Gov't Ex. 28 at 44. Dr. Shi had explained that Larry Yu, a colleague she had met at a conference, had requested the Lunesta for RefDrug and asked Dr. Shi to send the Lunesta to Mr. Z.Y. to

scanned documents were a ''Hospital's Central Gov. License,'' ''Doctor's Medical License,'' and a ''Prescription.'' Tr. 380–81; *See* Gov't Ex. 26 at 12, 14.

[29] This exhibit is titled as ''Customer End-Use Certification.'' Gov't Ex. 28 at 27; Tr. 453. An exporter is expected to know what the controlled substances it is exporting are being used for and this form includes questions regarding this use. Tr. 453–54. This is not a form created by the DEA, but rather a form ''the industry has come up with'' in order to meet the standards set forth in the Code of Federal Regulations. Tr. 454.

[30] DI 3 discussed the fact that the Respondent asserted in its prehearing statement that there was an Excel macro that affected some of the dates on OakmontScript's documents. Tr. 574. In this instance, the document is dated May 8, 2019, which was the date of one of DI 3's inspections. Tr. 575. Therefore, this could account for the incorrect date listed in this invoice. DI 3 stated that she became aware of the macro issue after the May 8, 2019 inspection, but OakmontScript never specifically brought this to her attention during her investigation. Tr. 1439–40. If DI 3 had been made aware of this issue at the time, she would have worked with OakmontScript to obtain the most accurate records. Tr. 1440–41.

[31] An ultimate user is the individual who will be ingesting the controlled substance or providing it for a pet's use, while an end-use certification addresses what the controlled substance is being used for and if it is going to be re-exported. Tr. 454–55.

[32] In response to DI 3's email, Dr. Shi sent a reply email stating that per the DHL shipping label, the shipment was made by a custom broker, Hangzhou Junyuan Meditech, LLC and the end-user is Changzhou Pharmaceuticals with an address in China, but no export date was provided. Tr. 461–62.

[33] DI 3 later testified that OakmontScript did submit a DEA Form 236, but it was subsequently cancelled. Tr. 909.

have him provide it in China as Dr. Yu was not able to acquire it. Tr. 515–16.

Dr. Shi confirmed for DI 3 that OakmontScript had purchased this Lunesta with its distributor registration and then distributed it to Mr. Z.Y. at his home address in New Jersey, which DI 3 testified was improper. Tr. 517–18. Dr. Shi did not believe that this incident was a violation and stated that because Disha Pharmaceutical Group was the end-user of this controlled substance that it did not have to be licensed or registered with the DEA to obtain this controlled substance. Tr. 518. In contrast, DI 3 believed that Disha was not the end-user or ultimate user [34] because it was seeking the Lunesta in order to conduct research as opposed to using it for personal medical use. Tr. 518–19, 772–73.

DI 3 conducted searches to see whether certain parties in this transaction had a DEA registration. Tr. 545. She conducted a search for Mr. Z.Y., RefDrug, Inc., L.Y., P.Z., Disha Pharmaceutical Group, and the address in Kearny, New Jersey, and found no results for any active or inactive DEA registrations for any of these searches. Tr. 545–54. DI 3 also conducted a Google search of the Kearny, New Jersey, address and was not provided any information from OakmontScript that this was a freight forwarding facility. Tr. 555–56, 558.

Invoice OKS–00715 (Lyrica)

A variety of Lyrica strengths were shipped on November 21, 2018, to J.F. at YaoPharma. Tr. 558–72; Gov't Ex. 31 at 1–4, 27 at 3, 31 at 1, 3–4. However, other documentation provided by Dr. Shi indicates that the date is November 21, 2019. Gov't Ex. 12 at 12.[35] Dr. Shi also sent an email stating that the label for the Lyrica was created on November 21, 2018, and the drop-off date was December 4, 2018. Gov't Ex. 20 at 10. Other documents list the date as March 29, 2019. Gov't Ex. 31 at 3. Other documents list an invoice date of May 8, 2019. Gov't Ex. 26 at 102.[36] The date of the invoice was also listed as August 8, 2018. Gov't Ex. 28 at 48. OakmontScript did not file a DEA Form 236 for this export. Tr. 572–73; Gov't Ex. 48.

Invoice OKS–00753 (Briviact)

Briviact 50 milligram and 100 milligram, a Schedule V drug, was received on October 22, 2018, the shipping label was created on October 25, 2018, and it was shipped on November 2, 2018. Tr. 579–96; Gov't Exs. 12 at 8, 20 at 10. Other documentation provided by OakmontScript states that this was shipped on October 26, 2018. Gov't Exs. 17 at 2, 18 at 4. The commercial invoice is dated September 26, 2018 and the ''bill to'' and ''ship to parties'' are Y.P. at Zhejiang Le Pu Technology Limited Company in China. Gov't Exs. 26 at 106, 28 at 53.[37] In other documentation provided by OakmontScript, no shipping date is provided. Gov't Ex. 27 at 3–4. OakmontScript did not have the authority to export Briviact. Tr. 580–81, 599, 1434–35; Gov't Ex. 11. OakmontScript did not fill out a DEA Form 236 for this controlled substance. Tr. 596, 1435–36; Gov't Ex. 48.

DI 3 found Dr. Shi's statement regarding drug codes to demonstrate a lack of candor because she had specifically asked Dr. Shi if OakmontScript was handling other controlled substances outside those listed and Dr. Shi reported that she had not. Tr. 600, 724, 788.

Invoice OKS–00902 (Belviq)

Belviq, 10 milligrams was received by OakmontScript on January 30, 2019, transferred from its distributor license to its export license on February 14, 2019, and shipped on February 15, 2019, to Beijing HeMingTang Pharmaceutical Company Limited. Tr. 602–13; Gov't. Exs. 12 at 5, 18 at 4, 26 at 121, 27 at 4, 28 at 60, 82. However, other documentation provided by Dr. Shi listed a packing slip date of January 16, 2019. Gov't Ex. 26 at 119. Other documentation listed an invoice date of May 8, 2019. Gov't Ex. 26 at 122.[38] Other documentation lists the billing date from McKesson as January 16, 2019. Gov't Ex. 28 at 18. OakmontScript did not file a DEA Form 236 for the Belviq. Tr. 609, 1435–36; Gov't Ex. 48. OakmontScript did not have the authority to export Belviq at this time. Tr. 612, 1435; Gov't Ex. 11.

DI 3 believed Dr. Shi's previous statement regarding drug codes demonstrated a lack of candor because she had specifically asked Dr. Shi if OakmontScript was handling other controlled substances outside those listed and Dr. Shi failed to report that OakmontScript had recently exported Belviq. Tr. 613, 724, 788.

Invoice DIW–0019 and NEEC–0019 (Clobazam)

Clobazam is a Schedule IV controlled substance. Tr. 614; Gov't Ex. 10 at 4. OakmontScript received a shipment of clobazam on February 28, 2019, and shipped it on March 5, 2019, to Patient J.L.'s home address in China. Tr. 613–41, 673–723, 727–33, 907, 912; Gov't Exs. 12 at 21, 26 at 15–16, 27 at 4, 28 at 65.

However, in other documentation provided by OakmontScript, there is no indication that clobazam was shipped or it is not listed on the invoice. Gov't Exs. 17 at 2–3, 18 at 3–4. OakmontScript did not have the authority to export clobazam and DI 3 was unable to confirm that it was used for a legitimate scientific, research, or medical purpose. Tr. 612–13; Gov't Ex. 11. OakmontScript also did not fill out a DEA Form 236 for this invoice. Tr. 615, 1435–36; Gov't Exs. 26 at 16, 28 at 76, 48 at 1.

At the May 8, 2019 visit, DI 3 asked why there was a discrepancy and Dr. Shi stated that the request had come to export the clobazam for direct patient use. Tr. 617–18. During this conversation, Dr. Shi stated that she had ''begged'' Dr. L.W. for about a week to write a prescription to legitimize this export of controlled substances and although he initially said no, he ''eventually relented'' and wrote the prescription, but asked that Dr. Shi not ask him to write a prescription like that again. Tr. 619–20, 621, 673, 769, 912, 1456.

It was DI 3's understanding that Patient J.L. was treated at Boston Children's Hospital, had returned to China, and was now seeking an export of clobazam to China. Tr. 620. Dr. Shi never provided this prescription to DI 3. Tr. 621–22.[39]

[34] 21 U.S.C. 802(27) defines ''ultimate user'' as ''a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.''

[35] DI 3 discussed these issues with Dr. Shi on April 23, 2019, and Dr. Shi indicated that this was an incorrect date and the date should be listed as November 21, 2018. Tr. 564.

[36] This incorrect date could be related to the macro issue, but regardless, having these incorrect dates caused confusion for DI 3. Tr. 576–77.

[37] While this exhibit was being discussed, Dr. Shi objected and explained that this ''page of the shipping label is different. So it's our mistake to put the shipping label of 715 in here. So this shipping label should not be discussed with this, it's our fault to misplace this page.'' Tr. 591. This issue is discussed *infra,* during Dr. Shi's testimony.

[38] This could have also been related to the macro issue as the invoice was dated May 8, 2019, one of the dates DI 3 was present for an inspection.

[39] Other documentation provided by OakmontScript indicates that the prescription was transferred to a doctor's office in the United States, which would appear to be a domestic distribution, but during the May 8, 2019 conversation, Dr. Shi indicated that the controlled substance was directly exported to Patient J.L. in China, which she asserted a distributor is able to do. Tr. 624, 633, 641, 726, 915; Gov't Ex. 20 at 11.

Administrative Subpoenas

DI 3 and DI 6 met with Dr. L.W. in January or February of 2020. Tr. 674. Upon arriving, both DIs explained the reason for the visit, identified themselves, and showed their credentials. Tr. 674. Dr. L.W. indicated he would be fine to answer questions. Tr. 674. During the interview, Dr. L.W. indicated that he was a consulting physician for OakmontScript, was paid a monthly stipend, and received extra compensation each time he wrote a prescription for OakmontScript. Tr. 675. It was unclear what his position was with NEEC. Tr. 675. Dr. L.W. reviewed the material transfer document that indicated the clobazam, invoice NEEC–019, was shipped directly to him and he stated that he had never taken physical possession of the clobazam or any controlled substances. Tr. 676, 677, 730. *See* Gov't Ex. 26 at 16. Dr. L.W. told DI 3 that he wrote prescriptions for OakmontScript after OakmontScript provided him with medical records for foreign patients who were being treated for illnesses in other counties and he would determine whether the drug OakmontScript wanted to export was the appropriate drug for the treatment of those patients. Tr. 677. He further stated that he had never seen Patient J.L. and did not have any medical records for Patient J.L. Tr. 678, 682. He stated that he did not have authority to write prescriptions for patients located outside of the United States, nor does he have foreign medical licenses or overseas privileges as a practitioner. Tr. 678.

DI 3 served an administrative subpoena on Dr. L.W. that was dated January 2, 2020. Tr. 678–79; Gov't Ex. 35. Dr. L.W. later called DI 3 to discuss the subpoena she had served on him. Tr. 681. Dr. L.W. stated that he did not have a response to the subpoena and he had not written prescriptions for controlled substances for OakmontScript. Tr. 681–82; Gov't Ex. 36. DI 3 asked him to email her his official response and he sent DI 3 an email stating this. Tr. 681–82; Gov't Ex. 36.

On March 6, 2020, DI 3 had an email exchange with Attorney Schumacher, in response to the administrative subpoenas that were served on OakmontScript and NEEC. Tr. 690; Gov't Ex. 40. *See* Gov't Exs. 37, 38. Mr. Shumacher indicated that he had no response to the subpoenas. Tr. 687–706; Gov't Exs. 39, 40, 41, 42.

Regarding the clobazam prescription,[40] Mr. Schumacher indicated that the prescription had been initiated or authorized by Dr. G.T. from a hospital in China and that this physician did not have a relationship with OakmontScript or NEEC. Tr. 710–11; Gov't Ex. 44 at 1. DI 3 conducted a search for Dr. G.T. in the DEA registration database known as RICS or CSA2 to determine whether Dr. G.T. or his hospital ever had a DEA registration associated with them and the search turned up no results. Tr. 715–17, 722.

Regarding the clobazam, 019 invoice, DI 3 found that Dr. Shi demonstrated a lack of candor because she initially provided documents indicating the clobazam had been exported, but then later provided information that it was actually transferred domestically to a doctor's office in Massachusetts and Dr. Shi continued to provide conflicting information. Tr. 730–31. This lack of candor made it difficult for DI 3 to understand what had actually been exported. Tr. 731, 788–89.

OakmontScript did not provide return information or a DEA Form 236 for the exports discussed at the hearing including, invoice OKS–00243 (Diazepam), invoice OKS–00301 (Briviact), invoice OKS–00315/OKS–00315–1 (Belviq), invoice OKS–00315/OKS–00315–2 (Lyrica), invoice OKS–00108 (Belviq XR), invoice OKS–00715 (Lyrica), invoice OKS–00753 (Briviact), invoice OKS–00902 (Belviq), and invoice DIW–0019/NEEC–0019 (clobazam). Tr. 732–35.

Overall, DI 3's investigation of OakmontScript identified record-keeping issues including, not having an initial inventory,[41] exporting before receiving its exporter registration,[42] and commingling records.[43] During her investigation in 2019, DI 3 requested that Dr. Shi provide specific dates of export, which is the actual date the controlled substance left the registrant's registered location and the date that the controlled substance was released by a customs official, which must be recorded within thirty days after the registrant learns of the export or within ten days if the Administrator asks for it earlier. Tr. 759–60, 807. The manner in which OakmontScript was conducting business violated the CSA and DEA regulations, which made it a potential threat to public safety. Tr. 762, 786. Although Dr. Shi and OakmontScript provided information upon request, the information was consistently conflicting and not necessarily helpful to DI 3. Tr. 765. Even if part of the exportation process occurred after OakmontScript obtained its exporter registration on December 5, 2017, this would not have legitimized the export because OakmontScript's intent to export the controlled substances was there once it transferred them to the common carrier. Tr. 1442–44.

DI 3 effectively explained her interactions with OakmontScript employees, including Dr. Shi and Dr. L.W. As a public servant, DI 2 has no personal stake in the outcome of the instant investigation or in the revocation of the Respondent's registration. There was no indication during her testimony that she had any animus against OakmontScript or any of its employees. I therefore find her testimony to be credible and it will be afforded considerable weight.

The Respondent's Case

The Respondent's case-in-chief consisted of the testimony of four witnesses: (1) Yujing Liu, (2) DI 3,[44] (3) Donghui Yu, Ph.D., and (4) Jufang Shirley Shi. Below is a summary of the testimony of these witnesses.[45]

Yujing Liu

Yujing Liu graduated from Northeastern University in 2015 with a major in project management. Tr. 814–15. Ms. Liu has been working for OakmontScript since February 2018 and coordinates logistics for OakmontScript including monitoring and tracking shipments, and preparing documents to support the exporting process. Tr. 815–16, 844. Ms. Liu also maintains OakmontScript's records on exports in a computer system that she reviews for accuracy, but all OakmontScript employees have access to these records. Tr. 849–50. A commercial invoice is part of the documents that are required to show the sale price of the drug. Tr.

[40] DI 3 obtained a translation of the clobazam prescription. Tr. 713–16; Gov't Ex. 46.

[41] Tr. 735–41; Gov't Exs. 9, 13.

[42] DI 3 learned that OakmontScript had exported thirteen controlled substances prior to being granted its export license on December 5, 2017, which was counted based on each drug and strength. Tr. 864. DI 3 offered an example for the Briviact shipment, which was 10 milligrams and 100 milligrams, which would count as two separate controlled substances. Tr. 864–68.

[43] There were issues with recordkeeping as OakmontScript had commingled records. Tr. 739. For instance, OakmontScript was keeping inventories for both its distributor registration and its exporter registration on the same document and it was difficult to discern under which registration each transaction had occurred. Tr. 743–48, 782; Gov't Ex. 12. DEA registrants are also required to take a physical hand count of all controlled substances that they have on hand under that DEA registration and document the results, which OakmontScript failed to do prior to the March 29, 2019 inspection date. Tr. 749, 778; Gov't Ex. 12.

[44] The Respondent called DI 3 as a witness for its case-in-chief. Tr. 862–63. The testimony elicited from DI 3 by the Respondent is incorporated into the summary of DI 3's testimony discussed above.

[45] I do not make any findings of fact in these summaries. Any facts necessary for a disposition of this case are set forth in the Analysis section of this Recommended Decision.

834. A commercial invoice's ''Bill to Address'' and ''Shipping to Address'' are not always the same. Tr. 834–35. After creating the commercial invoice, Ms. Liu will save the document as a PDF because the Excel formula [46] of OakmontScript's working documents does not capture the accurate date. Tr. 854–58. When Ms. Liu provided export records to DI 3, she provided OakmontScript's internal documents from the Dropbox, which are the working templates, rather than the PDF versions. Tr. 831–32.

Ms. Liu knows how to fill out a DEA Form 236 and DEA Form 161, which is not difficult to do if the drug code is available or assigned to OakmontScript and the national level import permit is available. Tr. 817, 830, 859–61.

The exporting process includes many events, including tracking when the shipment passes Customs. Tr. 816, 844. It is difficult for Ms. Liu to track when Customs clears a shipment and she cannot record that date. Tr. 844–45. Instead of providing that exact date, OakmontScript records ''every step we did,'' which includes when Customs clears a controlled substance to leave the United States, but not when the controlled substance is released by the country it is being shipped to. Tr. 845–48. OakmontScript uses the date on the customer's import permit, which is the customer's deadline to receive the export and finish the customer clearance date. Tr. 848. OakmontScript uses the common carrier DHL, but can only track DHL shipments for three months because the DHL system only provides three months of history. Tr. 848–49. Therefore, if the shipment arrives with the client outside this three-month window, OakmontScript is not able to track the exact date the shipment arrives and although a client will tell OakmontScript when it receives a shipment, OakmontScript does not record this information. Tr. 849.

On cross-examination, Ms. Liu agreed with Government counsel that the dates of shipment for invoice OKS–00715, as recorded in the Respondent's documentation admitted as Government Exhibits 26 (showing a shipment date of May 8, 2019) and 31 (showing a shipment date of March 29, 2019) are incorrect, based on the Respondent's documentation admitted as Government Exhibit 27 (showing a shipment date of November 21, 2018). Tr. 856–58.

Throughout her testimony, Ms. Liu was generally consistent and credible. As an employee of OakmontScript, she has a personal stake in the outcome of the instant investigation as well as the revocation of the Respondent's registrations. Her testimony generally involved her job duties with OakmontScript. At one point, she also agreed with Government counsel that the dates of shipment for invoice OKS–00715 were incorrect, based on different documents providing conflicting dates. Overall, I found Ms. Liu's testimony credible.

Donghui Yu, Ph.D.

Donghui Yu has a Ph.D. in Pharmacology and her post-doctoral training was at Dana-Farber Cancer Institute and Harvard Medical School. Tr. 918. Her research focus was in oncology research and cancer drug development. Tr. 918. She was a teaching assistant at the School of Medicine in Beijing University, a Research Scientist at the Cubist Pharmaceutical, and an Investigator at Infectious Diseases at Novartis in Cambridge, Massachusetts. Tr. 918. During 2011 and 2015, she volunteered at Boston Children's Hospital by hosting weekly craft activities and saw children who had diseases that were still not cured.[47] Tr. 919. She worked in a health-related facility in Needham, Massachusetts, helping her husband, from 2012 through 2017. Tr. 1015–16.

Dr. Yu started working at OakmontScript in June 2017 and she enjoys working for OakmontScript because it gives her the opportunity to serve people in need in the medical and science field. Tr. 919, 930, 1015. She is the Executive Director and helps Dr. Shi train new employees by using OakmontScript's Standard Operating Procedure (''SOP''), and ensures that the Drug Supply Chain Security Act is implemented in the SOP and that OakmontScript is complying with the FDA and following the rules of other countries.[48] Tr. 921, 925, 932. She also ensures that the SOP is timely updated, the employees are trained properly, and all the procedures are followed in the SOP. Tr. 921, 923, 930. Client validation is a very important part of compliance and OakmontScript considers customer verification a top priority as the drug abuse epidemic was caused by controlled substances being distributed for a non-legitimate use. Tr. 922. OakmontScript invested in security including having a security system, a safe box, a door lock, an alarm, and temperature control in the warehouse where pharmaceutical products are being stored. Tr. 925–26.

In order to export controlled substances legally in the United States, the person conducting the export of the controlled substance must have a DEA registration. Tr. 1029–30. Dr. Yu agreed with Government counsel's statement that applying for a DEA registration is not the same thing as having a DEA registration. Tr. 1030. Furthermore, a registrant can only export controlled substances for which it has authorization to do so. Tr. 1030–34.

OakmontScript obtained its DEA export registration on December 5, 2017. Tr. 1030. Dr. Yu stated that before DI 2 performed her on-site inspection,[49] OakmontScript was not aware that to do an export, it needed to transfer the controlled substances from its distributor registration to its exporter registration. Tr. 1011. As a result, after DI 2's inspection, OakmontScript updated its export process SOP to include the ''license transfer document.'' Tr. 1011. When a new customer comes to OakmontScript, OakmontScript checks the customer's business card, makes sure it belongs to the company it claims, ensures that person is the company's legal representative, obtains the company's business registration, and checks the company's website. Tr. 923. If there is an export of controlled substances to a Chinese client, OakmontScript asks the client to provide its business authorization for controlled substance usage, development, or manufacture. Tr. 923. OakmontScript also requires clients to fill out a form that ''covers all the business, and the history, and their financial situation, so on, so on.'' Tr. 923. In cases where clients need a clinical trial registration, OakmontScript will ask them to provide their clinical registration in order to go through its clinical trial protocol and once OakmontScript makes sure it is for a legitimate use, OakmontScript enters this information in a specific Dropbox database. Tr. 924.

OakmontScript's company goal is to serve the clients and the public and to make sure every step of its SOP is executed properly. Tr. 926–27. Otherwise, it can impact public safety and OakmontScript always discusses and modifies the SOP when it finds a problem that is not perfectly described in the SOP. Tr. 927.

Dr. Yu is familiar with the CSA and DEA regulations and it would be wrong for a DEA registrant to fail to comply with these. Tr. 1023–25. However, what

[46] The Excel formula is a macro that populates the current date that the document is open. Tr. 857–58.

[47] Dr. Yu was connected to Patient J.L.'s parents when he had surgery at Boston Children's Hospital. Tr. 920.

[48] This includes working with a Chinese client and needing to comply with the Chinese National Medical Product Administration. Tr. 933.

[49] DI 2 performed her on-site inspection on July 26, 2018. Tr. 126–27.

is wrong or correct is defined by the DEA and not everything can be defined as black and white. Tr. 1024. For instance, some substances that are controlled substances in the United States are not controlled substances in China including Lyrica, Belviq, Briviact, and clobazam, while substances like caffeine, are not controlled in the United States, but are considered controlled substances in China. Tr. 936.

It is difficult for OakmontScript to obtain the LONO *[E] from other countries, particularly China, and instead the clients present the permits from the local province. Tr. 937. Dr. Yu noted that one example occurred with Belviq, OKS Invoice 00902. Tr. 1048–49. Because Belviq was not a controlled substance in China, OakmontScript was unable to obtain a LONO letter for the Belviq. Tr. 1049. In addition, OakmontScript did not complete a DEA Form 236 for this shipment of Belviq. Tr. 1049. Further, on the date that OakmontScript shipped clobazam, invoice number NEEC–019, it did not have a drug code for clobazam and did not submit a DEA–236. Tr. 1049–51. Finally, on the date that OakmontScript shipped Briviact, invoice number 753, it did not have a drug code for Briviact and did not file a DEA–236. Tr. 1051–53.

Dr. Yu's understanding of a drug code is that it is used for a controlled substance export only and is for controlled substance identification purposes as different dosage forms or formulations of drug substances could be assigned different drug codes. Tr. 970–71. This does not apply to Schedule V controlled substances, where only one drug code is assigned for different doses and populations. Tr. 971. The DEA field agents told OakmontScript that there were several ways to obtain new drug codes, including filling out an online application, emailing the local DI agent, and adding new drug codes when it renews its license. Tr. 972. OakmontScript is not a manufacturer and does not deal with controlled substance manufacturers in the United States. Tr. 982.

Dr. Yu discussed the macro issue that Ms. Liu had previously mentioned in her testimony, and noted that once OakmontScript realized this caused a potential problem, Dr. Yu corrected the template. Tr. 984, 1053–60. Dr. Yu would also create separate PDFs that list the correct date, and save them to the same folder. Tr. 1055–57. OakmontScript's SOP does not contain the ''concept of date of export'' as OakmontScript feels it ''is unable to define'' it. Tr. 986. Instead, OakmontScript ''just document[s] every step we handled'' because an ''export is really a process.'' Tr. 986. Therefore OakmontScript ''had nothing to present'' when DI 3 asked about a ''specific export time.'' Tr. 987. Although DI 3 used the shipping labels, OakmontScript did not believe the shipping label was proper to use as the export date. Tr. 987. Dr. Yu was ''frightened'' when DI 3 asked about the date of export at the February 19, 2019, inspection because she did not know the exact document to show her. Tr. 991–92. However, Dr. Yu later went on to confirm that the date of shipment is the date the controlled substance departed from the registered location. Tr. 1046.

There is a date of EEI [50] and all shipments need to claim EEI for the customs declaration for export. Tr. 988. The shipping label is created and OakmontScript prints out the label, but the package is not necessarily ready to be shipped. Tr. 988. OakmontScript then needs to send the shipping label to its clients to let them start the import process. Tr. 988. The most important part is ''custom clearance ticket obtaining'' and that process depends on how the country handles that and different city customs handle the speed differently, which could be a couple weeks to several months. Tr. 988–89, 990.

There is a date of custom clearance, which is a cutoff date in which OakmontScript has an obligation to help the customer finish before the due date, or the whole purchase becomes invalid. Tr. 989. If the DEA Form 236 is available, OakmontScript records that transaction date. Tr. 989, 1039–41. At the end of the transaction, OakmontScript receives verbal confirmation from the client that it received the product. Tr. 989. Ms. Liu generates the shipping labels and takes care of the customs clearance and EEI. Tr. 989–90.

It would be ideal to use the DHL database to record the export date, but this was not part of OakmontScript's SOP. Tr. 990. Doing this is not always practical because the DHL online system only displays the last ninety days and if the package is dropped off several weeks after the shipping label was created, then it may fall out of this ninety-day window and OakmontScript cannot track this package. Tr. 991. Other issues occur when a client picks its own private carrier to pick up the package and OakmontScript can only get verbal confirmation from the client that it received the package. Tr. 991. OakmontScript records the date the client verbally tells it the package was received. Tr. 989, 991.

Physicians can order medications from distributors without a prescription, which includes foreign physicians who, in the name of the patient, order medication from an exporter or distributor. Tr. 993. Distributors or exporters need to verify the doctor's medical license. Tr. 993. As a DEA-registered distributor and exporter, OakmontScript is able to fill medical orders to serve hospitals, physicians, and other entities domestically and foreign research organizations. Tr. 993–94. Specifically, as it relates to the clobazam prescription, OakmontScript's client included the Chinese medical doctor, the hospital, and also pharmacists who ''have the medical history based on Boston Children's Hospital.'' Tr. 994. Without a legal prescription from a local hospital or physician, the controlled substance would not be permitted to enter the receiving country. Tr. 994. The foreign prescription has two functions: (1) Showing the medical necessity of the patient and (2) providing evidence to show when the controlled substance is imported at the Chinese border, acting as an import permit. Tr. 994–95.

For Patient J.L., the doctor's instruction is required to show that the patient was not hospitalized and instead had a chronic condition. Tr. 995. Per the doctor's instruction, OakmontScript contacted the patient and learned from his family that he was no longer in the hospital. Tr. 995–96, 1071. It is OakmontScript's practice to send controlled substances directly to patients if it receives a doctor's order to do so. Tr. 1066–67, 1070.

During the February 19, 2019, inspection, DI 3 told OakmontScript that it needed to fill out a DEA Form 236 for controlled substances Schedules III, IV, and V prior to shipping, and after receiving the approved DEA Form 236, it needed to wait for fourteen days to start shipping, which was new information to Dr. Yu. Tr. 996, 1025–26, 1028. Dr. Yu was not sure if this is what the regulation stated and was unable to confirm this is what the regulation actually required. Tr. 996–97, 1025–28. *See* 21 CFR 1312.27(a).[51]

*[E] Although LONO was not defined in the RD, it is believed to reference a Letter of No Objection.

[50] Dr. Yu did not provide the full term for this acronym, however, DI 3 defined this during her testimony as ''Electronic Export Information.'' Tr. 480.

[51] The regulation states that DEA Form 236 must be filed with DEA ''not less than 15 calendar days

As a scientist, Dr. Yu believes it is important to keep complete and accurate records, and even though mistakes are possible, failing to keep accurate records can lead to further mistakes. Tr. 1017–18. Dr. Yu feels lucky to work at OakmontScript and finds it to be a good opportunity and the work OakmontScript does is meaningful to the whole pharmaceutical industry. Tr. 997–98. She and her colleagues work together every day to learn and grow, but sometimes they make mistakes and Dr. Shi takes full responsibility and never blames them. Tr. 998.

Overall, Dr. Yu provided consistent testimony. She testified regarding her employment and noted that client verification is a top priority for OakmontScript. As the Executive Director of OakmontScript, she has a direct stake in the outcome of this case and whether OakmontScript loses either of its registrations. It was evident throughout her testimony that Dr. Yu had a strong allegiance to Dr. Shi and that she had been thoroughly coached on her direct examination. Dr. Yu had nothing but positive things to say about Dr. Shi and even refused to provide a specific answer to a question because the answer was not ''black and white.'' Tr. 1024. At one point Dr. Yu testified that she was ''frightened'' when DI 3 asked about the date of export at the February 19, 2019, inspection because she did not know the exact document to show her. Tr. 991–92. However, Dr. Yu later went on to confirm on cross examination that the date of shipment is the date the controlled substance departed from the registered location. Tr. 1046. Such inconsistencies in her testimony, coupled with Dr. Yu's evident allegiance to Dr. Shi, does not allow me to fully credit Dr. Yu's testimony.

Jufang ''Shirley'' Shi

Background

Dr. Shi came to the United States to study as a graduate student in 1988. Tr. 1075. She received her Ph.D. in Pharmaceutical Sciences from Duquesne University in Pittsburgh, Pennsylvania, and a Pharm.D., and then worked in various industries as a scientist. Tr. 1076, 1280. She also taught pharmacodynamics and pharmacokinetics to pharmacy students at Northeastern University during 2005 and 2007. Tr. 1277–78. After fifteen years, she dedicated herself to becoming a clinical pharmacist and has been registered as a pharmacist in Massachusetts since 2008. Tr. 1076, 1276–77. She has contributed to technology that led to eight patents. Tr. 1076–77. She became a fellow in the American Society of Consultant Pharmacists (''FASCP'') after passing a pharmacist exam and the Certificate of Geriatric Pharmacotherapy (''CGP'') for which she needed to know how to apply a safe protocol to her client. Tr. 1278–79. She also worked in retail pharmacies and an institutional pharmacy, as well as hospitals. Tr. 1077–78. This included working for PharmMerica and Lahey Hospital. Tr. 1280–81. Based on these experiences, she ''decided to take some risk and to start a company'' to aid in the support of the ''global research need.'' Tr. 1078.

Dr. Shi started OakmontScript in May 2016 as the owner, chief pharmacist, and president. Tr. 1078–79, 1283–85. She is familiar with the CSA and DEA regulations including 21 CFR 1306.04, 1306.05(a). Tr. 1079, 1280–82. Dr. Shi needed to obtain a license from the state prior to receiving OakmontScript's ''federal license.'' Tr. 1080–81; Resp't Ex. 4. After receiving OakmontScript's DEA registration for Schedule III, IV, and V controlled substances, Dr. Shi requested to add Schedule II controlled substances and had updated its security system by adding a monitor and camera, updated the safe, and worked on updating the alarm system. Tr. 1082–84. Dr. Shi's thought process was to first obtain access to Schedule III, IV, and V controlled substances and later request the Schedule II drugs. Tr. 1084–91; Resp't Ex. 5, 6, 7.

Dr. Shi received the first state license as a distributor for Schedules III, IV, and V within a couple of months. Tr. 1086. After receiving the state license, it took less than a month for Dr. Shi to obtain the Federal distributor COR, on October 7, 2016. Tr. 1086–87. Dr. Shi then applied for the Schedule II DEA registration, for which the approval process took about eight months. Tr. 1088–89. During this time, Dr. Shi made sure OakmontScript was in compliance and she spent more time training her employees. Tr. 1088–89.

Exporter Registration

OakmontScript applied for its first exporter COR on April 26, 2017 and applied for its second exporter COR on May 10, 2017. Tr. 1091, 1286, 1289–91, 1308; Gov't Ex. 4 at 6–8. At the time OakmontScript submitted the second exporter application on May 2017, the first application filed in April 2017 was still pending. Tr. 1291. At some point in May 2017, DI 1 informed Dr. Shi that the applications were duplicates and Mr. L.U. and DI 1 discussed OakmontScript getting an importer COR. Tr. 1291–92. Dr. Shi recalls discussions regarding converting an exporter application to an importer application, but did not recall if it was ever done. Tr. 1293–95.[52] Regardless, Dr. Shi recalled withdrawing the May 2017 application in October 2017 and OakmontScript never obtained an importer registration. Tr. 1295–97. Dr. Shi felt that the April application was ''neglected'' by the DEA and the May 10 application was ''mistreated.'' Tr. 1093, 1493.[53] Although Dr. Shi has a ''great appreciation for'' DI 1, she ''feel very bad'' because her application had ''been mistreated.'' Tr. 1094. In an email to DI 1 dated April 28, 2017, Dr. Shi indicated that OakmontScript had not exported any controlled substances as of that date. Tr. 1287–88; Gov't Ex. 4 at 1.

An inspection took place on June 22, 2017, with DI 1 and a Senior Investigator from the Massachusetts Department of Health. Tr. 1297–98.[54] At that time, Dr. Shi stated that she had not distributed or exported controlled substances as of that date. Tr. 1298. DI 1 also told Dr. Shi ''everything that's required'' including the requirement to maintain initial and biennial inventories, DEA Form 161s, DEA Form 236s, and foreign documents or invoices. Tr. 1298–99. DI 1 also explained that records must be maintained for at least two years, records for the DEA registrations must be maintained separately according to business activity, and theft or loss of controlled substances must be reported immediately. Tr. 1299. Overall, DI 1 was able to help OakmontScript address issues and problems. Tr. 1353–54.

As of July 26, 2017, Dr. Shi was aware that OakmontScript's exporter application was still being reviewed by the DEA, but that it was ''coming any

prior to the anticipated date of release by a customs officer at the port of export.'' 21 CFR 1312.27(a).

[52] After several unsuccessful attempts by Government counsel to elicit a response regarding whether Dr. Shi was aware whether OakmontScript had converted one of its exporter applications to an importer application, the tribunal intervened and asked Dr. Shi to directly answer the Government's question and—even then—the tribunal needed to ask the question four times. Tr. 1294–95.

[53] This is not the first or only time Dr. Shi blamed the DEA or made disparaging comments about the DEA. Most notably, Dr. Shi made the following comments about the DEA in her closing statement: ''Despite all evidence showed to their face, I'm very concerned about DEA's manner of how to treat the public, how to treat a small business, and how to treat the people who have a bundle of knowledge while they obviously lack it.'' Tr. at 1497.

[54] Based on Dr. Shi's testimony on cross-examination, it appears that Dr. Shi was under the impression that DI 1's June 22, 2017, inspection was based on OakmontScript's request to add Schedule II drugs to its exporter application. Tr. 1308–10. However, Mr. L.U. had not yet made a request to add Schedule II to OakmontScript's exporter application when DI 1 scheduled the inspection. Tr. 1309–10.

time.'' Tr. 1300–01.[55] As of July 26, 2017, Dr. Shi did not recall receiving a DEA communication about OakmontScript's April 2017 exporter application being approved. Tr. 1305. While waiting for OakmontScript's exporter registration, Dr. Shi assured her staff the exporter registration ''should be coming any time, should be coming any minute. But it didn't come. And I thought it's coming any minute,'' because it was her experience with the DEA that it only took about a month for the DEA to process an application for registration. Tr. 1095. She continued to tell her staff that the registration ''should be coming any time'' and that they should ''start preparing'' because ''[i]t should come in any minute.'' Tr. 1096.

Dr. Shi put too much trust in Mr. L.U., her chief pharmacist, who was her previous boss, but she also shares in the responsibility for not following up regarding the exporter application and leading her ''people to believe the license coming any day.'' Tr. 1096–97, 1305. Dr. Shi ''made [the] assumption it should come in any minute'' and ''misled [her] people'' by saying the exporter registration was on the way and thus OakmontScript started taking orders for Schedules III, IV, and V controlled substances. Tr. 1097–98. Dr. Shi began instructing her employees in June 2017 to start working on preparing controlled substances to be exported. Tr. 1311. OakmontScript ultimately received its exporter registration on December 5, 2017, in the mail.[56] Tr. 1099; Gov't Ex. 4 at 6–8.

OakmontScript's Export Process

Based on DI 3's request for an exact export date, Dr. Shi created a document to track various parts of the export process. Tr. 1126–27. First, OakmontScript verifies the clients and records their import permit and sometimes their research proposal. Tr. 1126. The next step is to go through the contract to make sure everybody agrees on fees and that all parties are satisfied with the arrangement. Tr. 1127. The third step is to go through the ''contract process'' which is needed to finish the exporting process so the customer does not have to go back and reapply. Tr. 1127. OakmontScript also checks with Customs and Border Protection to see what type of license it needs to file. Tr. 1127–28. The U.S. Custom and Border Protection (''CBP'') also has updates that OakmontScript cannot ''log into the process'' if the value of the reported drugs are less than $2500, and this number is currently even lower. Tr. 1128. Dr. Shi updates the SOP based on the rules and regulations from the CBP, FDA, and the local government regarding the exporting process. Tr. 1128–29.

OakmontScript then prepares the shipping label and the customer ticket, which usually takes about two to four weeks. Tr. 1129–30. Dr. Shi instructs her staff to record what things happen, as opposed to providing the ''right date'' and she does not ''want her people to have any concept about what is the right date'' as this is not how this industry operates. Tr. 1130, 1366–67, 1495, 1498–99. Dr. Shi noted that ''because we lack of the drug code . . . our export process foundation didn't lay out perfectly for my people'' as it relates to the DEA Form 236. Tr. 1130–31. Dr. Shi does not ''want to blame the government[ ] who didn't give'' her a drug code. Tr. 1132. OakmontScript was not able to fill out DEA Form 236s for the diazepam 243 invoice, the Briviact 301 invoice, the Belviq 315 or 315–1 invoice, the Lyrica 315 or 315–2 invoice, or the Belviq 108 invoice. Tr. 1355.

OakmontScript did not export controlled substances prior to receiving its exporter registration on December 5, 2017, because the exporting process is not based around a specific date, but rather a customer's need. Tr. 1133. Dr. Shi started telling her employees that by May 2017, they ''could start the business'' because ''the license [was] on the way.'' Tr. 1134. The ''right'' date does not apply to OakmontScript because sometimes projects get cancelled and then reinstated. Tr. 1135. It takes about six to twelve months for OakmontScript to ''work[ ] out each detail'' to complete an export. Tr. 1136. The customer gives OakmontScript a due date and states when it wants OakmontScript to finish it. Tr. 1136–37. The exact date of export is not when the shipping label is created and the export is not defined by the exact date of export. Tr. 1138, 1495.

Dr. Shi discussed using a ''buy and bill'' model and how OakmontScript has collaborated with other companies including Biologics, Accredo, McKesson, and Specialty Biologics. Tr. 1209. If the buy and bill model has problems, then OakmontScript will establish another channel by using its ''doctors to provide another channel to support'' patients. Tr. 1209–10.

OakmontScript must submit the DEA Form 236 about two weeks before the planned export, so OakmontScript needs to have the anticipated date of departure from the port of export. Tr. 1371–72. For its exports, OakmontScript has the information required by section 3b of the DEA Form 236, but the information is ''recorded differently.'' Tr. 1375; *See* Gov't Ex. 47. The foreign client provides a custom clearance ticket that is issued by the country, which provides a window of time in which the export must occur and can be as far as a year into the future. Tr. 1376–77. OakmontScript records the required DEA Form 236 section 3a information in the app because if OakmontScript does not record, then things ''cannot move forward'' and the logistical team uses ''that app to record everything.'' Tr. 1379. After ''things done,'' OakmontScript then downloads the information to the Dropbox. Tr. 1379–80. If the foreign clients do not call OakmontScript or report any problems, OakmontScript reports the due date for section 3b. Tr. 1380. Otherwise, OakmontScript's record will show any issues. Tr. 1380. OakmontScript records the anticipated arrival date in the app and will save a copy to the Dropbox ''once things finish.'' Tr. 1381. OakmontScript only provided ''a portion'' of the information to DI 3 based on her subpoena because ''it's Chinese so she cannot read anyway, then. And so I stopped our oversharing with her, right.'' Tr. 1381. DI 3, from the app, ''should see that . . . all [OakmontScript's] process is being recorded in the app.'' Tr. 1381. Dr. Shi did not tell DI 3 that OakmontScript was using the app, but ''screenshotted a portion of the . . . app.'' Tr. 1381–82.

Dr. Shi reviewed DEA regulations and conducted her own research to learn about drug codes because OakmontScript had ''no guidelines . . . no laws, no rules'' and was ''left without being able to support our community of the research.'' Tr. 1149–50. She reviewed the DEA's website and 21 CFR 1308.03. Tr. 1156–61. The DEA has a lot of resources and Dr. Shi wishes she was ''led to a better source'' regarding drug codes. Tr. 1161. Dr. Shi continues to study the law, rules, and regulations in order to understand and ''better to learn how to help the people in this situation.'' Tr. 1194.

OakmontScript's Interactions With DI 3

DI 3 initially told Dr. Shi that she wanted to help OakmontScript, but through this hearing, Dr. Shi learned that DI 3's duty was not to help her. Tr.

[55] Again, Government counsel made several attempts to get Dr. Shi to answer a specific question, in this case whether as of June 26, 2017, Dr. Shi was aware that OakmontScript's exporter application was still being reviewed. Tr. 1300–05. And again, the tribunal needed to interject and direct Dr. Shi to ''listen to this question very carefully and give a direct response.'' Tr. 1304.

[56] According to the Government's Certification of Registration History, the Respondent was assigned an exporter Certificate of Registration number on December 5, 2017. Gov't Ex. 1B.

1147. Dr. Shi disagrees with the Government's accusation that she lacked candor. Tr. 1167–71. During the inspection in ''the beginning,'' OakmontScript showed DI 3 two lists and when DI 3 asked if OakmontScript was handling any other drugs, Dr. Shi said ''thank you for asking,'' ''praised'' DI 3 for asking this question, and stated that she was having trouble with another list of drugs for which OakmontScript did not have drug codes. Tr. 1172.

Dr. Shi provided two lists to DI 3 for clobazam with one list listing the clobazam and the other not listing the clobazam because DI 3 had repeatedly told her ''I come in to help your business'' and Dr. Shi did not know what DI 3's ''true agenda'' was. Tr. 1172–73. Dr. Shi did not ''keep complete and accurate records'' based on DI 3's standards, ''so that should not be basis for lack of candor.'' Tr. 1173. Dr. Shi ''shared more than'' she should have and believed that DI 3 would take all of the information they had discussed and ''dialogue with'' her. Tr. 1174–76, 1351. Dr. Shi never provided updated records to DI 3 after Dr. Shi found errors in the spreadsheets Dr. Shi had previously provided. Tr. 1321–23.[57]

OakmontScript's Use of the WeChat App

OakmontScript uses an app [58] to communicate with foreign customers and uses this app to explain what is needed for an export. Tr. 1196–98. OakmontScript is not able to export to a hospital in bulk, such as tens of thousands of bottles. Tr. 1197. OakmontScript can only export if it has the name of a patient. Tr. 1197.

Dr. L.W. is part of the app and does not write prescriptions, but is there as a physician consultant and ''check'' for Dr. Shi as he ''know[s] the medical record,'' that a medication is being used for a legitimate purpose, and ensures that OakmontScript is delivering the treatment to the right patient. Tr. 1197–99.

OakmontScript will exchange documents with foreign clients through this app and will respond to clients with urgent issues. Tr. 1382–83.[59]

OakmontScript's Record-Keeping System [60]

OakmontScript keeps accurate and complete records for controlled substances in a database system so all records are readily retrievable as required by the DEA based on OakmontScript's SOP. Tr. 1248–49, 1250. These folders contain subfolders and capture any changes that are made to an order. Tr. 1249–50. Each file has a name with a label and a number and these numbers are then assigned to a specific team to complete that order. Tr. 1250–52. Dr. Shi also created a link that a party can access if she gives that person authority to open a file. Tr. 1260. On the date of DI 3's March 29, 2019, inspection, Dr. Shi's printer had ink problems, so she wanted to be able to electronically download files and give access to DI 3, but DI 3 stated that she would only accept paper copies. Tr. 1260–61.

OakmontScript maintains separate inventory records for Schedule II, III, IV, and V controlled substances. Tr. 1268. There are separate folders for Schedule II and then Schedules III through V, for the initial inventory, for the biennial inventory, for exports, and for the distributions. Tr. 1268–69.

Corrective Measures

At the June 22, 2017 meeting, DI 1 told Dr. Shi there was an issue with OakmontScript's alarm system and OakmontScript then took steps to fix the alarm issue. Tr. 1313–14. DI 1 came back at some point to check the alarm. Tr. 1315–16. During DI 1's return visit to check the alarm, she also informed Dr. Shi that OakmontScript would need to get a different safe. Tr. 1316. In mid-September 2017, OakmontScript notified DI 1 that it was going to install a new safe. Tr. 1316–17. The new safe was installed in late September or early October 2017. Tr. 1317. At some point, DI 1 came back to OakmontScript to check the new safe and DI 1 stated that it ''was okay.'' Tr. 1317–18.

In approximately November 2017, Dr. Shi recalls having a conversation with DI 1 regarding requesting excessive drug codes. Tr. 1324–25. DI 1 walked Dr. Shi through how to delete the excess codes, and Dr. Shi deleted the codes. Tr. 1324–28.

Dr. Shi did not review 21 CFR 1301.26 when shipping the diazepam invoice number 243 and clobazam invoice number 0019 overseas because it is ''a U.S. law'' and ''of course, I cannot base[ ] on that'' and if the DEA is able to provide ''such a law'' that shows this regulation is applied globally, she ''will be happy.'' Tr. 1365. Before a controlled substance leaves the United States, OakmontScript complies with United States law and then ''after border, [OakmontScript] comply[ ] whatever the law required upon'' OakmontScript by the recipient country. Tr. 1366.

Alteration of Distributor Certificate of Registration

Dr. Shi met the intern through the intern's grandmother who was also Dr. Shi's teacher. Tr. 1395. Around Christmastime of 2016, the intern started working for OakmontScript as Dr. Shi's intern. Tr. 1395. The intern altered OakmontScript's distributor Certificate of Registration by using Adobe Shop on her personal laptop. Tr. 1405–06. Once Dr. Shi learned that the intern had changed OakmontScript's registration to state it was a pharmacy, Dr. Shi immediately analyzed the situation, realized the intern made a mistake and was still only learning so it was ''not all her fault.'' Tr. 1397. *See* Gov't Ex. 14. Therefore, Dr. Shi did not fire the intern and instead moved her to a different position with OakmontScript making shipping labels, which is a ''more straightforward job.'' Tr. 1397.

When Dr. Shi did business with other partners, including PBA and its staff, they would say they wanted OakmontScript to submit a pharmacy license. Tr. 1409. Dr. Shi believed that the intern made a change to the registration based on lack of experience. Tr. 1410–11.[61] Dr. Shi hoped to create an account with PBA so OakmontScript could purchase drugs from PBA. Tr. 1411–12. Dr. Shi believes that PBA

[57] Again, Government counsel made several attempts to get Dr. Shi to answer a specific question, in this instance, whether Dr. Shi provided updated spreadsheets to DI 3. Tr. 1321–22. And again, the tribunal interjected and instructed that Dr. Shi answer the question posed by Government counsel, noting that the Government ''is asking you very direct questions and we need direct answers for clarity of the record on this. Please answer . . . and please respond directly to the question that's asked.'' Tr. 1322.

[58] This app is called ''WeChat.'' Tr. 1382.

[59] Dr. Shi reviewed an example of her use of the WeChat app. Tr. 1383–90; Gov't Ex. 26 at 23. Dr. Shi translated this conversation, which was predominantly in Chinese. Tr. 1384–85. Part of this included a woman explaining that there was a child in her family that had seizures and she wanted to help that child. Tr. 1384. Dr. Shi explained that this person needed to send her the patient record, doctor's information, doctor's prescription, and the doctor's and hospital's registration so Dr. Shi could establish an account with her. Tr. 1385. Dr. Shi then obtained more information from a doctor in China. Tr. 1386. This document was then ''dumped'' to the Dropbox once this Order was done. Tr. 1385–86.

[60] Dr. Shi noted that Government Exhibit 28, page 54, was misplaced and should actually be page 51 and with the other documents for invoice OKS–00715. Tr. 1391–92.

[61] Dr. Shi mentioned that OakmontScript has an ''all-in-one license'' from the state. Tr. 1396–97; 1409; ALJ Ex. 26 at 3–4. It is unclear what Dr. Shi believes the effect of this ''all-in-one-license'' is on its DEA registration. Regardless, it is clear that the intern altered OakmontScript's DEA distributor registration to state ''Pharmacy'' after B.W. indicated that PBA would only conduct business with pharmacies. Gov't Exs. 14, 55.

distributes to other distributors. Tr. 1412–13. Essentially, PBA told the intern that it needed some information about a pharmacy license associated with OakmontScript and the intern then used her laptop to edit the distributor registration to indicate it was a pharmacy registration, without specific instruction from an OakmontScript employee to do so. Tr. 1414–15.

The intern left OakmontScript in February 2018 for multiple reasons, including that her visa expired. Tr. 1398. Dr. Shi explained to DI 3 that she ''could have fired'' the intern, but thought this would be ''a little too much'' because it was only the intern's ''first week she ever entered the job.'' Tr. 1399–1400.

Dr. Shi testified that it is a serious issue to falsify a DEA registration based on the consequences, but this issue did not get ''somebody killed'' or cause ''some pandemic'' and the intern was allowed to bring her laptop and continue to access OakmontScript files after this issue, but was limited to the ''non-vendor'' part. Tr. 1417–18. Furthermore, in her closing statement, Dr. Shi stated ''this is not a controlled-substance-related issue,'' yet the DEA ''continued to maintain their limited understanding about controlled substances.'' Tr. 1496. Dr. Shi went on in her closing to state that OakmontScript ''did more than the minimum, we did 500 times more than what's required to address this incident.'' Tr. 1496.

Invoice OKS–00243 (Diazepam)[62]

Two of the documents provided by OakmontScript indicate that diazepam was shipped on May 18, 2017. Tr. 1311–12; Gov't Exs. 17 at 3, 18 at 3. Another document indicates that the diazepam was shipped on June 10, 2017. Tr. 1313;[63] Gov't Ex. 12 at 14. Dr. Shi had indicated that OakmontScript had not exported controlled substances at the June 22, 2017, meeting with DI 1, but both of these dates are prior to the meeting date with DI 1. Tr. 1313. Dr. Shi was not able to provide the date the diazepam was shipped because the USPS updated its online system sometime in 2017 and ''erased all the information'' during the upgrade. Tr. 1368–69.

Invoice OKS–00650 (Lunesta)

As it pertained to the Lunesta invoice, Dr. Shi testified that this transaction was an export and not a domestic distribution as claimed by the Government, because the address was the contact address for a company representative, Z.Y., who was taking this prescription to China and the company in China was the end-user. Tr. 1180–82, 1359. Dr. Shi had used ''common sense'' when sending this prescription because the representative of the company signed a contract with OakmontScript, the address was named on the PO contact,[64] it gave OakmontScript its import permit, and it signed the end-user certification. Tr. 1182. An ''end-user is the person who signed the end-user statement to give [OakmontScript] a certificate.'' Tr. 1183.

Dr. Shi noted this was an ''informal channel'' and ''since this incident and since DI 3 have point this out, [OakmontScript] no longer accept[s] informal channel of delivery for any order.'' Tr. 1182, 1183.

Subpoena Served on May 8, 2019[65]

Dr. Shi acknowledged that dates entered on OakmontScript's shipping labels are not actual shipping dates. Tr. 1342–43. Dr. Shi noted that ''[w]e have, we have of course, we have the date, we have all the records.'' Tr. 1344. After receiving the May 8, 2019 subpoena, Dr. Shi did not provide the specific information of the shipping date because it was ''not required. [DI 3] didn't, she didn't ask for it'' and DI 3 was ''so confused about what is the shipping date, she don't know what to ask.'' Tr. 1343–46. Furthermore, there is ''no such things as the export date . . . [the regulations] do not require the export date to be recorded. That's, that's actually pity . . . wrong information to ask.'' Tr. 1347. However, Dr. Shi provided export dates when DI 3 asked for them. Tr. 1347–48; Gov't Ex. 20 at 9.

Invoice OKS–00301 (Briviact)

Briviact was shipped on August 2, 2017. Tr. 1314; Gov't Exs. 12 at 7, 27 at 2.

Invoice OKS–00315–1 (Belviq)

OakmontScript shipped Belviq on November 1, 2017, based on the shipping label. Tr. 1318–19; Gov't Exs. 12 at 3, 27 at 2. However, the shipping label is an estimated time. Tr. 1319.

Invoice OKS–00315–2 (Lyrica)

Documentation provided by OakmontScript indicates that Lyrica was shipped on November 20, 2017. Tr. 1328–35;[66] Gov't Ex. 12 at 9–10.[67] However, other documentation provided by OakmontScript indicated that the Lyrica was shipped a day later, on November 21, 2017. Tr. 1339; Gov't Ex. 27 at 2. Dr. Shi does not know which document is incorrect and claims that regardless, it is ''one days apart. This is not like somebody get killed or something.'' Tr. 1340. Dr. Shi went on to say ''I know it's mistake. It's 20 or 21st.'' Tr. 1340. Moments later, Dr. Shi stated ''I can say both [dates] are correct, or I mean, both are incorrect . . . I also can say both are right. Because that's just the date.'' Tr. 1341. Dr. Shi stated OakmontScript did the best it could when entering these dates into the spreadsheets. Tr. 1341. OakmontScript has the exact date because in ''the record, we have every app, the people coming to pick up. And then, all those too.'' Tr. 1342. Regarding dates that OakmontScript's products were provided to the common carrier, Dr. Shi stated ''[w]e have the record. But I didn't give it to DI 3'' and ''whatever cannot be exact, I cannot provide to her because that complicated her understanding.'' Tr. 1349–50.

Invoice OKS–00108 (Belviq)

Some documentation indicates that the Belviq was shipped on December 1, 2017. Tr. 1351; Gov't Exs. 12 at 3, 27 at 2.

Invoices DIW–0019 and NEEC–0019 (Clobazam)

Patient J.L.'s family came into contact with Dr. Yu, who learned about Patient J.L.'s situation while doing community service at Boston Children's Hospital. Tr. 1195. When the family returned to China, they wanted to continue the therapy and they supplied

[62] This invoice indicates that OakmontScript's address is 15 New England Executive Park, which is the same as the 1500 District Avenue address, because after 2017, the District of Burlington was acquired and updated by a development company, National Development Corporation. Tr. 1393–94; Gov't Ex. 26 at 20.

[63] During Dr. Shi's response on cross-examination regarding the shipping date of this diazepam, the tribunal needed to interject and instruct Dr. Shi to ''[j]ust respond to the question please.'' Tr. 1312.

[64] It is unclear what Dr. Shi meant by ''PO contact.''

[65] The subpoena was admitted as Government Exhibit 24.

[66] Again, Government counsel made several attempts to get Dr. Shi to answer a specific question, in this instance, how Dr. Shi's employees would have filled out documents. Tr. 1331. And again, the tribunal interjected and instructed Dr. Shi to answer the ''straightforward question'' posed by Government counsel. Tr. 1331. The tribunal needed to interject again during this cross-examination regarding the Lyrica and instructed Dr. Shi that she needed ''to answer the question'' and to ''[l]isten carefully to the question.'' Tr. 1334.

[67] Dr. Shi was evasive in testifying that the ''ship to date'' was indeed the date the Lyrica was shipped. Dr. Shi continued to claim that there were several steps in the export process and this was likely the date the shipping label was created and this Lyrica would have been shipped ''approximately around'' November 20, 2017. Tr. 1338–39.

OakmontScript with the hospital discharge paper, the prescription from China, and the prescription from the United States. Tr. 1194–96.

As the founder and President of OakmontScript, Dr. Shi has the most at stake in this case involving the potential revocation of OakmontScript's CORs. Throughout her testimony, she was often evasive in answering the questions posed by opposing counsel to the point where Government counsel had to repeat questions multiple times and the tribunal even needed to intervene multiple times to instruct Dr. Shi to answer direct questions posed by the Government.[68] By her own admission, Dr. Shi purposely withheld documents that OakmontScript had in its possession and were requested in not one, but two administrative subpoenas that were served on OakmontScript. During her testimony, she condoned these actions and even when confronted with documents that provided conflicting export dates, she continued to be evasive and refused to admit there were errors. I therefore cannot make a wholly positive credibility finding with respect to Dr. Shi's testimony.

Analysis

The Government seeks revocation of the Respondent's distributor and exporter CORs based on its contention that the Respondent, through its employees, has committed acts that would render its registration inconsistent with the public interest as that term is defined in 21 U.S.C. 823(b), (d), and (e), 824(a), and/or 958. ALJ Ex. 1 at 1. The Government alleges that the Respondent's CORs should be revoked because it exported controlled substances prior to obtaining its exporter COR, exported controlled substances it was not approved to export, demonstrated a lack of candor to DEA investigators regarding its business activities, falsified a copy of its DEA distributor COR, distributed controlled substances to a non-DEA registered individual, exported controlled substances to fill prescriptions for underage patients, and commingled the records for its two registrations and otherwise failed to keep complete and accurate records.

Although the burden of proof at this administrative hearing is a preponderance-of-the-evidence standard, *see Steadman* v. *SEC,* 450 U.S. 91, 100–01 (1981), the Acting Administrator's factual findings will be sustained on review to the extent they are supported by ''substantial evidence.'' *Hoxie* v. *DEA,* 419 F.3d 477, 481 (6th Cir. 2005). [Omitted for brevity.] While ''the possibility of drawing two inconsistent conclusions from the evidence'' does not limit the Acting Administrator's ability to find facts on either side of the contested issues in the case, *Trawick* v. *DEA,* 861 F.2d 72, 77 (4th Cir. 1988), all ''important aspect[s] of the problem,'' such as a respondent's defense or explanation that runs counter to the Government's evidence, must be considered. *Wedgewood Vill. Pharmacy* v. *DEA,* 509 F.3d 541, 549 (D.C. Cir. 2007).

[Omitted for brevity.] It is well-settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this Recommended Decision are entitled to significant deference, *see Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951), and that this Recommended Decision constitutes an important part of the record that must be considered in the Acting Administrator's decision, *see Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Acting Administrator and do not limit the exercise of that discretion. 5 U.S.C. 557(b); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* 8 (1947).

Public Interest Determination: The Standard

The Government seeks revocation of the Respondent's DEA CORs based on its allegations that continuation would be inconsistent with the public interest as that term is defined in 21 U.S.C. 823(b), (d), and (e). The CSA provides that the Agency may suspend or revoke a registrant's COR ''upon a finding that the registrant . . . has committed such acts as would render [its] registration under section 823 . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). The Government specifically alleged that the Respondent violated the law regarding its distributor registration by: (1) Falsifying its distributor registration, (2) displaying a lack of candor regarding this falsified registration, (3) domestically distributing Lunesta, a controlled substance, to a non-registrant in May 2018, and (4) commingling records. The Government further alleges that the Respondent violated the law regarding its exporter registration by: (1) Exporting controlled substances prior to obtaining its exporter COR, (2) exporting controlled substances it was not approved to export, (3) exporting controlled substances to fill foreign prescriptions for underage patients, and (4) failing to keep complete and accurate records of controlled substances it had exported.

The Government bears the burden of proving that the Respondent's continued registration would be inconsistent with the public interest. 21 CFR 1301.44(e). Where the Government has met its burden by making a *prima facie* case for revocation (or some other sanction), the burden of production then shifts to the registrant to show that, given the totality of the facts and circumstances in the record, revocation (or any other sanction) would not be appropriate. *Southwood Pharm., Inc.,* 72 FR 36487, 36498, 36504 (2007) (citing *Gregory D. Owens, D.D.S.,* 67 FR 50461, 50464 (2002)).

Any additional facts necessary for a disposition of this case are set forth in the balance of this Recommended Decision.

Distributor Registration

As to its distributor COR, the Government alleges that the Respondent violated the CSA and its implementing regulations by: (1) Altering its distributor registration to state that it was a pharmacy and then representing to another DEA registrant that it was a pharmacy by presenting the altered DEA COR, (2) displaying a lack of candor regarding this falsified registration, (3) domestically distributing Lunesta (eszopiclone, a schedule IV controlled substance) to a non-registrant in May 2018, and (4) commingling its distributor records with records pertaining to its exporter registration. The Government seeks the revocation of the Respondent's distributor COR based on its allegations that the Respondent's continued registration would be inconsistent with the public interest as that term is defined in 21 U.S.C. 823(b) and (e).

The CSA provides that ''[a] registration . . . to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render [its] registration under section 823 . . . inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4).

Congress has provided the following factors to be considered in the public interest analysis as it relates to

[68] *See supra* at 36 n.52, 37 n.55, 40 n.57, 44 n.63, 45 n.66, 45 n.67.

distributors of controlled substances, as set forth in 21 U.S.C. 823(b) and (e):[69]

(1) Maintenance of effective control(s)[70] against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of [the registrant] under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

21 U.S.C. 823(b), (e). The factors are considered in the disjunctive, and the Agency may give each factor the weight it deems appropriate in determining whether to revoke a registrant's registration. *Masters Pharm., Inc.,* 80 FR 55418, 55472–73 (2015) (citing *Green Acre Farms, Inc.,* 72 FR 24607, 24608 (2007); *ALRA Labs., Inc.,* 59 FR 50620, 50621 (1994)). Moreover, the Agency is ''not required to make findings as to all of the factors.'' *Masters Pharm., Inc.,* 80 FR at 55473 (quoting *Hoxie,* 419 F.3d at 482).

Factor One: Maintenance of Effective Controls Against Diversion of Particular Controlled Substances Into Other Than Legitimate Medical, Scientific, and Industrial Channels

Evidence properly considered under Factor One of the public interest analysis for a distributor registrant includes the adequacy of the registrant's recordkeeping. *CBS Wholesale Distrib.,* 74 FR 36746, 36749 (2009) (citing *Holloway Distrib., Inc.,* 72 FR 42118, 42123 (2007); *Rick's Picks, L.L.C.,* 72 FR 18275, 18278 (2007); *John J. Fotinopoulos,* 72 FR 24602, 24605 (2007)). Although the Government failed to allege a specific public interest factor for this allegation, I find that the commingling of records allegation should be analyzed under Factor One.

21 CFR 1304.21(c) requires that ''[s]eparate records shall be maintained by a registrant for each independent activity and collection activity for which he/she is registered or authorized, except as provided in § 1304.22(d).'' Therefore, as OakmontScript possesses both an exporter and distributor registration, it must maintain separate records for each registration. 21 CFR 1304.21(c). ''Recordkeeping, reporting and security requirements are also more rigorous for those who manufacture and distribute controlled substances.'' *Wedgewood Vill. Pharmacy,* 71 FR 16593, 16594 (2006).

On September 16, 2016, DI 1 conducted an on-site inspection of OakmontScript with a Senior Investigator with the Massachusetts Department of Health regarding OakmontScript's distributor registration. Tr. 44–45. At this time, DI 1 instructed Dr. Shi that OakmontScript needed to ensure it did not commingle records from its distributor registration with any future exporter registration. Tr. 51.

On July 26, 2018, a second DI, DI 2, conducted an inspection of OakmontScript's distributor registration and noted that OakmontScript was commingling records by keeping some of its distributor records with its exporter records. Tr. 129–33, 135–36. After she identified this issue, she discussed it with Dr. Shi, who indicated that she understood and stated that OakmontScript would not commingle records in the future. Tr. 133. DI 2 did not ''believe [Dr. Shi] knew about the commingling but once corrected, she understood.'' Tr. 133.

A third DI, DI 3 noted that there were issues with recordkeeping as OakmontScript had commingled records. Tr. 739. For instance, OakmontScript was keeping inventories for both its distributor registration and its exporter registration on the same document and it was difficult for DI 3 to discern under which registration each transaction had occurred. Tr. 743–48, 782; Gov't Ex. 12. DI 3 specifically noted that it was difficult to discern if the Lunesta invoice OKS–00650 was a distribution or export as the spreadsheet provided by OakmontScript had both CORs listed on the spreadsheet. Tr. 746–47; Gov't Ex. 12 at 17.

As discussed, prior to DI 3's most recent inspections, OakmontScript had been told by two DI investigators that it needed to maintain separate inventories for its distributor and exporter registrations. Tr. 51, 131–36. Despite this, when DI 3 performed her initial inspection on March 29, 2019, the only records OakmontScript provided for the biennial inventory included commingled records that contained information for both its distributor and exporter registrations. Tr. 351, 739, 744–49; Gov't Ex. 12. In fact, DI 3 was only able to discern invoice OKS–00243 was an export after reviewing the license transfer document for this export. Tr. 747–48; Gov't Ex. 26 at 21. However, another spreadsheet provided for this export at the March 29, 2019, inspection did not indicate this was an export or that the diazepam had been transferred from OakmontScript's distributor license to its exporter license. Tr. 747; Gov't Ex. 12 at 14.

I therefore find that OakmontScript commingled records that were provided to DI 3 at the March 29, 2019 inspection, after being put on notice of this not once, but twice. This commingling of OakmontScript's distributor and exporter records makes it difficult, if not at times impossible, to discern whether a particular controlled substance was distributed or exported.[71]

Accordingly, in review of the evidence of record, including stipulations of the parties, OSC Allegation 21.b is *sustained.* [Based on Respondent's failure to maintain complete, accurate, and separate records, in accordance with federal law, I find that Factor One weighs against Respondent.]

Factor Five: Such Other Factors as May Be Relevant to and Consistent With the Public Health and Safety

The Government has alleged that Factor Five is relevant to the public interest analysis regarding the Respondent's distributor COR. ALJ Ex. 1 at 4, 5 ¶ 13.[72] Although the Government failed to explain under which factor the lack of candor allegation falls, the tribunal finds that the allegations regarding the Respondent's lack of candor fall squarely within the purview of Factor Five. *See John V. Scalera,* 78 FR 12092, 12093, 12100 (2013) (considering under Factor Five, the respondent's lack of candor based on lies made to DEA investigators and false testimony under oath at the hearing). Further, the DEA has consistently held that ''[c]andor during DEA investigations, regardless of the severity of the violations alleged, is considered by the DEA to be an important factor when assessing whether a . . . registration is consistent with the public interest'' and that a registrant's ''lack of candor and failure to take responsibility for his [or her] past legal troubles . . . provide substantial evidence that his

[69] Subsection (b) applies to distributors of controlled substances in schedule I or II and subsection (e) applies to distributors of controlled substances in schedule III, IV, or V.

[70] 21 U.S.C. 823(b) uses the term ''control,'' whereas 21 U.S.C. 823(e) uses the term ''controls.'' The origin of the variance appears typographical, not substantive. The text of subsections (b) and (e) is otherwise identical.

[71] Although it appears that OakmontScript attempted to rectify this issue, any attempts to do so were made after the March 29, 2019 inspection. *See* Gov't Ex. 28 at 83–97 (several of these inventory forms indicate that the forms were recreated on April 25, 2019). Dr. Shi provided these documents to DI 3 via email on May 10, 2019. Tr. 781. *See* Gov't Ex. 28.

[72] The Government alleged that Factor Five applied to the Respondent's violation of 21 U.S.C. 843(a)(3), but did not provide its reasoning as to why this violation should be reviewed under Factor Five. ALJ Ex. 1 at 4–5 ¶ 13.

registration is inconsistent with the public interest.'' *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010) (quoting *Hoxie,* 419 F.3d at 483); *see also Mark P. Koch, D.O.,* 79 FR 18714, 18736 (2014) (assessing the respondent's candor); *Ronald Lynch, M.D.,* 75 FR 78745, 78754 (2010) (same); *Prince George Daniels, D.D.S.,* 60 FR 62884, 62887 (1995) (same).

A lack of candor may properly be considered by the DEA as something that threatens public health and safety. *Annicol Marrocco, M.D.,* 80 FR 28695, 28705 (2015). ''Because of the authority conveyed by a registration and the extraordinary potential for harm caused by those who misuse their registrations, DEA places significant weight on an applicant/registrant's candor in the proceeding.'' *Alan H. Olefsky, M.D.,* 76 FR 20025, 20031 (2011). A registrant's dishonesty under oath downplays the registrant's acceptance of responsibility and shows that the registrant ''cannot be entrusted with a registration.'' *Rose Mary Jacinta Lewis, M.D.,* 72 FR 4035, 4042 (2007). The degree of candor displayed by a registrant during a hearing is ''an important factor to be considered in determining . . . whether [the registrant] has accepted responsibility'' and in formulating an appropriate sanction. *Hills Pharmacy, LLC,* 81 FR 49815, 49845 (2016) (citing *Michael S. Moore,* 76 FR 45867, 45868 (2011)).

Additionally, the Respondent's falsification of its COR should be considered under Factor Five. For example, in another case where the registrant was put on notice that her registration was being improperly used to order controlled substances, her failure to take prompt and reasonable action to investigate the misuse constituted additional conduct that threatened public health and safety. *Lewis,* 72 FR at 4041–42 (citing 21 CFR 1301.71(a)). Further, DEA can consider under Factor Five evidence that a registrant was aware that his DEA registration was being improperly used and took no action to stop its improper use. *Kevin Dennis, M.D.,* 78 FR 52787, 52800 (2013). Even if the ''Respondent did not obtain possession of the controlled substances . . . misconduct can still be actionable as an attempt to obtain controlled substances by fraud or misrepresentation.'' *Jana Marjenhoff, D.O.,* 80 FR 29067, 29068, 29069. *See* 21 U.S.C. 843(a)(3), 846.

Finally, the Respondent's domestic distribution of Lunesta to a non-registrant should be considered under Factor Five. In a similar situation, a previous Acting Administrator examined a pharmacy's distribution of a controlled substance to a non-registered location under Factor Four of 21 U.S.C. 823(f). *Sewanee Pharmacy,* 55 FR 29279, 29281 (1990). Section 823(f)(4), defines Factor Four as ''[c]ompliance with applicable State, Federal, or local laws relating to controlled substances'' and roughly corresponds with section 823(e) Factor Two, except that section 823(e)(2) omits ''Federal'' and only includes ''compliance with applicable State and local law.'' As distribution of a controlled substance to a non-registered location is a violation of Federal law, it does not fit within the parameters of Factor Two. Nor does it fit within the definitions of Factors One, Three, or Four of section 823(e). Thus, it is properly considered under Factor Five. *See Perry County Food & Drug,* 80 FR 70083, 70112 (2015) (where DEA applied the analogous Factor Five ''such other conduct'' in the context of a pharmacy registrant where the violations at issue were ''not covered by application of the other four public interest factors.'').

Falsified Registration Certificate

The Government alleges that the Respondent violated 21 U.S.C. 843(a)(3), which states that ''[i]t shall be unlawful for any person knowingly or intentionally . . . to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.'' 21 U.S.C. 843(a)(3). The Government alleges that the Respondent violated 21 U.S.C. 846 which states, ''[a]ny person who attempts or conspires to commit any offense defined in this subchapter shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy.'' The Government alleges that OakmontScript violated these statutes and that such conduct constitutes conduct that is inconsistent with the public health and safety, in violation of 21 U.S.C. 823(b)(5) and (e)(5).[73] ALJ Ex. 1 at 4–5 ¶ 13.

Dr. Shi met the intern through the intern's grandmother, who was also Dr. Shi's former teacher. Tr. 1395. The intern started working for OakmontScript as Dr. Shi's intern in January 2017 and her responsibilities included establishing relationships with OakmontScript's competitors to determine how they conduct business. Tr. 293–94, 1395. Dr. Shi hoped to create an account with PBA so OakmontScript could purchase drugs from PBA. Tr. 1411–12. Dr. Shi told the intern to ''do whatever is needed'' and to ''[g]ive [PBA], basically, whatever they want in order to establish this . . . client relationship with them.'' Tr. 303. When Dr. Shi conducted business with companies, including PBA, these companies would sometimes request OakmontScript to submit a copy of a pharmacy license as some distributors will only work with pharmacies. Tr. 275, 1409. Dr. Shi was ''too busy'' to help the intern so she told the intern to ask Mr. L.U. what letter to send to PBA. Tr. 1414.

After PBA requested that OakmontScript submit a pharmacy registration, the intern altered OakmontScript's distributor COR No. RO0504680 by using Adobe Shop on her personal laptop. Tr. 1405–06; Gov't Ex. 14. Without being told to do so, she modified the business activity of the distributor registration to indicate it was a pharmacy registration. Tr. 1414–15. Even though Dr. Shi was ''on the email chain being cc'ed'' regarding this application to PBA, she testified that she did not notice the altered registration document which was an attachment. Tr. 1415. During the tribunal's questioning of Dr. Shi, Dr. Shi agreed that the intern had changed the business activity from ''distributor'' to ''pharmacy'' and this altered registration was sent to PBA in order to open an account with PBA. Tr. 1396.

While DI 3 was reviewing OakmontScript's case files, she discovered a report filed by the Kansas City District Office of the DEA, naming OakmontScript as fraudulently creating a DEA registration. Tr. 275. PBA holds its own DEA registration and DI 3 spoke to one of PBA's Regulatory Compliance Team Leaders, B.W., via email correspondence that noted PBA ''only sell[s] to pharmacies'' and it does not ''sell to other distributors.'' Tr. 275–78; Gov't Ex. 55. PBA also requires potential customers to send a copy of their State pharmacy licenses and a copy of their DEA registrations when they submit their account application. Tr. 278; Gov't Ex. 55. B.W. further noted that OakmontScript sent PBA a DEA registration indicating it was a pharmacy and after PBA performed its due diligence, PBA discovered that the document had been altered. Tr. 278; Gov't Ex. 55. PBA reported OakmontScript and denied OakmontScript's request to open an account. Tr. 278; Gov't Ex. 55.

On April 23, 2019, DI 3 and Dr. Shi discussed this issue on the phone. Tr. 293. DI 3 learned that after PBA initially refused to establish a relationship with OakmontScript, the intern altered the

[73] Although the Government failed to provide why the Factor Five, ''catch-all'' provision applies in this instance, I agree that this allegation would fall under a Factor Five Analysis as the Respondent has violated Federal law.

DEA registration to list OakmontScript as a pharmacy. Tr. 294; Gov't Ex. 14. During this phone call, Dr. Shi indicated that she ''could have fired'' the intern, but thought this would be ''a little bit too much'' because it was only the intnern's ''first week she ever entered the job.'' Tr. 1399–1400. In an email that Dr. Shi sent to DI 3 on April 24, 2019, Dr. Shi indicated that the intern's employment dates were January 1, 2017 to February 2018 and that the intern had moved back to China. Tr. 297; Gov't Ex. 20 at 13. Dr. Shi also texted information regarding this incident to DI 3 in May 2019 and she said if the incident regarding the falsified registration ''constitutes any offensive sort, 'I' should take responsibility. If any actions taken toward, please address to me directly.'' Tr. 300–01; Gov't Ex. 29 at 3. OakmontScript ''does not contest that this incident occurred'' and, in fact, the parties have stipulated to the basic facts. ALJ Ex. 26 at 2; ALJ Ex. 7 at 3, Stipulation 10.

It was DI 3's understanding from the April 23, 2019, phone call that the intern had been fired. Tr. 294–95. Therefore, when on the following day DI 3 received the email from Dr. Shi that the intern had indeed not been fired for falsifying the registration, she understandably viewed her phone conversation with Dr. Shi on April 23 and the email from Dr. Shi on April 24 to be in ''direct conflict.'' Tr. 297–98.

Because Dr. Shi had ties with the intern's family, she felt pressure to keep the intern employed. Tr. 302. The intern left OakmontScript in February 2018 for multiple reasons, including that her visa expired. Tr. 1398. DI 3 was never able to contact the intern to discuss the registration falsification incident with her. Tr. 304.

As the Government noted in its post-hearing brief, although OakmontScript was not able to establish a customer relationship with PBA and therefore was unable to purchase any controlled substances, ''had [OakmontScript] been successful'' in opening an account, (ALJ Ex. 27 at 17), ''OakmontScript [would] have had the capacity to order controlled substances'' from PBA. Tr. 304. In its post-hearing brief, the Respondent asserts that ''[t]his concern . . . is misplaced'' because OakmontScript has established ''multiple accounts with other trading partners'' and ''in its five years of operation, never suffered any losses, theft, inventory discrepancies, or other incidents relating to controlled substances'' and therefore OakmontScript ''has proven itself to be a trustworthy DEA registrant and true to its professional obligations.'' ALJ Ex. 26 at 2–3. To the contrary, OakmontScript's falsification of a DEA registration displays the antithesis of trustworthiness. As DI 3 testified, ''DEA registrants hold a public trust position'' and because controlled substances that are used improperly can be dangerous, ''DEA registrants have to be licensed and registered with the proper authorities.'' Tr. 305. *See* 21 U.S.C. 822(a).

Furthermore, the fact that the ''Respondent did not obtain possession of [any] controlled substances'' is irrelevant and her misconduct is still ''actionable as an attempt to obtain controlled substances by fraud or deception.'' *Marjenhoff,* 80 FR at 29069.

As both parties stipulated to the registration being falsified, and based on Dr. Shi's own admission that she was aware that the intern had altered OakmontScript's distributor registration to reflect that it was a pharmacy, it is uncontroverted that OakmontScript falsified a copy of its DEA registration. I therefore find that the intern working for OakmontScript, altered OakmontScript's distributor COR by using a computer program to change the registration so that the word ''Distributor'' was replaced with ''Pharmacy'' under the ''Business Activity'' section of the registration. I further find that this registration was altered in an attempt for OakmontScript to establish a relationship with PBA to ultimately obtain controlled substances from PBA, which is in violation of Federal law, specifically 21 U.S.C. 846.

Accordingly, in review of the evidence of record, including stipulations of the parties,[74] [I find that Respondent's submission of a falsified registration to PBA represented an attempt to obtain controlled substances outside of the CSA's closed regulatory system, and as such, is conduct that is not ''consistent with the public health and safety'' under Factor Five.] *[F]

Lack of Candor

The Government alleges that Dr. Shi exhibited a lack of candor as it relates to this allegation. When Dr. Shi learned that the intern had altered OakmontScript's registration to list its business activity as a pharmacy, Dr. Shi ''analyzed the situation.'' Tr. 1397. Dr. Shi believed that the intern made this error because she was ''a new intern'' and due to her ''lack of experience.'' Tr. 1410–11. Because this was ''not all her fault,'' Dr. Shi did not fire the intern and instead ''changed her to a different position'' and moved her to a ''more straightforward job.'' Tr. 1397.

During her testimony, DI 3 indicated that during the April 23, 2019, phone call Dr. Shi had informed her that she had fired the intern, but DI 3 later learned that the intern remained employed at OakmontScript for an additional thirteen months after this incident. ALJ Ex. 1 at 5 ¶ 14; Tr. 297–98, 307, 788. Dr. Shi sent an email the next day, on April 24, 2021, to DI 3 indicating that the intern was employed from January 1, 2017 through February 2018 and left the United States because her work visa expired. Tr. 297.

Based on the testimony of the parties, I do not find that Dr. Shi exhibited a lack of candor. I do not find that DI 3 was being disingenuous regarding her testimony that ''it was [her] understanding that [the intern] had been fired due to the fraudulent DEA registration'' in January 2017 and that she had been ''led . . . to believe that [the intern] had been fired'' based on this incident. Tr. 295, 297–98, 793. Rather, I find that it is more likely there was a miscommunication between DI 3 and Dr. Shi as opposed to a lack of candor.

As discussed *supra,* only one day after DI 3's and Dr. Shi's phone conversation regarding this incident, Dr. Shi sent an email to DI 3 responding to DI 3's request for more information regarding the intern and stating that the intern was employed until February 2018, when her visa expired. It does not make sense that Dr. Shi would claim to have fired the intern, and the very next day, put in writing that she continued the intern's employment for over another year, until the intern's visa expired. Moreover, DI 3's email does not reference any conversation she had with Dr. Shi from the previous day that the intern was fired. Dr. Shi was consistent in her testimony regarding this allegation and admitted she may have stated that she ''could have fired'' the intern while speaking with DI 3. Tr. 1399. Dr. Shi was also adamant and consistent in her testimony that the intern had ''made that mistake'' and instead of firing the intern, which Dr. Shi believed would be ''a little bit too much,'' she was using this as a ''training opportunity'' and despite this being a ''huge risk,'' Dr. Shi kept the intern as a staff member and instead moved her

[74] *See* Stips. 10 and 11.

*[F] I agree with the ALJ that there was evidence on the record to support the conclusion that Respondent violated 21 U.S.C. 846 by attempting to establish a relationship with PBA in order to obtain controlled substances by fraud. However, because there is considerable other evidence on the record that demonstrates that Respondent's registration is inconsistent with the public interest, I do not find that it is necessary for me to determine whether Respondent has violated 21 U.S.C. 846. I may consider this conduct under Factor Five without finding a violation of this statute.

to a different part of OakmontScript. Tr. 1397, 1400–01. Based on these circumstances, I do not find a lack of candor by Dr. Shi regarding statements she made about how the intern's employment with OakmontScript came to an end.

Accordingly, in review of the evidence of record, including stipulations of the parties, OSC Allegation 14 is *not sustained* to the extent that Dr. Shi exhibited a lack of candor in her statements made to DI 3 on April 23, 2019.*[G]

Distribution of a Controlled Substance to a Non-Registrant [75]

The CSA's general criminal provision is contained in 21 U.S.C. 841(a), and in relevant part states: ''Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . (1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance . . . .'' 21 U.S.C. 841(a)(1). ''Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA'' to prevent abuse and diversion of controlled substances. *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). A vital component of the CSA's closed regulatory system requires that any person who handles controlled substances must obtain a registration from the DEA. *Wedgewood Vill. Pharmacy,* 71 FR at 16594 (citing 21 U.S.C. 822).

''Distribute'' is defined as ''to deliver (other than by administering or dispensing) a controlled substance or a listed chemical.'' 21 U.S.C. 802(11). ''The term 'distributor' means a person who so delivers a controlled substance or a listed chemical.'' 21 U.S.C. 802(11). A distributor can only distribute to another DEA registrant who holds the appropriate authority to handle that controlled substance. 21 U.S.C. 822(a). A distributor is not permitted to distribute controlled substances to an ultimate user and there is no coincidental activity that permits a distributor to provide controlled substances to non-DEA individuals or persons or companies. *See* 21 CFR 1301.13(e)(1) (distributing to a non-registered person is not listed as a coincident activity).

Although OakmontScript's records have inconsistent information regarding the Lunesta invoice OKS–00650 shipment, I find that the most likely scenario is that OakmontScript received Lunesta in May 2018 and shipped the Lunesta to Mr. Z.Y. at an address in the United States of [omitted for privacy], Kearny, New Jersey [ ] in May 2018. Tr. 499–535, 1455; Gov't Exs. 12 at 17, 17 at 3, 18 at 3, 22 at 10–11.

Dr. Shi also indicated the following in an email dated April 30, 2021:

> Lunesta was shipped on *May 21, 2018* to Mr. [Z.Y.] at his USA address. Mr. [Z.Y.] is an executive member of the company. At the time of this purchase request, he still in US division while he was planning to move to China Disha Pharmaceutical group. The shipping logistics was arranged such: OakmontScript shipped his US address, and then his China Disha Pharma carried out the rest of shipping from NJ to China. Disha pharma is a manufacturer, they are not required to have DEA license, and they are the end user.
>
> Lunesta is not controlled drug in China.
>
> Mr. [Z.Y.] now in China Disha Pharma Group, as a director.

Gov't Ex. 22 at 10 (emphasis in original).

After reviewing OakmontScript's records, DI 3 initially believed this transaction was an export, but upon further investigation, realized that this was a domestic distribution or a distribution to a registrant in the United States. Tr. 508, 510, 529, 533–34; Gov't Exs. 22 at 10–11, 26 at 88, 89, 92, 27 at 3, 28 at 66, 67, 68.

DI 3 discussed this invoice with Dr. Shi on May 8, 2019, when she conducted another inspection of OakmontScript. Tr. 513–14. Dr. Shi stated that L.Y., a colleague Dr. Shi had met at a conference, requested that Dr. Shi send the Lunesta to Mr. Z.Y. prior to Mr. Z.Y. going to China as Dr. Yu was not able to acquire it. Tr. 515–16. Mr. Z.Y. then provided her a business card showing that he was an employee of Disha Pharmaceutical Group, a pharmaceutical company in China. Tr. 534. Mr. Z.Y. was planning to move to China, and asked that the Lunesta be shipped to his home address in New Jersey, and paid via personal payment. Tr. 514, 516, 531, 534–35. This invoice indicates that the ''bill to'' party was Disha Pharmaceutical Group. Tr. 530–31; Gov't Ex. 28 at 44. At some time in May 2019, DI 3 discussed with Dr. Shi that this was improper. Tr. 518.

OakmontScript purchased this Lunesta with its distributor registration and then mailed it to Mr. Z.Y. at his home address in New Jersey. Tr. 517–18. Disha was not the end user or ultimate user because it was seeking the Lunesta in order to conduct research as opposed to using it for personal use. Tr. 518–19, 772–73. *See* 21 U.S.C. 802(27) (defining ''ultimate user'' as ''a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.'').

DI 3 conducted a search of the DEA registration database for Mr. Z.Y., Disha Pharmaceutical Group, and the address in Kearny, New Jersey and discovered that none of them have any active or inactive DEA registrations. Tr. 545–54. There is also no indication that the Kearny, New Jersey, address could be a freight forwarding facility.[76] Tr. 555–56, 558.

Dr. Shi testified that this transaction was an export and not a domestic distribution as claimed by the Government, because Mr. Z.Y. was taking this prescription to a company in China, Disha Pharmaceutical, which was the end-user. Tr. 1180–82, 1359. Dr. Shi also asserts that an end-user or ultimate user [77] is the person who signed the end-user statement to give OakmontScript a certificate. Tr. 1183. In fact, OakmontScript created a license transfer document, transferring the Lunesta from OakmontScript's distributor license to its exporter license. Gov't Ex. 26 at 93.

*[G] The ALJ stated that OSC Allegation 14 was ''SUSTAINED IN PART to the extent that Dr. Shi maintained the intern's employment for an additional thirteen months after the falsification occurred and the intern left OakmontScript because her work visa expired, rather than being fired.'' RD, at 58. However, it is unclear what allegation the ALJ is sustaining. Paragraph 14 of the OSC alleges that Respondent exhibited a lack of candor during the investigation by initially indicating that the intern was fired. The ALJ found that there was no lack of candor related to this charge. Based on the ALJ's interpretation of the evidence and testimony, I do not find any additional allegations in paragraph 14 to sustain.

[75] Although the Government failed to allege a specific public interest factor, I find that this best fits under Factor Five as it is a violation of Federal law.

[76] A freight forwarding facility is defined as:

> A separate facility operated by a distributing registrant through which sealed, packaged controlled substances in unmarked shipping containers (*i.e.,* the containers do not indicate that the contents include controlled substances) are, in the course of delivery to, or return from, customers, transferred in less than 24 hours. A distributing registrant who operates a freight forwarding facility may use the facility to transfer controlled substances from any location the distributing registrant operates that is registered with the Administration to manufacture, distribute, or import controlled substances, or, with respect to returns, registered to dispense controlled substances, provided that the notice required by § 1301.12(b)(4) of Part 1301 of this chapter has been submitted and approved. For purposes of this definition, a distributing registrant is a person who is registered with the Administration as a manufacturer, distributor (excluding reverse distributor), and/or importer.

21 CFR 1300.01(b).

[77] DI 3 explained that these terms are synonymous. Tr. 773.

OakmontScript did this even before it likely received the Lunesta shipment. *See* Gov't Ex. 26 at 89, 90 (The packing slip from McKesson for the distribution to OakmontScript is dated May 9, 2018, while the license transfer document is dated May 7, 2018.)

Although Dr. Shi indicates that OakmontScript no longer uses this ''informal logistical arrangement,'' Dr. Shi continues to believe this was a proper way to export controlled substances. ALJ Ex. 26 at 12. OakmontScript references 21 U.S.C. 822(c)(2)[78] as an exception that allowed Mr. Z.Y. to transport the Lunesta to China. *Id.* As Dr. Shi noted in her testimony, Mr. Z.Y. is an employee of Disha, Tr. 1180–82, not of a ''common or contract carrier or warehouse.'' 21 U.S.C. 822(c)(2). Therefore, OakmontScript would not meet this exception. Furthermore, OakmontScript did not provide any documentation to DI 3 that indicated Mr. Z.Y. had actually delivered the Lunesta to Disha Pharmaceutical in China. Tr. 1455–56.

I find that OakmontScript shipped Lunesta to an address in Kearny, New Jersey, United States, which makes this a domestic distribution as opposed to an export. I also find that the Lunesta was shipped to Mr. Z.Y. at his home address in Kearny, New Jersey, Mr. Z.Y. did not possess a DEA registration, and this transaction did not meet any exceptions provided by the regulations.

Accordingly, in review of the evidence of record, including stipulations of the parties, OSC Allegations 16 and 17 are *sustained.* [Additionally, I consider this violation under Factor Five to weigh against Respondent's continued distributor registration based on Respondent's unlawful domestic distribution of a controlled substance.]

[Summary of the Public Interest Factors for Respondent's Distributor Registration

I find that the Government has proven that Respondent failed to maintain complete, accurate, and separate records for its distributor registration; that Respondent submitted a falsified pharmacy registration to PBA in an attempt to obtain controlled substances outside of the CSA's closed regulatory system; and that Respondent unlawfully distributed a controlled substance domestically. Accordingly, I find that Factors One and Five weigh strongly in favor of revoking Respondent's distributor registration.]

Exporter Registration

As to its exporter COR, the Government alleges that the Respondent violated the CSA and its implementing regulations by: (1) Exporting controlled substances prior to obtaining its exporter COR, (2) exporting controlled substances it was not approved to export, (3) exporting controlled substances to fill prescriptions for underage patients, and (4) commingling its exporter records with records pertaining to its distributor registration and otherwise failing to keep complete and accurate records of controlled substances it exported. The Government seeks the revocation of the Respondent's exporter COR based on its allegations that the Respondent's continued registration would be inconsistent with the public interest as that term is defined in 21 U.S.C. 958.

The CSA, as codified at 21 U.S.C. 958, provides that ''[t]he Attorney General may . . . revoke or suspend a registration under subsection (a) or (c) of this section,[79] if he determines that such registration is inconsistent with the public interest . . . .'' 21 U.S.C. 958(d)(2).

Congress has provided the following factors to be considered in the public interest analysis, as set forth in 21 U.S.C. 823(d), which relates to exporters of schedule III, IV, and V controlled substances pursuant to 21 U.S.C. 958(c)(1):

(1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

21 U.S.C. 823(d).

As with the public interest factors applicable to the Respondent's distributor registration, these factors are considered in the disjunctive, and the Agency may give each factor the weight it deems appropriate in determining whether to revoke a registrant's registration. *Edmund Chein, M.D.,* 72 FR 6580, 6593–94 (2007) (quoting *ALRA Labs., Inc.,* 59 FR at 50,621). Moreover, and also in alignment with determinations applicable to other categories of registrants, the Agency is ''not required to make findings as to all of the factors.'' *Chein,* 72 FR at 6594 (quoting *Hoxie,* 419 F.3d at 482).

Factors One and Five: Maintenance of Effective Controls Against Diversion and the Existence in the Establishment of Effective Controls Against Diversion

In engaging in the public interest analysis regarding an exporter, the Deputy Administrator has noted that, ''[b]oth factors one and five inquire into whether [a registrant] has effective controls against diversion.'' *Chein,* 72 FR at 6594. At issue in *Chein,* and considered under these factors, was the Respondent's failure to provide compliant initial and biennial inventories, an essential recordkeeping responsibility. *Id.* Likewise, other recordkeeping requirements are at issue in the instant case, namely accurate recording of documentation regarding dates of transfer, dates of export and the identity of purchasers. Finally, as discussed in the portion of this Recommended Decision dealing with the Respondent's distributor registration, the commingling of records is a recordkeeping issue that falls within the maintenance of effective controls factor. *See supra* at 50.

DEA registrants are required to keep complete and accurate records related to controlled substances. 21 U.S.C. 827(a) and (b); 21 CFR 1304.21(a). The Deputy Administrator has stated, including in the context of an exporter, that ''[a]ccurate inventories are essential to conduct accountability audits and to determine whether diversion has occurred.'' *Chein* at 72 FR at 6594. Registrants must ensure that inventories

[78] 21 U.S.C. 822:

(c) Exceptions

The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this subchapter:

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment.

[79] Subsection (c) applies to exporters of schedule III, IV, or V controlled substances and states that ''[i]n determining the public interest, the factors enumerated in paragraphs (1) through (6) of section 823(d) of this title shall be considered.'' 21 U.S.C. 958(c)(1).

Subsection (a) applies to exporters of schedule I or II controlled substances and states that ''[i]n determining the public interest, the factors enumerated in paragraph (1) through (6) of section 823(a) of this title shall be considered.'' Although the Respondent is registered to export schedule II controlled substances, the Government made no allegations regarding the Respondent's exporter registration and schedule II controlled substances, thus sections 958(a) and 823(a) are not relevant to the instant proceedings.

of controlled substances in Schedules III, IV, and V are ''readily retrievable.'' 21 CFR 1304.04(f)(2). ''DEA regulations define the term 'readily retrievable' to mean 'that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records *in a reasonable time.*''' *Chein,* 72 FR at 6593 (emphasis in original)(citations omitted). ''While what constitutes 'a reasonable time' necessarily depends on the circumstances, under normal circumstances if a practice is open for business, it should be capable of producing a complete set of records within several hours of the request.'' *Id.*

OakmontScript failed to keep complete and accurate records, did not record an initial inventory for its exporter registration, and did not keep separate records for its exporter and distributor license.[80] [I find that Factors One and Five weigh against Respondent's continued exporter registration based on these recordkeeping violations.]

Inaccurate Records [81]

Invoice OKS–00243 (Diazepam)

OakmontScript received diazepam, 10 milligram gel on May 16, 2017 from McKesson. Tr. 356–57; Gov't Ex. 18 at 3. OakmontScript provided documentation to DI 3 that indicates this diazepam was exported on both May 18, 2017 and June 10, 2017. Tr. 352–53, 366. Tr. 356, 1448; Gov't Exs. 17 at 3, 18 at 3.[82] OakmontScript provided documentation to DI 3 that indicates Par Pharmaceutical, an Endo International Company, was the recipient. Tr. 356, 1448; Gov't Ex. 17 at 3. In other documentation, the recipient is listed as Cangzhou People's Hospital in China. Tr. 357, 1449; Gov't Ex. 18 at 3.

When questioned regarding the exact export date of the diazepam, Dr. Shi sent an email to DI 3 on April 23, 2019 indicating that she did not know the exact date of export because the ''shipping label was not retrievable due to USPS system update'' and Ms. Liu has ''made edit in the date multiple times and she thought the proper date is on the date of payment . . . .'' Tr. 358–59, 386, 1449; Gov't Exs. 20 at 8, 28 at 22. In this response email, the ''ship to name'' is listed as H.H. at Cangzhou People's Hospital in China and Dr. Shi's guess of the ''best possible date'' of shipment was the date of payment on May 18, 2017. Tr. 361–63, 1449–50; Gov't Ex. 21 at 9. In other documentation provided by Dr. Shi at the May 8, 2019 inspection, the use was listed as ''for research'' and the ''bill to'' party was H.X.Z. at Par Pharmaceutical and the ship to party was Dr. H.H. at Cangzhou People's Hospital in China. Tr. 365; Gov't Ex. 26 at 19.

One of the license transfer documents for this export indicates that the diazepam was transferred from OakmontScript's distributor registration to its exporter registration on May 7, 2018. Tr. 371–72, 435; Gov't Exs. 26 at 21, 28 at 77. A different license transfer document indicates that the date of transfer was May 20, 2017. Tr. 371–72, 436; Gov't Ex. 26 at 22. Other documentation provided by OakmontScript states that the diazepam prescription was made based on a request from a family in China for Patient S.Z. and was shipped sometime in May 2019. Tr. 407–09; Gov't Ex. 44 at 1–2. OakmontScript was unable to complete a DEA Form 236 for this export.[83] Tr. 352–53; Gov't Exs. 12 at 14, 16 at 2.[84]

DI 3 confronted Dr. Shi regarding this conflicting information at the on-site inspection on May 8, 2019. Tr. 363. Dr. Shi recalled that this diazepam had been shipped for direct patient use in China. Tr. 363–64. Dr. Shi stated that OakmontScript had to label the reason for export as ''research'' in order to get the shipment past Chinese Custom Officials and that the actual intended use of the diazepam was for direct patient use. Tr. 366, 1446.

DI 3 was also confused by documents provided by Dr. Shi because although they appeared to be the exact same documents—a prescription written in Chinese, a hospital's government licenses, and a doctor's medical license—these documents were provided in stacks for two different invoices. Tr. 380–83; Gov't Ex. 26 at 12–14, 30–32. Based on a translation that DI 3 ultimately obtained for these documents, DI 3 learned that both prescriptions were for diazepam. Tr. 383.

Invoice OKS–00753 (Briviact)

OakmontScript provided DI 3 with documents that indicated that Briviact 50 milligram and 100 milligram, was received on October 22, 2018, the shipping label was created on October 25, 2018, and was shipped on November 2, 2018. Tr. 579–96; Gov't Exs. 12 at 8, 20 at 10, 26 at 103, 105, 28 at 16. Other documentation provided by OakmontScript indicated that this Briviact was shipped on October 26, 2018. Gov't Exs. 17 at 2, 18 at 4. In other documentation provided by OakmontScript, no shipping date is provided. Gov't Ex. 27 at 3–4. OakmontScript did not fill out a DEA Form 236 for this controlled substance. Tr. 596, 1435–36; *See* Gov't Ex. 48.[85]

Invoice OKS–00315–2 (Lyrica)

OakmontScript provided documentation to DI 3 indicating that a variety of Lyrica strengths were shipped on November 21, 2018, to J.F. at YaoPharma. Tr. 558–72; Gov't Ex. 31 at

[80] The analysis regarding the commingling of records is the same as discussed above. *See supra* at 50–51.

[81] On the last day of the hearing Dr. Shi indicated that she ''want[ed] to see if we can submit our record, which I'll look at in the app.'' Tr. 1429. She further stated that she needed ''to check back because some of the things that happened three or four years ago, if I can retrieve it'' and that ''[a]t this point, I don't have any evidence ready to present and I didn't prepare additional.'' Tr. 1429. To be clear, Dr. Shi had several opportunities to submit any additional records that had not previously been provided to DI 3 at the February 19, 2019 inspection, including the inspections DI 3 conducted in March 29, 2019, May 8, 2019, May 13, 2019, and February 28, 2020. OakmontScript also could have provided these records as an exhibit with its Prehearing Statement, Amended Prehearing Statement, Supplemental Prehearing Statement, Hearing Exhibits, or even offered them during the hearing, if it could have demonstrated good cause. As noted by Dr. Shi, she ''has the records'' but decided not to give them to DI 3 and also did not prepare them for the hearing.

[82] As noted *supra,* this McKesson invoice listed OakmontScript's address as 15 New England Executive Park. Dr. Shi explained that this address and the 1500 District Avenue address (OakmontScript's current address) are the same address. Tr. 367. Dr. Shi stated that the area where OakmontScript is located got ''reorganized'' and although OakmontScript's address changed, its physical location never changed.

[83] This is noted as ''no XFER'' in the spreadsheets, which indicates that OakmontScript was not able to fill out a DEA Form 236 for a particular drug. Tr. 202.

[84] Although the OSC did not include any allegations regarding the Respondent's failure to complete DEA Form 236 for controlled substances that it exported, the Government did include these allegations in its Prehearing Statement. *See* ALJ Ex. 5 at 43. Where an allegation is not included in the OSC, but the Government includes the allegation in its Prehearing Statements, adequate notice is provided to a respondent. *Jose G. Zavaleta, M.D.,* 78 FR 27431, 27439 (2013) (Where the Government did not allege material falsification on the respondent's application in the OSC, but did raise the issue in its Supplemental Prehearing Statement, the respondent was on notice that the issue would be considered at the hearing); *Treasure Coast Specialty Pharmacy,* 76 FR 66965, 66967 (2011) (The respondent's argument that it was denied due process because the Government had not alleged lack of state authority in the OSC was rejected, because the scope of the proceedings before the Administrative Law Judge was not defined by the OSC ''but rather by the Government's prehearing disclosures'' as well); *John Stafford Noell,* 59 FR 47359, 47361 (1994) (Notice of allegations were adequate where they were not included in the OSC, but they were contained in the Government's Prehearing Statement).

[85] The allegation specific to this invoice was made on page 29 of the Government Prehearing Statement (''GPHS''). ALJ Ex. 5 at 29.

1–2, 27 at 3, 31 at 1, 4. However, other documentation provided by Dr. Shi indicates that this Lyrica was exported on November 21, 2019. Gov't Ex. 12 at 12.[86] Dr. Shi also sent an email stating that the label for the Lyrica was created on November 21, 2018, and the drop-off date was December 4, 2018. Gov't Ex. 20 at 10. Other documents list the date as March 29, 2019. Gov't Ex. 31 at 3. Other documents list an invoice date of May 8, 2019. Gov't Ex. 26 at 102.[87] The date of the invoice was also listed as August 8, 2018. Gov't Ex. 28 at 48. OakmontScript did not file a DEA Form 236 for this export. Tr. 572–73.[88]

Accordingly, in review of the evidence of record, including stipulations of the parties, OSC Allegations 20.a.a, 20.a.b, 20.a.c, 20.a.d, 20.b, 20.c.e, and 20.c.f[89] [related to Respondent's failure to keep complete and accurate records] are *sustained*. [I find that Factors One and Five weigh against Respondent's continued exporter registration based on these recordkeeping violations.]

Lack of Initial Inventory

Pursuant to 21 CFR 1304.11, ''[e]very person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable'' and ''[i]n the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.'' 21 CFR 1304.11(b).

On September 16, 2016, DI 1 conducted an on-site inspection of OakmontScript with a Senior Investigator with the Massachusetts Department of Health. Tr. 44–45. DI 1 explained that OakmontScript was required to create an initial inventory of controlled substances OakmontScript has on site. Tr. 50. DI 1 and the Senior Investigator conducted a pre-registration inspection of OakmontScript for its exporter application on June 22, 2017. Tr. 69–71. They discussed with Dr. Shi that OakmontScript was required to create an initial inventory and maintain records for at least two years. Tr. 71–72.

DI 3, DI 4, and DI 1 conducted an inspection of OakmontScript on February 19, 2019. Tr. 156–58. They discussed recordkeeping and the DIs explained that they would be conducting a controlled substance accountability audit. Tr. 159. Although the closing inventory for the accountability audit was good because ''it tied out to zero,'' there were issues with OakmontScript's recordkeeping, including a failure to take an initial inventory, which OakmontScript was unable to produce. Tr. 190, 736, 763. Specifically, during the February 19, 2019 inspection, OakmontScript informed DI 3 ''that they had forgotten to take the initial inventory when they received the export registration.'' Tr. 735–36. DI 3 discussed these issues with her group supervisor and her group supervisor asked her to return to conduct an expanded controlled substance accountability audit going back to December 5, 2017, when OakmontScript first received its DEA exporter registration. Tr. 192–93.

I find that OakmontScript failed to record an initial inventory for its exporter registration, which is a violation of 21 CFR 1304.11(b). This is also particularly concerning because OakmontScript has a distributor license and was aware of these requirements. Furthermore, both DI 1 and DI 2 had explained to Dr. Shi that an initial inventory was required once OakmontScript's exporter application was approved.

Accordingly, in review of the evidence of record, including stipulations of the parties, OSC Allegation 21.a is *sustained*. [I find that Factors One and Five weigh against Respondent's continued exporter registration based on Respondent's failure to conduct an initial inventory.]

Factor Six: Such Other Factors as May Be Relevant to and Consistent With the Public Health and Safety

The Government alleges that Factor Six is relevant to the public interest analysis regarding the Respondent's exporter COR. ALJ Ex. 1 at 7.[90]

The Respondent's exporting of controlled substances prior to having an exporter COR, its exporting of controlled substances for which it did not have approved drug codes and its exporting to fill individual prescriptions do not fall under any of the first five factors that are to be considered in determining the public interest for an exporter and thus are appropriately addressed under Factor Six. *See Perry County Food & Drug,* 80 FR at 70,112 (DEA applied the analogous Factor Five ''such other conduct'' in the context of a pharmacy registrant where the violations at issue were ''not covered by application of the other four public interest factors.'').

Additionally, as discussed in the portion of this Recommended Decision dealing with the Respondent's distributor registration, the lack of candor is an issue that falls within the category of ''such other factors as may be relevant to and consistent with the public health and safety.'' [91] *See supra* at 52–53.

Pre-Registration Exports

The CSA requires that in order to export a controlled substance a person must be properly registered to do so. 21 U.S.C. 957(a) specifically states: ''No person may . . . export from the United States any controlled substance . . . unless there is in effect with respect to such person a registration issued by the Attorney General under section 958 of this title . . .'' Further, DEA regulations state that ''[n]o person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person.'' 21 CFR 1301.13(a). These requirements have been applied in DEA decisions. *Chein,* 72 FR at 6592 (citing 21 U.S.C. 957(b), and 21 CFR 1301.13(a)). Additionally, another regulation applying specifically to exports states that ''[n]o person shall in any manner export, or cause to be exported from the United States any controlled substance . . . unless and until such person is properly registered under the Act . . .'' 21 CFR 1312.21(a).

The parties stipulated that the Respondent's exporter COR was first issued on December 5, 2017. Stipulation 2. Moreover, it is established by the Certification of Registration History for the Respondent's exporter registration that the COR number was assigned on December 5, 2017. Gov't Ex. 1B. Therefore, there is no dispute that the Respondent first had DEA authority to export controlled substances on December 5, 2017.

Invoice OKS–00243 (Diazepam)

The testimony by both DI 3 and Dr. Shi, as well as the documentation

[86] DI 3 discussed these issues with Dr. Shi on April 23, 2019, and Dr. Shi indicated that this was an incorrect date and the date should be listed as November 21, 2018. Tr. 564.

[87] This incorrect date could be related to the macro issue, but regardless, having these incorrect dates caused confusion for DI 3. Tr. 576–77.

[88] The allegation specific to this invoice was made on page 22 of the GPHS. ALJ Ex. 5 at 22.

[89] It appears that the Government had formatting issues when identifying various paragraphs of the OSC.

[90] The Government failed to state why Factor Six is applicable and only specifically stated that Factor Six applied to the allegation that OakmontScript filled prescriptions for underage patients in China.

[91] For other categories of registrants, the ''such other factors'' or ''such other conduct'' is listed as Factor Five. *See, e.g.,* 21 U.S.C. 823(b) & (e) (applicable to distributors) and 21 U.S.C. 823(f) (applicable to practitioners).

admitted at the hearing, provided conflicting dates for the export of this diazepam. The dates in the documentation and discussed by both witnesses are May 18, 2017 and June 10, 2017. Tr. 352–53, 356, 357, 366, 424–25, 432, 1311–12, 1313, 1448, 1449; Gov't Exs. 12 at 14, 17 at 3; 18 at 3; 26 at 20. Dr. Shi admitted she did not know the date of export because of a USPS system update that resulted in the loss of shipment information for this invoice. Tr. 358–59, 386, 1449; Gov't Exs. 20 at 8, 28 at 22. However, there was no testimony or other documentation that suggested an export date other than May 18, 2017 or June 10, 2017. Indeed, at the hearing, Dr. Shi offered testimony that ''the best possible date'' of shipment was May 18, 2017, despite telling DI 1 during her June 22, 2017, pre-registration inspection that she had not exported any drugs. Tr. 361–63, 1313, 1368–69, 1449–50; Gov't Ex. 21 at 9.

Based on the testimony and admitted exhibits, it is evident that this diazepam was exported on either May 18, 2017, or June 10, 2017. Regardless of which date the diazepam was actually shipped, both dates are approximately six to seven months before the Respondent's registration as an exporter was issued on December 5, 2017.

I therefore find that the Respondent exported this controlled substance when it was not properly registered to do so in violation of 21 U.S.C. 957(a) and 21 CFR 1312.21.

Invoice OKS–00301 (Briviact)

DI 3 testified that this Briviact was shipped on August 2, 2017. Tr. 440. The documentation that DI 3 received from the Respondent also indicates an export date of August 2, 2017. Gov't Ex. 12 at 7, 26 at 36, 27 at 2. Furthermore, correspondence from Dr. Shi states the shipping label was created on August 2, 2017. Gov't Ex. 20 at 8. Dr. Shi confirmed the August 2, 2017 date in her testimony at the hearing. Tr. 1313–14.

Based on the testimony and admitted exhibits, this Briviact was exported on August 2, 2017. This date is approximately four months before the Respondent's registration as an exporter was issued on December 5, 2017.

I therefore find that the Respondent exported this controlled substance when it was not properly registered to do so in violation of 21 U.S.C. 957(a) and 21 CFR 1312.21.

Invoice OKS–00315 (Belviq)

DI 3 testified that this Belviq was shipped on November 1, 2017. Tr. 459. The documentation that DI 3 received from the Respondent also indicates an export date of November 1, 2017. Gov't Ex. 12 at 3, 26 at 38–39, 27 at 2. In her testimony, Dr. Shi confirmed the November 1, 2017 date in the documentation she provided to the Government as reflected in Government Exhibits 12 and 27, but also testified it was an estimated date.[92] Tr. 1318–20.

Based on the testimony and admitted exhibits, this Belviq was exported on November 1, 2017. This date is approximately one month before the Respondent's registration as an exporter was issued on December 5, 2017.

I therefore find that the Respondent exported this controlled substance when it was not properly registered to do so in violation of 21 U.S.C. 957(a) and 21 CFR 1312.21.

Invoice OKS–00315/OKS–00315–2 (Lyrica)

DI 3 testified that this Lyrica was shipped on November 20, 2017. Tr. 471. Some documentation that DI 3 received from the Respondent also indicates an export date of November 20, 2017. Gov't Ex. 12 at 9–10. Other documentation that DI 3 received from the Respondent provides a date of November 17, 2017 (Gov't Ex. 28 at 32), November 19, 2017 (Gov't Ex. 28 at 78), or November 21, 2017 (Gov't Ex. 27 at 2). Dr. Shi acknowledged the date on Government Exhibit 12, but stated that ''[i]t's just the date we entered'' before later agreeing that her employees enter the dates on which events actually occurred.[93] Tr. 1330, 1331.

Based on the testimony and admitted exhibits, this Lyrica was exported sometime between November 17 and 21, 2017. November 21, 2017, is approximately two weeks before the Respondent's registration as an exporter was issued on December 5, 2017.

I therefore find that the Respondent exported this controlled substance when it was not properly registered to do so in violation of 21 U.S.C. 957(a) and 21 CFR 1312.21.

Invoice OKS–00108 (Belviq XR)

DI 3 testified that this Belviq was shipped on December 1, 2017. Tr. 484. The documentation that DI 3 received from the Respondent also indicates an export date of December 1, 2017. Gov't Ex. 12 at 3, 26 at 47, 27 at 2. Dr. Shi confirmed the December 1, 2017, shipping date for this Belviq in Government Exhibits 12 and 27 in her testimony at the hearing. Tr. 1351–52.

Based on the testimony and admitted exhibits, this Belviq was exported on December 1, 2017. This date is four days before the Respondent's registration as an exporter was issued on December 5, 2017. I therefore find that the Respondent exported this controlled substance when it was not properly registered to do so in violation of 21 U.S.C. 957(a) and 21 CFR 1312.21.

Faced with the fact that the Respondent exported controlled substances pursuant to the above-referenced invoices prior to being registered as an exporter, the Respondent makes the argument that it had applied for the registration, had been inspected by DEA, passed the security measures, and that the registration would be forthcoming at any time.[94] Tr. 1303. It should be noted that in her testimony, Dr. Shi emphasized numerous times that she felt her registration would be coming ''any minute.'' Tr. 1095:4–5, 1096:8, 1097:4, 23, 1303:20–21, 23. Also, tellingly, Dr. Shi admitted that she ''misled my people, say this export license on the way.'' Tr. 1097. Dr. Shi then went on to admit that she ''prepared my business, say that license should be coming'' which led to ''schedule 3, 4, 5 being processed and we started taking order.'' Tr. 1097–98. Dr. Shi further admitted ''I didn't do my part.'' Tr. 1098.

In *Chein,* the Deputy Administrator stated the following:

> DEA has recognized that acting with a 'good faith belief that [one is] properly registered with DEA . . . is a mitigating factor in determining the public interest,' . . . DEA has recognized this defense in only two situations. The first is where a person had previously held a registration for the activity and believed it to be still valid pending an appeal of a final order of revocation. *See Stanley Alan Azen, M.D.,* 61 FR 57893, 57895–96 (1996). The second is where an applicant applied for a registration and received from DEA controlled substance order forms that were imprinted with a new DEA number. *See Howard,* 62 FR at 32660. *Howard* is therefore properly understood as a case involving reliance on an affirmative act of the government.

[92] Dr. Shi did not offer an alternative date in her testimony.

[93] Again, Dr. Shi did not offer any alternative date for a shipment of the drugs for this invoice.

[94] The Respondent also argued that DEA had ''neglected'' and ''mistreated'' its application with the result that its exporter registration ''didn't come in on time.'' Tr. 1093–94, 1493. To the extent that the Respondent is making an argument that its exporter application was mishandled, [which was not supported by any record evidence], there is no exemption from registration because one has submitted an application which was subsequently mishandled. *Chein* 72 FR at 6589 (quoting *Dennis Robert Howard, M.D.,* 62 FR 32658, 32661 (1997) (''there is no 'good faith' exemption from liability in administrative proceedings'' under the CSA)).

Chein, 72 FR at 6589 (alterations in original).[95]

Neither of the mitigating factors discussed in *Chein* is present in this case. First, the Respondent had never previously held a valid exporter registration. Second, the Respondent did not receive documentation regarding a new registration number and, in fact, Dr. Shi admitted that although she thought ''the registration would be coming any day,'' she did not receive the registration. Furthermore, the Respondent's expectation that she would shortly receive her registration or that she had met all the requirements for the registration are not a substitute for having actually been issued a valid registration by DEA.

Accordingly, in review of the evidence of record, including stipulations of the parties, OSC Allegations 7.a, 7.b, 7.c, 7.d, and 7.e are *sustained.* [I find that Factor Six weighs against Respondent's continued exporter registration based on Respondent's repeated exporting of controlled substances prior to obtaining a registration.]

Exporting Without the Required Drug Code

In addition to the requirement in 21 U.S.C. 957 that a registrant have a registration to export controlled substances, the CSA also requires that a registrant shall not ''export controlled substances other than those specified in the registration.'' 21 U.S.C. 958(b). DEA has explained that ''[t]he mechanism by which a controlled substance is specified in a registration is through the use of its Administration Controlled Substance Code Number.'' [96] Changes in Administration Controlled Substances Code Numbers, Final Rule, 52 FR 5951 (1987); Gov't Ex. 53. As DI 1 further explained in her testimony, these ''drug codes'' are used for ''identification purposes'' for certain types of registrants, including exporters. Tr. 86. The regulations also require that ''[a]pplicants for import and export permits must include the appropriate code number on the application . . . .'' 21 CFR 1308.03(a).

Both DI 1 and DI 3 explained the use of the drug codes to Dr. Shi and assisted her in having the appropriate drug codes associated with the Respondent's exporter registration. Tr. 86–89, 96–97, 100, 175–76, 183, 597. However, the Respondent later expanded the types of controlled substances it was exporting and Dr. Shi testified that the Respondent lacked the necessary drug codes. Tr. 1130–31.

The CSA also requires that appropriate export documentation be completed. For nonnarcotic controlled substances in schedule III or IV and controlled substances in schedule V, 21 U.S.C. 953(e) requires certain documents, including ''such export permit, notification, or declaration as the Attorney General may by regulation prescribe.'' 21 U.S.C. 953(e)(2). Regulations implementing this section require that the registrant complete and file a DEA Form 236. 21 CFR 1312.21(b), 1312.27(a), 1312.28(a); Tr. 996, 1025, 1028; *See* Gov't Ex. 47.

As to DEA Form 236 requirements, Dr. Shi testified that DI 1 covered the DEA–236 requirements at the June 22, 2017 inspection. Tr. 1298–99. Dr. Yu testified that DI 3 provided the Respondent with instructions regarding the DEA Form 236 during the February 19, 2019 inspection. Tr. 996, 1025. However, Dr. Shi acknowledged in her testimony that the Respondent's DEA–236 forms ''didn't get filled because lack of drug code.'' Tr. 1131.

Invoice OKS–00753 (Briviact)

The Respondent shipped Briviact to China under this invoice on either October 26, 2018 or November 2, 2018. Tr. 579–96; *Compare* Gov't Exs. 17 at 2 and 18 at 4 *with* Gov't Ex. 20 at 10.

DI 3 testified that the drug code for Briviact is 2710. Tr. 581; Gov't Ex. 10 at 3. DI 3 testified that the Respondent was not authorized to handle Briviact under its exporter registration because it did not have drug code 2710 associated with that registration. Tr. 581, 1434–35; Gov't Ex. 11. On cross-examination, Dr. Yu agreed that on the date of shipment for this controlled substance, the Respondent did not have a drug code for Briviact. Tr. 1052. Therefore, the uncontested evidence is that the Respondent exported this controlled substance without having the required drug code for its exporter registration, in violation of 21 U.S.C. 958(b).

Furthermore, DI 3 testified that the Respondent did not fill out a DEA Form 236 for this controlled substance.[97] Tr. 596–97, 1435–36. There is also no record of the Respondent completing a DEA–236 in the documentary evidence that DI 3 obtained, which lists the DEA–236 forms that the Respondent filed with DEA. Gov't Ex. 48. In response to the Government's allegations, the Respondent provided no evidence that it successfully completed a DEA Form 236 for this export. Therefore, the evidence leads to the inescapable conclusion that the Respondent did not complete the required DEA Form 236, in violation of 21 U.S.C. 953(e) and 21 CFR 1312.21, 1312.27 and 1312.28.

Invoice OKS–00902 (Belviq)

The Respondent shipped Belviq to China under this invoice and, according to most of the evidence, the date of shipment was February 15, 2019. Tr. 602–13; Govt. Exs. 18 at 4, 26 at 121, 27 at 4, 28 at 60.

DI 3 testified that the drug code for Belviq is 1625. Tr. 602; Gov't Ex. 10 at 2. DI 3 testified that the Respondent was not authorized to handle Belviq under its exporter registration because it did not have drug code 1625 associated with that registration. Tr. 612, 1435; Gov't Ex. 11. On cross-examination, Dr. Yu agreed that on the date of shipment for this controlled substance, the Respondent did not have a drug code for Belviq. Tr. 1049. Therefore, the uncontested evidence is that the Respondent exported this controlled substance without having the required drug code for its exporter registration, in violation of 21 U.S.C. 958(b).

Furthermore, DI 3 testified that the Respondent did not fill out a DEA Form 236 for this controlled substance.[98] Tr. 609. There is also no record of the Respondent completing a DEA–236 in the documentary evidence that DI 3 obtained, which lists the DEA–236 forms that the Respondent filed with DEA. Gov't Ex. 48. In response to the Government's allegations, the Respondent provided no evidence that it successfully completed a DEA Form 236 for this export. Therefore, the evidence leads to the inescapable conclusion that the Respondent did not complete the required DEA Form 236, in violation of 21 U.S.C. 953(e) and 21 CFR 1312.21, 1312.27 and 1312.28.

Invoice DIW–0019 and NEEC–0019 (Clobazam)

The Respondent shipped clobazam to China on March 5, 2019. Tr. 613–41, 673–723, 727–33, 907, 912; Gov't Exs. 26 at 15–16, 27 at 4, 28 at 65.

[95] In a footnote, the Deputy Administrator declined to extend the good faith defense, citing a threat to public safety. *Chein,* 72 FR at 6589, n.16.

[96] The DEA Controlled Substances Code Numbers (''drug codes'') assigned to each controlled substance are listed in the regulations at 21 CFR 1308.11–.15. The tribunal also admitted Government Exhibit 10, which lists the drug codes for each controlled substance and according to DI 3 is the ''DEA drug code book'' that is arranged by DEA Drug Code Number. Tr. 181–82.

[97] Although the OSC did not include any allegations regarding the Respondent's failure to complete DEA Form 236s for controlled substances that it exported, the Government did include these allegations in the GPHS. ALJ Ex. 5 at 9, 11–12. The allegation specific to this invoice was made on page 29 of the GPHS. ALJ Ex. 9 at 29.

[98] The allegation regarding the Respondent's failure to complete a DEA Form 236 that is specific to this invoice was made on page 30 of the GPHS. ALJ Ex. 9 at 30.

DI 3 testified that the drug code for clobazam is 2751. Tr. 614; Gov't Ex. 10 at 4. DI 3 testified that the Respondent was not authorized to handle clobazam under its exporter registration because it did not have drug code 2751 associated with that registration. Tr. 615, 1435; Gov't Ex. 11. On cross-examination, Dr. Yu agreed that on the date of shipment for this controlled substance, the Respondent did not have a drug code for clobazam. Tr. 1049–50. Therefore, the uncontested evidence is that the Respondent exported this controlled substance without having the required drug code for its exporter registration, in violation of 21 U.S.C. 958(b).

Furthermore, DI 3 testified that the Respondent did not fill out a DEA Form 236 for this controlled substance.[99] Tr. 615, 1435–36. There is also no record of the Respondent completing a DEA–236 in the documentary evidence that DI 3 obtained which lists the DEA–236 forms that the Respondent filed with DEA. Gov't Ex. 48. In response to the Government's allegations, the Respondent provided no evidence that it successfully completed a DEA Form 236 for this export. Therefore, the evidence leads to the inescapable conclusion that the Respondent did not complete the required DEA Form 236, in violation of 21 U.S.C. 953(e) and 21 CFR§ 1312.21, 1312.27 and 1312.28.

Based on my review of the testimony by DI 3 and by the Respondent's witnesses, as well as the documentary evidence, the Respondent did not have the required drug codes for the Briviact (Invoice OKS–00753), Belviq (Invoice OKS–00902), and clobazam (Invoice OKS–DIW–0019/NEEC–0019) listed under these invoices and consequently did not have the authority to export them. Accordingly, in review of the evidence of record, including stipulations of the parties, OSC Allegations 9.a, 9.b, and 9.c are *sustained*.

In addition, I find that the Respondent did not complete the required DEA Form 236 for any of these three exports. Accordingly, in review of the evidence of record, including stipulations of the parties, the additional allegations from the GPHS (ALJ Ex. 5 at 9, 29, 30, 37) that the Respondent failed to file DEA–236 forms regarding invoices OKS–00753, OKS–00902, and DIW–0019/NEEC–0019 are *sustained*. [I find that Factor Six weighs against Respondent's continued exporter registration based on Respondent's repeated exporting of controlled substances that it was not authorized to export and Respondent's repeated failure to fill out required DEA forms.]

Lack of Candor Regarding Exports

Although the Government failed to explain under which factor the lack of candor allegation regarding the Respondent's exporter registration falls, as with the tribunal's previous discussion of the lack of candor allegation regarding the Respondent's distributor registration, the tribunal finds that the allegations regarding the Respondent's lack of candor appropriately fall under Factor Six. I incorporate by reference the discussion, *supra* at 52–53, regarding the legal standard that applies to a lack of candor finding.

On February 19, 2019, DIs conducted an on-site investigation of the Respondent pertaining to its exporter registration. Tr. 156–57; *See* Gov't Ex. 7. DI 3 testified that as part of that inspection she reviewed the drugs that the Respondent was authorized to handle and inquired of Dr. Shi as to whether the Respondent was handling any other drug codes. Tr. 159, 169, 175–76. DI 3 testified that the drug codes that the Respondent was authorized to export as of February 19, 2019, are listed in Government Exhibit 11, which she created sometime after her inspection by using her notes from the inspection and the DEA registration system. Tr. 184–87. DI 3 testified that these are the drug codes that she asked Dr. Shi about during the February 19, 2019 inspection. Tr. 188. DI 3 explained that she read through the list of drugs and stated the controlled substance name and ''asked if there were any additional drug codes that OakmontScript was handling or exporting at the time'' and that Dr. Shi stated there were no other drug codes. Tr. 189, 597–98. In her testimony, Dr. Shi admits that she had a conversation with DI 3 about drug codes and that she showed DI 3 two lists. Tr. 1172. The first list was a list for which the Respondent had drug codes.[100] Tr. 1172. After DI 3 asked whether the Respondent was handling any other drugs, Dr. Shi showed DI 3 another list and explained ''I really have trouble with another, the list of the drugs which we don't have drug codes.'' [101] Tr. 1172. Dr. Shi also raised these two lists in her cross-examination of DI 3. Tr. 888–89. After DI 3 repeated her recollection that Dr. Shi stated she had not handled any other controlled substances, Dr. Shi asked whether DI 3 recalled whether she gave her a second list of drugs with which they were having difficulties.[102] Tr. 889. DI 3 stated she did not recall this. Tr. 889.

As to the Briviact that is the subject of Invoice OKS–00753, when this was the subject of the Government's questioning of DI 3 on direct, DI 3 testified that Dr. Shi stated OakmontScript was not handling any other controlled substances and that this demonstrated a lack of candor. Tr. 600. As to the Belviq that is the subject of Invoice OKS–00902, DI 3 again testified that Dr. Shi did not advise her of the Respondent's recent export of this drug, which DI 3 believes demonstrates a lack of candor. Tr. 612–13. I find that there was more to this conversation than a simple denial by Dr. Shi. As described above, on at least three separate occasions during the hearing, Dr. Shi referenced a ''second list'' of drugs, with which she was having problems, that she gave to DI 3 as part of their conversation regarding drug codes and controlled substances that the Respondent was exporting. At a minimum, it seems that Dr. Shi wanted to continue the conversation regarding drug codes and drugs that the Respondent wanted to export, but had encountered difficulties. Based on this attempt by Dr. Shi at further communication on this issue, I cannot make a finding that Dr. Shi exhibited a ''lack of candor'' regarding the Briviact and Belviq.

As to the clobazam that is the subject of invoice DIW–0019 and NEEC–0019, for the reasons I have just outlined I make the same finding that there was not a lack of candor. However, my finding that there was not a lack of candor is supported by additional facts. On direct examination, DI 3 was asked why Dr. Shi's failure to identify the clobazam as a drug that was being handled was not a true and accurate statement. Tr. 724. In responding, DI 3 admitted that the February 19, 2019, inspection was prior to the Respondent's clobazam export, but maintained ''they're clearly handling other controlled substances that they were not allotted to or authorized to handle.'' Tr. 724. I find this statement to be troubling. First, in response to the specific question regarding clobazam, DI 3 did not specifically state that the Respondent was handling that drug, but instead made a generalized statement

[99] The allegation regarding the Respondent's failure to complete a DEA Form 236 that is specific to this invoice was made on page 37 of the GPHS. ALJ Ex. 9 at 37.

[100] Dr. Shi did not identify what drugs were on this list.

[101] Dr. Shi also did not identify what drugs were on this second list.

[102] Dr. Shi also references this second list in her ''objection'' to DI 3's statement on direct examination that Dr. Shi stated OakmontScript had not handled any other controlled substances besides those that DI 3 had listed. Tr. 598–99.

about ''other controlled substances.'' Tr. 724. Second, the Government offered no evidence to show that any clobazam was associated with the Respondent's exporter registration on or before February 19, 2019. As previously discussed, the export of the clobazam did not occur until March 5, 2019. Furthermore, the invoice from McKesson indicated that the billing date for the clobazam was February 28, 2019. Gov't Ex. 26 at 1. Based on this evidence, the clobazam would not have been transferred to the Respondent's exporter registration until after the time of the investigators' February 19, 2019 inspection. Thus, for these additional reasons, and based on the evidence before me, I find that the Government has not demonstrated a lack of candor by the Respondent regarding its allegation that Respondent failed to disclose it was handling clobazam at the time of the February 19, 2019 inspection.

Accordingly, in review of the evidence of record, OSC Allegations 11.a, 11.b, and 11.c are *not sustained*.

Exporting To Fill Individual Chinese Prescriptions

DEA regulations provide that ''[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner. 21 CFR 1306.06. *See, e.g., Margy Temponeras, M.D.,* 77 FR 45,675, 45,677 (2012).

DEA regulations also provide that ''[a]ll prescriptions for controlled substances shall be dated as of, and signed on the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.'' 21 CFR 1306.05(a).

The Government alleges that the Respondent exported controlled substances on two occasions to fill individual prescriptions for ''underage patients'' in China and that the Respondent could not legally fill these prescriptions because it is not a registered pharmacy. The Government further alleges that these ''prescriptions'' did not contain valid DEA numbers for the prescribers and did not include other required information to be valid prescriptions.

Invoice OKS–00243 (Diazepam)

The Government's first allegation of improper exporting to fill a prescription for an individual in China involves the diazepam that the Respondent exported in May 2017. I have already found that this controlled substance was exported prior to DEA's issuance of an exporter COR to the Respondent, a violation of 21 U.S.C. 957(a) and 21 CFR 1312.21. The testimony and documentation further demonstrate that this controlled substance was exported by the Respondent for the purpose of filling a prescription issued in China for a person in China. DI 3 testified that that during her inspection of May 8, 2019, Dr. Shi stated this diazepam had been shipped for direct patient use in China. Tr. 363–64. However, the Respondent's documentation stated the ''Indicated Use'' as ''Research.'' [103] Gov't Ex. 26 at 22. Dr. Shi further stated to DI 3 that OakmontScript had to label the reason for export as ''research'' in order to get the shipment past Chinese Custom Officials and that the actual intended use of the diazepam was for direct patient use. Tr. 366.[104] The Respondent has also admitted, through counsel who was representing her at the time of DEA's investigation, that this export was for a Chinese patient. Tr. 407–08; Gov't Ex. 44 at 1. As DI 3 testified, the dispensing of controlled substances to fill prescriptions is not an allowed coincident activity for distributors and exporters. 21 CFR 1301.13(e)(1); Tr. 420.

In defense of its filling of foreign controlled substance prescriptions, the Respondent cited 21 U.S.C. 956 and 21 CFR 1301.26. These provisions exempt individuals who are traversing the United States border and possess no more than 50 dosage units of non-Schedule I controlled substances for personal medical use from the usual import/export requirements. However, the Government argued that this exemption is limited to a personal use exemption for international travelers. *See* ALJ Ex. 9 at 8–9. *See* 21 U.S.C. 956; 21 CFR 1301.26. I agree that these exemption provisions by their plain language apply only to individuals who are travelling with controlled substances for their own personal use. I therefore reject the Respondent's reliance on these provisions as a justification for its export to an individual in China.

The Respondent's other argument in its defense of exporting controlled substances to fill foreign prescriptions, is what it terms ''buy and bill distribution'' or ''provider's solution distribution.'' Tr. 1209–10. However, the Respondent provides no authority for these models, much less authority that they are a legitimate way to fill foreign prescriptions. *See* ALJ Ex. 26 at 13. The Respondent also objects to what it calls DEA's ''hypothesis'' that only pharmacies can fill prescriptions, but the Respondent provides no discussion as to why the Government's position is wrong, other than to contend it ''has the right to serve clients, which include foreign entities, with legitimate clinical and scientific needs.'' ALJ Ex. 26 at 14.

I find that the Respondent, which does not hold a pharmacy COR, unlawfully filled this prescription, in violation of 21 U.S.C. 822(a)(2) and (b) and 21 CFR 1306.06.

The tribunal admitted Government Exhibit 45, which included the prescription for the diazepam, as well as a declaration by a DEA linguist that included a translation of the prescription. Gov't Ex. 45. The translation shows that the prescription is for diazepam for a two-year and six-month old male.[105] Gov't Ex. 45 at 4. The prescription was issued by H.H. a practitioner in China. Tr. 365, 413, 435; Gov't Ex. 45 at 4. DI 3 could find no DEA registration associated with this person. Tr. 413–14. The prescription does not include a DEA number,[106] I therefore find that the prescription was invalid for failing to comply with the requirements of 21 CFR 1306.05(a). Due to portions of the prescription that the linguist found to be illegible, resulting in an incomplete translation of the information on the prescription, I find that the Government has not shown that the prescription is missing any other information required by 21 CFR 1306.05(a). Gov't Ex. 45 at 4.

Invoice DIW–0019 and NEEC–0019 (Clobazam)

The Government's second allegation of improper exporting to fill a prescription for an individual in China involves the clobazam that the Respondent exported on March 5, 2019. I have already found that the

[103] Dr. Shi testified at the hearing that her main purpose in starting her company was ''to support global research need.'' Tr. 1078, 1086. Nevertheless, there was also testimony that the Respondent fills individual prescriptions. Tr. 363–64.

[104] Dr. Shi's false statement on the export documentation is relevant in assessing Dr. Shi's credibility. If Dr. Shi was willing to falsify official documentation to advance the Respondent's business interests, it is indicative of the Respondent's propensity to make other false statements in support of its business endeavors.

[105] The translation states the name is ''ILLEGIBLE,'' but other evidence in the record identifies the patient as having the initials ''S.Z.'' Gov't Ex. 45 at 4; Tr. 408.

[106] The prescription in the original Chinese includes Arabic numerals which the linguist included on the English translation. Gov't Ex. 45 at 3, 4. Because none of these numbers correspond to a format for a DEA number, and based on the testimony, I find that no DEA number is present on the prescription. Gov't Ex. 45 at 4; Tr. 430–31.

Respondent exported this controlled substance without having the required drug code for its exporter registration, in violation of 21 U.S.C. 958(b). The testimony and documentation further demonstrate that this controlled substance was exported by the Respondent to the patient's home address in China for the purpose of filling a prescription issued by a Chinese doctor. Tr. 613–41, 673–723, 727–33, 907, 912; Gov't Exs. 12 at 21, 26 at 15–16, 27 at 4, 28 at 65.

For the reasons stated above with respect to the prescription that the Respondent filled for diazepam, I find that the Respondent, which does not hold a pharmacy COR, unlawfully filled this prescription, in violation of 21 U.S.C. 822(a)(2) and (b) and 21 CFR 1306.06.

The tribunal admitted Government Exhibit 46, which included a purported prescription for the clobazam, as well as a declaration by a DEA linguist with a translation of the prescription.[107] Gov't Ex. 46. The translation shows that the prescription is for clobazam for a nine-year old male with the initials ''J.L.'' Gov't Ex. 46 at 4. The prescription was issued by G.T., a practitioner in China. Tr. 710–11; Gov't Ex. 44 at 1. DI 3 could find no DEA registration associated with this person. Tr. 715–17, 722. The prescription does not include a DEA number.[108] The prescription also does not include the address of the patient. For these reasons, I find that the prescription was invalid for failing to comply with the requirements of 21 CFR 1306.05(a).

The Government also makes three additional allegations regarding the clobazam prescription.

In paragraph 19.c.ii of the OSC, the Government alleges that the Respondent provided a Material Transfer document that showed the clobazam was transferred to Dr. W. at NEEC in Burlington, MA. This document is present in the record as Government Exhibit 26 at 16–18 and shows the invoice number of NEEC–0019 and a date of March 5, 2019.[109] The Government alleges that this documentation is inconsistent with other documents and statements made by the Respondent that show the clobazam was exported to an address in Shandong, China. Tr. 622–23. For instance, a document provided by the Respondent that contains customer and shipping information shows clobazam under invoice NEEC–019 shipped to Shandong, China, on March 5, 2019. Gov't Ex. 27 at 4. A Customs Declaration dated March 5, 2019, also shows shipment of this clobazam to Shandong, China. Gov't Ex. 26 at 15.[110] I find that the inconsistencies in the Respondent's records show that it failed to keep complete and accurate records in violation of 21 U.S.C § 827(a) and (b) and 21 CFR 1304.21(a) with respect to clobazam invoice number NEEC–0019.

In paragraph 19.c.i of the OSC, the Government alleges a lack of candor by Dr. Shi based on her representations on April 24, 2019, that the clobazam was transferred to NEEC which conflicts with her statements on May 8, 2019, that the clobazam was exported to the patient at a personal address in Shandong, China. As I have just found, there are inconsistencies in the Respondent's records as to whether this clobazam was transferred to Dr. W. or exported to China. Similarly, Dr. Shi provided DEA investigators with differing accounts as to whether the clobazam was transferred to Dr. W. or exported to China. In an April 24, 2019 email, Dr. Shi wrote that the clobazam ''was NOT exported but transferred to Dr Office from New England Executive Care in MA of USA for a patient who used to be treated at Boston Children Hospital.'' Gov't Ex. 20 at 11; Tr. 616–17. However, on May 8, 2019, Dr. Shi told DI 3 that this clobazam was exported. Tr. 623–24. I find that Dr. Shi made conflicting statements regarding whether this clobazam was transferred domestically to a doctor or whether it was exported and that these conflicting statements demonstrate a lack of candor.

In paragraph 19.c.iii of the OSC, the Government alleges that Dr. Shi stated to DEA investigators that she pressured Dr. W. to write a clobazam prescription for Patient J.L. in order to legitimize the export of clobazam and that Dr. W. eventually did write a prescription. DI 3 testified in detail to her conversation with Dr. Shi regarding Dr. Shi's efforts to get Dr. W. to write a prescription for Patient J.L. Tr. 619–20, 1459. DI 3 never obtained any prescription written by Dr. W. for clobazam for Patient J.L. Tr. 621. In addition, DI 3 interviewed Dr. W. and he denied he ever wrote such a prescription. Tr. 681–82; Gov't Ex. 36. Dr. Shi testified at the hearing that, in his role with OakmontScript, Dr. W. does not write prescriptions ''but he know[s] the medical record.'' Tr. 1197–98. Dr. Shi did not specifically testify at the hearing regarding whether she asked Dr. W. to write a clobazam prescription for Patient J.L.

Given the documentation, discussed above, that shows the Respondent transferred the clobazam to Dr. W., as well as the detailed testimony by DI 3 recalling specific conversations she had with Dr. Shi about Dr. Shi's efforts to get Dr. W. to write the prescription, and given that DI 3 felt the need to follow-up on her conversation with Dr. Shi by interviewing Dr. W. and issuing a subpoena to him regarding any prescription he wrote, I credit DI 3's testimony that Dr. Shi made statements during the investigation that Dr. W. issued a clobazam prescription for Patient J.L. Further, Dr. Shi's testimony at the hearing that Dr. W. does not write prescriptions conflicts with what she told DI 3. Finally, the fact that the Respondent produced a prescription issued in China for the clobazam, but did not produce any prescription issued by Dr. W., leads to the conclusion that the only prescription for clobazam for Patient J.L. was from China. Based on these facts, I find that Dr. Shi's statements that Dr. W. issued a prescription for clobazam for Patient J.L. demonstrate a lack of candor.

Accordingly, in review of the evidence of record, including stipulations of the parties, OSC Allegations 18.a, 18.b, 19.a, 19.b, 19.c.i, 19.c.ii, and 19.c.iii are *sustained*. [I find that Factor Six weighs against Respondent's continued exporter registration based on Respondent's exporting of controlled substances to fill individual prescriptions in China.

Summary of the Public Interest Factors for Respondent's Exporter Registration

I find that the Government has proven that Respondent violated numerous federal laws by failing to maintain complete and accurate records, by exporting controlled substances prior to having an exporter COR, by exporting controlled substances for which it did not have approved drug codes, and by exporting to fill individual prescriptions. Accordingly, I find that Factors One, Five, and Six weigh strongly against Respondent, and I conclude that Respondent has engaged in misconduct which supports the

[107] Although both parties referred to the document as a prescription, the document describes itself as an ''instruction page'' and it appears to be more akin to a hospital medication order than a prescription. Gov't Ex. 46 at 4. Nevertheless, in the absence of any other documentation purporting to be a prescription, and because both parties relied on it as a prescription, I am evaluating it as a prescription.

[108] The prescription in the original Chinese includes Arabic numerals which the linguist included on the English translation, however these numbers pertain to the ''Patient ID.'' Gov't Ex. 46 at 3, 4.

[109] These three pages appear to be identical copies of the same one-page ''Material Transfer'' document. There is also a ''Service Transfer'' document in the Government's exhibits that shows a transfer of the clobazam for invoice NEEC–0019 to Dr. W. on March 5, 2019. Gov't Ex. 28 at 76.

[110] Another copy of the identical Customs Declaration is located in Government Exhibit 28 at 75.

revocation of its distributor and exporter registrations.

I therefore hold that the Government has established a *prima facie* case that continued registration of Respondent's exporter and distributor registrations ''would be inconsistent with the public interest.'' 21 U.S.C. 823(a), (b), (d), and (e); 824(a); and 958(a), (c), and (d).]

[Sanction] *[H]

Egregiousness, Deterrence, and Lack of Candor

[Where, as here, the Government has met its *prima facie* burden of showing that the respondent's continued registration is inconsistent with the public interest, the burden shifts to the respondent to show why it can be entrusted with the responsibility carried by its registration. *Garret Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018) (citing *Samuel S. Jackson,* 72 FR 23,848, 23,853 (2007)). DEA cases have repeatedly found that when a registrant has committed acts inconsistent with the public interest, ''the Respondent is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts.'' *Holiday CVS,* 77 FR at 62,339 (internal quotations omitted). *See, also, Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 483 (6th Cir. 2005); *Ronald Lynch, M.D.,* 75 FR 78,745, 78,749, 78,754 (2010) (holding that respondent's attempts to minimize misconduct undermined acceptance of responsibility); *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (noting that the respondent did not acknowledge recordkeeping problems, let alone more serious violations of federal law, and concluding that revocation was warranted).

The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations. *Jeffrey Stein, M.D.,* 84 FR 46,968, 46,972 (2019). A registrant's candor during the investigation and hearing is an important factor in determining acceptance of responsibility and the appropriate sanction, *Garret Howard Smith, M.D.,* 83 FR at 18,910 (collecting cases); as is whether the registrant's acceptance of responsibility is unequivocal, *Lon F. Alexander, M.D.,* 82 FR 49,704, 49,728 (2017) (collecting cases). In determining whether and to what extent a sanction is appropriate, consideration must be given to both the egregiousness of the offense established by the Government's evidence and the Agency's interest in both specific and general deterrence. *Wesley Pope,* 82 FR 14,944, 14,985 (2017) (citing *Joseph Gaudio,* 74 FR 10,083, 10,095 (2009)); *David A. Ruben, M.D.,* 78 FR 38,363, 38,364 (2013). *Cf. McCarthy* v. *SEC,* 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoption of ''deterrence, both specific and general as a component in analyzing the remedial efficacy of sanctions.'').]

Here, the egregiousness of the offense favors revocation. The Respondent exported controlled substances before even being issued its exporter COR and, after acquiring its exporter COR, repeatedly exported controlled substances when it did not have approved drug codes and found it could not complete the required DEA–236 forms. The Respondent distributed to a non-registrant and even altered its distributer COR to make it appear that it was a DEA-registered pharmacy.

Considerations of specific and general deterrence in this case militate in favor of revocation. Through the testimony of its owner, the Respondent has made it clear that in some instances it feels it did nothing wrong, such as in the case of its exports to fill prescriptions in China, where the Respondent has ''a bundle of knowledge while [DEA investigators] obviously lack it.'' Tr. 1497. In other instances, it feels that its violations were not so serious because they did not result in ''somebody killed'' or ''some pandemic we caused.'' Tr. 1417. The Respondent's owner appeared to value her personal relationships with her employees and her friends and acquaintances in China, over her responsibilities as a DEA registrant to adhere to the CSA and its regulations. The Respondent filled prescriptions for patients in China who had personal relationships with those who worked at OakmontScript. Tr. 363–64, 624, 1195; Gov't Ex. 44 at 1. The Respondent also failed to take decisive action against the employee responsible for altering its distributor registration—and with whose family the Respondent's owner had ties. Tr. 302. The Respondent's owner's comments lead to the conclusion that she is unwilling or unable to effectively submit to DEA oversight and regulation of her controlled substances operations. She believes she is and has been correct, and it can be confidently assumed that the absence of a registration sanction will result in the continuation of operations that run afoul of the safeguards required by the CSA and its regulations. Thus, the interests of specific deterrence, even standing alone, motivate powerfully in favor of the revocation of the Respondent's CORs.

The interests of general deterrence compel a like result. As the regulator in this field, the Agency bears the responsibility to deter similar misconduct on the part of others for the protection of the public at large. *Ruben,* 78 FR at 38,385. Where the record demonstrates that the Government has borne its burden and established that the Respondent has exported controlled substances from the United States without authority, failed to maintain the closed system of distribution with its distributor COR and levelled substantial blame for its violations against DEA investigators, rather than itself, the unmistakable message to the regulated community would be that such conduct can be overlooked with little or no consequence. Thus, on this record, the interests of general deterrence support the revocations sought by the Government.

Another factor that weighs significantly in favor of the revocation sanction sought by the Government is the lack of candor demonstrated by the Respondent's owner during certain of her interactions with DEA investigators and at the hearing. In making the public interest determination, ''this Agency places great weight on [a respondent's] candor both, during an investigation and in a subsequent proceeding. *Fred Samimi, M.D.,* 79 FR 18,698, 18,713 (2014) (quoting *Robert F. Hunt, D.O.,* 75 FR 49,995, 50,004 (2010)).

In regard to the investigation, I found the Respondent's owner demonstrated a lack of candor both in her representation that Dr. W. issued a prescription for Patient J.L., where she was unable to produce a copy of the prescription, Dr. W. denied to investigators that he issued a prescription, and a prescription from a Chinese practitioner was used as a basis for the export. Similarly, I found a lack of candor where the Respondent's owner made conflicting statements about whether the clobazam for invoice DIW–0019/NEEC–0019 was transferred domestically to NEEC or exported to China. Also disturbing was the Respondent's owner's creation of records for presentation to Chinese authorities that falsely stated the diazepam invoice OKS–00243 was for ''research'' rather than direct patient use, so that the package would clear Chinese customs. Finally, there were

*[H] I am replacing portions of the Sanction section in the RD with preferred language regarding prior Agency decisions; however, the substance is primarily the same.

several instances during the hearing where the Respondent's owner was evasive when answering questions posed by Government counsel and this tribunal. *See supra* at 36 n.52, 37 n.55, 40 n.57, 44 n.63, 45 n.67. Hence, the Respondent's lack of candor undermines the confidence that the Agency can have in the Respondent's ability to be a responsible DEA registrant.

For the above reasons, I find that the proven misconduct is egregious and that deterrence considerations weigh in favor of revocation.

Acceptance of Responsibility and Rehabilitative Measures

With the Government's *prima facie* burden having been met, an unequivocal acceptance of responsibility stands as a condition precedent for the Respondent to prevail. *George Mathew, M.D.,* 75 FR 66,138, 66,148 (2010). This feature of the Agency's interpretation of its statutory mandate on the exercise of its discretionary function under the CSA has been sustained on review. *MacKay* v. *DEA,* 664 F.3d 808, 822 (10th Cir. 2011). Acceptance of responsibility and remedial measures are assessed in the context of the ''egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others.'' *Ruben, M.D.,* 78 FR at 38,364.

Accordingly, the Respondent must present sufficient mitigating evidence to assure the Administrator that it can be entrusted with the responsibility incumbent with such registration. *Medicine Shoppe-Jonesborough,* 73 FR 363, 387 (2008); *Samuel S. Jackson,* 72 FR 23,848, 23,853 (2007). As past performance is the best predictor of future performance, DEA has repeatedly held that where an applicant has committed acts inconsistent with the public interest, the applicant must accept responsibility for his actions and demonstrate that it will not engage in future misconduct. *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir.). *See also Hoxie,* 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[ ]'' in the public interest determination).

Dr. Shi failed to take unequivocal acceptance of responsibility at any point during these proceedings. Although Dr. Shi made several references that an issue was her fault, such statements were immediately proceeded with a qualifying statement putting the onus on someone—or something—else. In fact, Dr. Shi put the blame on just about everyone else she has come into contact with, even going so far as to blame her printer,[111] the United States Postal Service,[112] and even her own clients.[113]

In regards to receiving OakmontScript's exporter registration and exporting controlled substances prior to receiving its exporter registration, Dr. Shi consistently blamed DI 1 and/or the DEA for ''mistreating'' and ''neglecting'' her exporter applications. Tr. 1094, 1115. Dr. Shi later went on to state that she did not ''want to blame [DI 1] for neglect'' and that Dr. Shi should have ''check[ed] every step,'' but also stated that the she had ''put too much trust on [her] 30-year pharmacist,'' L.U., who was also her former boss. Tr. 1096. She further stated that she ''shared in the responsibility,'' and believed that OakmontScript's exporter registration ''should be coming any time'' despite not receiving information to support such a belief. Tr. 1095. Because of this belief, she assured and ''soothed [her] people'' by telling them that they could ''start preparing'' because the registration was coming ''any minute.'' Tr. 1096. She continued to believe that the registration ''should come any minute'' and that it would ''come in before May.'' Tr. 1097. Dr. Shi specifically taught her ''people it's not to set up the date what is right. I teach my people say I just record what is things happen. I keep telling them I never allow them to assume what is the right date. They have to record what, how the things happen, right.'' Tr. 1130.

Even more startling, in her post-hearing brief, Dr. Shi states that OakmontScript ''shares responsibility'' regarding the issue of exporting prior to receiving its registration, however, Dr. Shi does not claim she should have waited to export. ALJ Ex. 26 at 8. Instead, she claims that OakmontScript ''needed to do more than fulfill its bureaucratic obligations to fill an application, pay the fee, and pass a security inspection; they also should have more strongly advocated for their correct application. . . .'' *Id.* Dr. Shi goes on to explain that OakmontScript ''takes the position that [OakmontScript] has fulfilled their obligation for proper registration on April 27, 2017 and should have been granted its license in June 2017 or prior.'' *Id.*

It is evident that Dr. Shi does not comprehend the gravity of her many violations. In particular, when asked for clarification by Government counsel about the Lyrica, invoice OKS–00315–2 having a different shipping date listed in different records provided by OakmontScript, Dr. Shi initially indicated that she did not know which document was incorrect and claimed that regardless, it is ''one days apart. This is not like somebody get killed or something.'' Tr. 1340. Dr. Shi went on to say ''I know it's mistake. It's 20 or 21st.'' Tr. 1340. But just moments later, Dr. Shi stated ''I can say both [dates] are correct, or I mean, both are incorrect . . . I also can say both are right. Because that's just the date.'' Tr. 1341. Dr. Shi stated OakmontScript did the best it could when entering these dates into the spreadsheets. Tr. 1341.

When Dr. Shi discussed controlled substances that OakmontScript had exported despite not possessing the proper drug code, she stated that she was ''not blaming'' DI 3 and it was not ''her fault'' for Dr. Shi not getting the drug code. Tr. 1149–50. Furthermore, in regards to not being able to file the proper information on the DEA Form 236 for the diazepam, invoice OKS–00243, Dr. Shi blamed a USPS system update that ''erase[d] all the information.'' Tr. 1368. According to Dr. Shi, the USPS maintained records on its website for up to ninety days, but sometime in 2017, the USPS performed an upgrade to its system and records during that time were ''not retrievable.'' Tr. 1369. Although she agreed that the departure date is information that OakmontScript would have, Dr. Shi failed to provide any reason why this information was not in OakmontScript's records that were provided to DI 3. Tr. 1368–71.

One of Dr. Shi's most shocking revelations occurred during her direct testimony when she declared that she had ''shared more than I should'' with DI 3. Tr. 1174, 1368 (Dr. Shi ''offer[ed] too much information.'') After being further prompted by the tribunal, Dr. Shi elaborated that she believed she had been ''too eager to share too much,'' or that there was a ''miscommunication'' between Dr. Shi and DI 3. Tr. 1176. At some point, Dr. Shi decided that she would ''stop[ ] our oversharing with [DI 3]'' and took the liberty of deciding what exactly this oversharing entailed. Tr. 1381. For instance, despite OakmontScript ''hav[ing] the date'' and ''hav[ing] all the records,'' Dr. Shi decided that she would only ''provide a portion'' of certain invoices to DI 3,

[111] Dr. Shi claimed that she did not provide some required documents to DI 3 because her printer did not have ink. Tr. 1260–61.

[112] Dr. Shi stated that OakmontScript was not able to provide the export date for diazepam because the USPS updated its online system sometime in 2017 and ''erased'' all the information during the upgrade. Tr. 1368–69.

[113] For instance, when discussing the export process, Dr. Shi noted that the custom ticket could ''tak[e] as fast as two to four weeks'' but if the client is a new employee, ''they might screwed up the whole process and taking years or something.'' Tr. 1130.

including invoices written in Chinese or that included ''customer information.'' Tr. 1344–45, 1347, 1373, 1381.

It is worth noting that although Dr. Shi may not have exhibited a lack of candor regarding the firing of her intern, what it is particularly disturbing in this instance is Dr. Shi's cavalier response to this incident. During cross-examination, Government counsel questioned Dr. Shi regarding the falsification of OakmontScript's distributor registration and the following exchange took place:

Q Do you agree that falsifying a DEA registration in this manner is a serious issue?

A I admit it. From, you know, when the DI 3 first time to—

Q I know you admitted it. But do you—or at some point you admitted it. But do you agree that this is a serious issue?

A Well, a serious issue to the consequences. And to the, you know, to what we're trying to do. And this is, *I know if somebody killed, or if some pandemic we caused,* or if something and it is a serious. But in our SOP we have layers, layers of the protection. So my explanation, just to try to alleviate some of your concern about our how dangerous this could be. Yes, I know that. We can be, imagine how serious it is. But we also, you know, need to be focused on how it happened and what have caused.

Tr. 1416–17 (emphasis added).

Dr. Shi's apparent notion that for something to be deemed a dangerous issue it must culminate in a client's or bystander's demise or cause a pandemic is particularly startling. Dr. Shi further stated that ''the falsification of the DEA distributor and the pharmacy . . . is not a controlled-substance related issue'' and OakmontScript had done ''more than the minimum[,] . . . did 500 times more than what's required to address this incident.'' Tr. 1496.

When questioned by the tribunal regarding this incident, Dr. Shi indicated that the intern had ''made that mistake,'' so she changed her to a different position instead of firing her. Tr. 1397. Dr. Shi also indicated that the reasons the intern had left OakmontScript were because her visa expired and it was a ''little far stretch'' for the intern, who had an interest in being a musician, to switch to pharmaceutical trading. Tr. 1398–99. Rather than leaving OakmontScript due to an employment termination for her misdeeds, the intern left of her own volition. Despite the ''huge risk'' that the intern's action imposed on OakmontScript's registration, Dr. Shi believed it would have been ''a little bit too much'' to fire her. Tr. 1400. Furthermore, not only did Dr. Shi decide not to terminate the intern's employment, but she also allowed the intern to continue bringing her personal computer into the office. Tr. 1407. Ultimately, it appears that Dr. Shi placed more value in her relationship with the intern and the intern's family in China than protecting the integrity of her business and its DEA registration.

In light of the foregoing, it is bewildering that Dr. Shi proclaims that she has ''a better than ever understanding'' of the law. Tr. 1422. Dr. Shi even goes so far as to state in her closing argument that the DEA ''should limit their authority on the controlled substance matter.'' Tr. 1496. According to Dr. Shi, OakmontScript never tried to cut corners and made significant efforts to stay in compliance. Tr. 1493. She also stated that OakmontScript encountered many difficulties while working with the DEA, including the DIs not having an understanding of how a drug code is different from a drug schedule and lacking a ''basic understanding about pharmaceutical industries.'' Tr. 1494. Dr. Shi asserts that throughout this entire process, OakmontScript ''has . . . demonstrated and we've tried to please, we tried to cooperate, we tried to be respectful,'' but ''things have been misunderstood.'' Tr. 1495. Although Dr. Shi expresses that her ''license is privilege, it's not my right,'' Tr. 1085, as the old adage goes, actions speak louder than words and Dr. Shi failed to take the proper actions.

I therefore find that the Respondent has not unequivocally accepted responsibility.[114]

Considering the entire record before me, the conduct of the hearing, and observation of the testimony of the witnesses presented, I find that the Government has met its burden of proof and has established a *prima facie* case for revocation. Furthermore, I find evidence that the Respondent poses an ongoing threat to the public health and safety. The Respondent also failed to take unequivocal responsibility for its conduct and it has not presented convincing evidence demonstrating that the Agency can entrust it to maintain its CORs.

Accordingly, I *recommend* that the Respondent's DEA CORs RO0504680 and RO0527082 be *revoked*, and any pending applications for renewal or modification of such registrations be *denied*.[115]

Dated: June 11, 2021.

Paul E. Soeffing,

U.S. Administrative Law Judge.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a); 21 U.S.C. 958(a), (c), and (d); and 21 U.S.C. 823(a), (b), (d) and (e), I hereby revoke DEA Certificate of Registration Nos. RO0504680 and RO0527082 issued to OakmontScript. Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a); 21 U.S.C. 958(a), (c), and (d); and 21 U.S.C. 823(a), (b), (d) and (e), I further hereby deny any pending applications for renewal or modification of these registrations, as well as any other pending application of OakmontScript for additional registration in Massachusetts. This Order is effective May 11, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–07719 Filed 4–8–22; 8:45 am]

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[114] Where a registrant has not accepted responsibility, it is not necessary to consider evidence of the registrant's remedial measures. *Ajay S. Ahuja, M.D.,* 84 FR 5479, 5498 n.33 (2019) (citing *1 Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.,* 81 FR 79,188, 79,202–03 (2016)). However, there were a few times that OakmontScript's witnesses mentioned remedial steps taken since being served with the OSC. For instance, after learning of the macro issue populating the current date in OakmontScript's templates, Dr. Yu stated that she has ''corrected this template'' and employees are now instructed to input dates manually before converting and saving the document as a PDF file. Tr. 985–86. Dr. Shi admitted during her testimony that the shipping of Lunesta to Mr. Z.Y. at his home address for further transport to China was an ''informal channel'' of exporting and ''since this incident and since DI 3 have point this out, we no longer accept informal channel of delivery for any order.'' Tr. 1182, 1183. These few measures, however, certainly do not overcome OakmontScript's past violations, or allow me to find that OakmontScript should be entrusted with a DEA COR.

[115] As discussed at the conclusion of the hearing, pursuant to 21 CFR 1316.66, the parties have twenty days from being served with this Recommended Decision to file any exceptions. Tr. 1507; 21 CFR 1316.66(a).

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